

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Resources
5630 Fishers Lane, Room 1061
Rockville Maryland 20859

1179 08 27 11:45

August 4, 2000

Re: Citizen petition to Request FDA Find Benzalkonium Chloride (0.11-0.13%) is Generally Recognized as Safe and Effective as Defined by the Tentative Final Monograph for Health-Care Antiseptic Drug Products.

Dear Sir or Madam:

CITIZEN PETITION

The undersigned submits this petition under the Federal Food, Drug and Cosmetic Act (FFDCA), Sections 502, 505 and 701(a), 21 U.S.C. §§ 352, 353 and 371(a) and 21C.F.R. 330.10, 333 and 369 to request that the Commissioner of Food and Drugs take the following actions:

A. Actions requested

1. Consider this submission as a petition to amend the Tentative Final Monograph for topical antimicrobial drug products for over the counter (OTC) human use despite the lack of a final monograph because good cause warrants consideration.
2. Find benzalkonium chloride in a concentration of 0.11% to 0.13% is generally recognized as safe and effective and not misbranded for use as the active ingredient in an OTC antiseptic hand sanitizer and include it in the final monograph for topical antimicrobial drug products for OTC human use by adding it to the active ingredients listed in subpart E, § 333.410 of the Tentative Final Monograph for Health-Care Antiseptic Drug Products.

B. Statement of Grounds

1. Consideration of this Petition

Information submitted after the expiration of the comment period on an OTC monograph is treated as a petition to amend the monograph. 21 CFR § 330.10(a)(7)(v). The Commissioner may consider new information in a petition to amend a monograph prior to publication of the final monograph if “good cause has been shown that warrants earlier consideration.” *Id.* The time period for submitting comments to the Tentative Final Monograph for Health-Care Antiseptic Drug Products (the Tentative Final Monograph; TFM), 59 Fed Reg 31402 (June 17, 1994), has expired but the monograph is not yet finalized. Good cause warrants the consideration of the information in this petition.

Specifically, the undersigned, Woodward Laboratories, Inc., (WLI), has developed a benzalkonium chloride preparation (0.13% active concentration) with surfactants and allantoin for use as an OTC antiseptic handwash that kills 99.99% of Gram-negative and Gram-positive bacteria, including methicillin-resistant *Staphylococcus aureus* and vancomycin resistant *Enterococcus fecalis* within 30 seconds *in vitro*, that exceeds the *in vivo* handwashing performance standard for healthcare personnel handwashes (10 handwash glove juice test with *Serratia marcescens*), and that has been shown in two separate studies to decrease illness absenteeism in elementary schools. The data supporting the safety and efficacy of this preparation are detailed below and attached to this petition. A recent news report noted established that, according to the U.S. Centers for Disease Control data, hospital-acquired infections (such as MRSA or VRE) will contribute to the deaths of 70,000 people in the United States. This finding is supported by a second review of this situation (See TAB 1; Binder 1). The WLI, product could help reduce the morbidity and attendant mortality associated with nosocomial infections. Accordingly, good cause warrants that this petition should be considered to amend the TFM despite the lack of a final monograph.

2. Benzalkonium chloride is effective and safe

a. Efficacy of Benzalkonium Chloride

The Agency has found Benzalkonium chloride to be generally recognized as safe and effective in products for short-term use, such as first aid antiseptic drug products. (See Fed Reg at 31254; 56 Fed Reg 33644, 33663 (July 22, 1991)). The TFM lists benzalkonium chloride as a Category III ingredient for any other use. Based on the data submitted with this petition, WLI requests that the Agency find that benzalkonium chloride is generally recognized as safe and effective for

use as the active ingredient in an OTC antiseptic handwash. WLI is therefore submitting this petition at this time to contribute to the review process already placed in motion by petitions such as 75N-183H/CP 3 filed on 04/06/00 supporting the use of benzalkonium chloride (0.11-0.13 %) in health-care antiseptic hand washes.

Benzalkonium Chloride has been the subject of prior Citizen Petitions, including as mentioned above, docket number 75N-183H/CP filed by International Laboratory Technologies, Inc. on 04/06/00. In that petition were submitted data supporting safety, efficacy and persistence claims, as well as support for the inclusion benzalkonium chloride for use in the TFM for Health-Care Antiseptic Drug Products (June 17, 1994). Effectiveness tests included a time kill study conducted per the (TFM) for Health-Care Antiseptic Drug Products dated June 17, 1994, partial MIC data on 50 strains of each organism listed in the monograph against the test product, 10 strains of each with the vehicle and a positive control (Hibiclens; chlorhexidine gluconate active). In addition, data were submitted from a healthcare antiseptic handwash study as outlined in the TFM, which included a total of 60 subjects, 30 treated with the test product and 30 treated with a reference product, and an agar patch test. In all of the tests, benzalkonium chloride (0.11-0.13%) passed per the specifications of the TFM. The time kill studies showed that benzalkonium chloride (0.11-0.13%) killed 99.9% of gram positive and gram negative bacteria and yeast within 60 seconds. Furthermore, a healthcare antiseptic handwash study (60 subjects) showed that benzalkonium chloride (0.11-0.13%) achieved a greater than three \log_{10} reduction by the first, third, seventh and tenth handwashes. The agar patch test indicated that benzalkonium chloride (0.11-0.13%) also achieved statistically significant persistence against *E. coli* for up to four hours post application, and the cylinder sampling test demonstrated a significant persistent antimicrobial effect for benzalkonium chloride (0.11-0.13%) at all study time points. It was concluded that those data support the safety and efficacy of benzalkonium chloride (0.11-0.13%) for use as the active ingredient in an OTC antiseptic handwash. (See TAB 2; Binder 1)

Based on the standard set forth by the Agency, and by the precedent set by data submissions in prior Citizen Petitions, WLI has performed the following studies, some of which have already been or are pending publication in peer reviewed journals:

1. Time kill and minimum inhibitory concentration studies including the majority of the Gram positive and Gram negative bacteria and yeast strains listed in the TFM for Health Care Antiseptic Drug Products dated June 17,

1994. These tests indicate that BAC (0.13%) is effective as defined in the TFM within 30 seconds of application. (SEE TAB 3; Binder 2)
2. A healthcare antiseptic handwash study (78 subjects) that showed that benzalkonium chloride (0.13%) exceeded Federal performance requirements with or without a water rinse following product use. In contrast, the reference products (62% and 70% ethanol) produced greater than 2 log₁₀ reduction of bacteria after the first handwash, but did not achieve a 3 log₁₀ reduction of bacteria by the tenth handwash with or without a water rinse step after product use. This study was published in the Association of Operating Room Nurses (AORN) Journal in August 1998. (SEE TAB 4; Binder 2)
 3. A second healthcare antiseptic handwash study (40 subjects) performed at the California College of Podiatric Medicine, San Francisco, CA, that showed that benzalkonium chloride (0.13%) exceeded Federal performance requirements without a water rinse following product use. In contrast, the reference products (62% ethanol) produced greater than 2 log₁₀ reduction of bacteria after the first handwash, but did not achieve a 3 log₁₀ reduction of bacteria by the tenth handwash without a water rinse step after product use. This study is pending publication in the Journal of the American Podiatric Medical Association. (SEE TAB 5; Binder 2)
 4. A third healthcare antiseptic handwash study (420 subjects ages 6-12; 10 weeks) evaluating the impact of the repeated daily use of the antiseptic handwash formulation with benzalkonium chloride (0.13%) on illness absenteeism. In this open-label population crossover study, which included education on the benefits of handwashing, and which allowed students to wash hands at-will with non-medicated soap, a 40% reduction in illness absenteeism was achieved. This study has been accepted for publication in the Journal of Family Medicine. (SEE TAB 6; Binder 2)
 5. A fourth healthcare antiseptic handwash study (769 students ages 6-12; 5 weeks) evaluating the impact of the repeated daily use of the antiseptic handwash formulation with benzalkonium chloride (0.13%) on illness absenteeism. In this double-blind placebo controlled study, which included education on the benefits of handwashing, and which allowed students to wash hands at-will with non-medicated soap, a 33% reduction in illness absenteeism was achieved. This study is being submitted to the Journal of School Nursing, and findings are presented in abstract form. The final submission draft will be presented as an addendum to this petition upon its completion (SEE TAB 7; Binder 2)

b. Safety of Benzalkonium Chloride:

Based on the standard set forth by the Agency, see 39 Fed Reg 33102, 33135 (September 13, 1974), published data and tests performed by WLI, and by other petitioners, including International Laboratory Technologies, Inc. in their petition 75N-183H/CP 3 filed on 04/06/00, support the safety of benzalkonium chloride (0.13%) as the active ingredient in an OTC antiseptic handwash.

A 1989 publication of the American Journal of Toxicology contains an article entitled "A final report on the safety assessment of benzalkonium chloride". This article represents current thinking in the medical and scientific communities, and includes data from numerous toxicology and safety studies performed with benzalkonium chloride. The panel concludes from the data that benzalkonium chloride is not sensitizing to healthy persons at concentrations of up to 0.1%. (See TAB 8; Binder 2). In addition, a general discussion on the subject of toxicity of quaternary amines, including benzalkonium chloride, has been included in order to provide perspective on human health risks associated with these active ingredients (see TAB 9; Binder 2).

In the petition 75N-183H/CP 3, data supporting the safety of BAC (0.10-0.13%) exists wherein BAC was less irritating than either a 62% gelled alcohol preparation or sodium dodecyl sulfate in a 24 hour skin irritation study (occlusive patch). In a semiocclusive patch test, benzalkonium chloride was found to be less irritating than sodium dodecyl sulfate, and produced the same results as 62% ethanol, and physiological saline. These data (obtained via FOI request) have been included for reference. (SEE TAB 10; Binder 2)

As mentioned in the 75N-183H/CP 3 petition, the Environmental Protection Agency has registered benzalkonium chloride (USEPA PC Code 069106) as an active ingredient in pesticides in concentrations much higher than 0.13%. Of the EPA-registered products that contain benzalkonium chloride, the one with the lowest concentration contains the active ingredient at a concentration of 3.0%. An EPA-registered product, is used in accordance with the labeled directions, is not expected to present "unreasonable risks" to human health, or to the environment. This information further supports a finding that benzalkonium chloride is generally recognized as safe.

WLI, has also performed tests of ocular toxicity, acute oral toxicity, and dermal irritation on prototype surgical scrub formulations containing benzalkonium chloride at concentrations of 1.0 % and found the following:

1. 14 Day Oral Toxicity Test in the Rat; Limit Test, Single Dose of 5 g/kg benzalkonium chloride formulation (1.0%): In this test, adult rats (10) were

administered a single dose of the benzalkonium chloride formulation (1.0%) by gavage at a 5 g/kg of body weight dose. The animals were observed for signs of toxicity one hour and 24 hours post dosing, and each day thereafter for a period of 14 days. The animals were weighed on day 7 and day 14 of the study. At the end of the 14-day period, the animals were sacrificed and a gross necropsy was performed. None of the test article-treated animals showed any toxicological effects, indicating that the WLI met the requirements of the 14-day Oral Toxicity Test in Rats, benzalkonium chloride formulation (1.0% active). (SEE TAB 11; Binder 2)

2. Primary eye irritation test (Draize): In a test of the benzalkonium chloride formulation (1.0% active) it was found that the test article caused only mild, reversible irritation to the ocular tissues of each rabbit on study. Overall, the benzalkonium chloride formulation (1.0% active) was classified as a Category III mild irritant under the conditions of the study. (SEE TAB 12; Binder 2)
3. Irritation assay for dermal and ocular irritation: The above results dealing with the benzalkonium chloride formulation (1.0% active) were confirmed by evaluations with the Irritation Assay System in order to predict its potential for ocular and dermal irritation. The ocular results of this test indicated that the sample benzalkonium chloride solution (1.0% active) was a mild irritant. The dermal results demonstrated that the sample was a borderline non-irritant/irritant. (SEE TAB 13; Binder 2)
4. 24 hour semioccluded patch test: A total of 7 volunteers received 0.2 ml of a test formulation containing benzalkonium chloride (1.0%) on the volar forearm. After 24 hours of exposure, none of the test subjects showed any signs of dermal irritation. (SEE TAB 14; Binder 2).

In addition, safety is indicated by the lack of adverse reactions in the studies cited above for daily use impact on illness absenteeism in children (SEE TABS 7,8). Taken as a whole, these data support the general conclusion of the petition 75N-183H/CP 3, and indicate that benzalkonium chloride at the concentration of 0.13% is safe for use as an active ingredient in an OTC antimicrobial handwash.

3. Conclusion

Based on the data from WLI testing, and from other petitions supporting the use of benzalkonium chloride at a concentration of 0.1-0.13%, (e.g. 75N-183H/CP 3), the FDA should find that benzalkonium chloride is generally recognized as safe and effective for use as the active ingredient in an OTC antimicrobial handwash / rinse-free hand sanitizer. If the Agency requires any additional data, or would like to discuss the submitted data, please do not hesitate

to contact WLI, who will endeavor to expeditiously submit any additional data required.

C. Environmental Impact

Pursuant to FDA regulations, action on an OTC monograph that does not increase the use of the active moiety, or if it increases the use of the active moiety the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 part per billion, are categorically excluded from an environmental impact assessment (21CFR 25-31(a)-(b)). Thus, no environmental assessment is required.

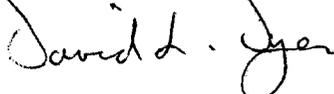
D. Economic Impact

Information on the economic impact of this proposal will be submitted if requested by the Commissioner.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petitioner relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,



David L. Dyer, Ph.D.

Director

Research and Development

Woodward Laboratories, Inc.

11132 Winners Circle, Building 100

Los Alamitos, CA

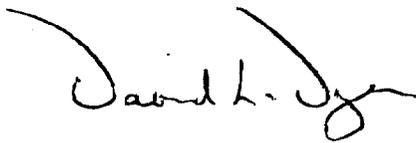
90720

(562) 598-0800

August 28, 2000

To Whom It May Concern:

I hereby authorize the FDA to display information, including that marked
"Confidential" pertinent to my Citizen Petition for acceptance of benzalkonium chloride
as a safe and effective active ingredient for healthcare personnel applications.

 6/28/2000

David L. Dyer

Director

Research and Development

Woodward Laboratories, Inc.

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David L. Dyer, Ph.D.
Director
Research and Development
Woodward Laboratories, Inc.
11132 Winners Circle, Building 100
Los Alamitos, CA
90720
(562) 598-0800

TAB Binder 1

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TAB 1

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November 9, 1999

Doctors Are Reminded: 'Wash Up!'

By EMILY YOFFE

March 27 was John Allen's last good day. He had been semicomatose in the days leading up to his heart transplant surgery, but now the transplant was working well and he was alert and communicative. "He was his old self," recalled his wife, Sandy, a psychiatric nurse, who lives in Manhattan.

There was, though, a troubling part of his recovery: the inability of his doctors to wipe out a type of antibiotic-resistant staph infection, usually spread on the hands of health care workers. But Sandy Allen says that when she returned home that day, she was hopeful her husband might soon be coming home himself. The next day she got a call from one of his doctors. John Allen, 52, the father of two teen-agers, was dead, killed by septic shock, an overwhelming infection of the bloodstream.

There is no sure way of knowing exactly how Allen picked up this hospital-based infection. But if years of studies of health care workers are right, two things are certain. First, most of the people who treated him during his hospitalization would swear they had washed their hands before they touched him. And second, many of them would be fooling themselves.



Ozier Muhammad/The New York Times

A water-free hand cleaner, operated by a foot pump, may make

themselves.

hospitals safer.

"Hands are the most dangerous thing in the hospital," said Dr. Robert A. Weinstein, director of infectious diseases for the Cook County Bureau of Health Services in Chicago.

That unclean hands can transmit germs is not news to anyone who attended nursery school. More than 150 years ago a Hungarian physician, Dr. Ignaz Semmelweis, discovered that "childbed fever," the infection that routinely killed women who had just given birth, was being spread on his colleagues' bacteria-laden hands. Yet a recent study -- conducted at the Duke University Medical Center and published last month in *The Lancet*, a medical journal -- found that only 17 percent of physicians treating patients in an intensive care unit washed their hands appropriately.

Research reported in *The Annals of Internal Medicine* this year found that the lowest rates of compliance in a hospital were among the busy staff members in a high-risk intensive care unit.

According to the Centers for Disease Control and Prevention, 5 percent of the people admitted to hospitals, about 1.8 million patients a year, will pick up an infection there. The infections cost \$4.5 billion to treat, the CDC estimates, and it says better infection control could have prevented one-third of those cases.

Twenty thousand will die as a direct result of contracting an infection in the hospital; by contrast, 17,171 Americans died of AIDS in 1998. And hospital-acquired infections will contribute to the deaths of 70,000 people, far more than the 44,190 Americans who died of breast cancer in 1997.

The problem is getting worse. Though hospital stays are shorter and less frequent than they were 20 years ago, today's patients are generally sicker and more vulnerable. As a result, in the last two decades the rate of hospital-acquired infection has risen 36 percent. And the danger has intensified in recent years with the rise of new strains of common microbes that are resistant to antibiotics.

Take staphylococcus aureus, the infection contracted by John Allen. It is carried by about 30 percent of adults with no ill effect. But a strain that has emerged in hospitals is resistant to methicillin, the most effective antibiotic used against it. Known as MRSA, the strain is most commonly spread on the hands of health care workers who pick up the microbes on one patient and pass them to another; about 80,000 patients a year contract it.

When the organism causes pneumonia or gets into the bloodstream of someone with lowered resistance, it can be lethal. This decade has seen the emergence of a number of similar hospital-based mutants spread hand by hand to patient after patient.

Nevertheless, said Dr. Elaine Larson, a professor at the Columbia University School of Nursing, "I think health care professionals wonder if it really is as important as everybody says.

The unpredictable and largely untraceable nature of these infections also helps keep workers from feeling responsible for any given case, said Larson, who has researched hand-washing practices. "Let's say you decided you didn't need to wash your hands today and a patient doesn't get an infection for a week. By then they're out of the hospital, so there's very little link."

There are no national regulatory requirements for hand-washing practices at hospitals, clinics and doctors' offices. But the Association for Professionals in Infection Control and Epidemiology recommends a vigorous soaping of 10 to 15 seconds, followed by a thorough rinse with water before and after contact with body secretions, mucous membranes or blood.

Dr. William Jarvis, chief of the Investigation and Prevention branch of the Hospital Infections Program at the CDC, recommends washing hands before and after casual patient contact. He says patients who have no visible signs of infection may be colonized with potentially dangerous antibiotic-resistant microbes. "We don't know

who's colonized or who's not," he said.

But complying with these recommendations could mean dozens to hundreds of hand washings a day.

In a letter to *The British Medical Journal* challenging recommendations like Jarvis', Dr. Andrew Weeks, a gynecologist, wrote that if such compelling evidence existed for the need to wash hands between each patient contact, "then why do I and the vast majority of my colleagues not do it?" He added, "I have never seen any convincing evidence that hand washing between each patient contact reduces infection rates."

But Dr. Abdul Zafar, now the director of infection control at Prince George's Hospital Center in Maryland, has witnessed a significant outbreak of resistant infections, which he attributed to inadequate hand-washing. When Zafar worked in Virginia, the cases developed in the newborn nursery: 22 infants contracted severe skin infections over the course of three months.

"This bacteria cannot jump or fly," Zafar said. "It was transferred hand to hand from a health care worker." The outbreak ended only when the hospital obtained antibacterial soap that smelled good and did not dry out the skin.

Jarvis was co-author of a report in *The Annals of Internal Medicine* this summer about an effort to reduce the incidence of a hospital-acquired, antibiotic resistant bloodstream infection among hospitalized cancer patients. Health care workers were monitored to make sure they were following all guidelines for isolation and infection control, including hand washing. The incidence of the infection was reduced by four-fifths.

Despite such evidence, other studies continue to show inadequate compliance with washing guidelines. Reasons include lack of time, inaccessible sinks, rough paper towels and chapped hands from excessive washing. Larson says the nature of hand washing itself -- it is tedious, repetitive and low-tech -- makes it unappealing. "It's more exciting to put in a cardiac bypass machine than wash your hands," she said.

If efforts to get people to wash their hands fail, gloves can help solve the problem. Experts agree that proper glove use works. But in a demonstration of the law of unintended consequences, because health care workers feel protected, they often engage in reckless behavior.

In a study of glove use in a long-term care center, researchers found that gloves were worn 82 percent of the time when their use was indicated, but changed appropriately only 16 percent of the time. And a 1997 study in *The Journal of Infection Control and Hospital Epidemiology* found that 42 percent of hospital personnel who touched only the surfaces of the rooms of contaminated patients ended up with drug-resistant microbes on their gloves.

"A lot of health care workers see gloves as protecting themselves," said Weinstein, of Cook County. "They put them on at the beginning of the day and don't take them off, which is the same as not washing your hands."

In the absence of a continuing outbreak, there are few incentives for hospitals to monitor their infection rates aggressively. In an era of cost containment, Jarvis said, infection control departments are under pressure to have fewer staff members because hospital administrators see them as a revenue drain.

"If you don't do good surveillance," he said, "you don't detect infections, which means they don't exist and you look great." The CDC does not require reporting of hospital-acquired infections; the agency tracks estimated rates through a voluntary and confidential program involving about 200 hospitals.

Even the people who are paying to treat the infections are not trying to force changes in behavior. "Right now we're not trying to do anything about it," said Dr. Lee N. Newcomer, a senior vice president at UnitedHealth Group, a managed care company. "Hospitals say they are paying attention to this, and I'm sure many are, but if they're not succeeding, no one cares."

Dr. Don Nielsen, senior vice president for quality leadership at the American Hospital Association, though acknowledging that hand washing fell below the ideal, disagreed with Newcomer's assessment. "Hospitals are aware of the danger and are doing everything they can to prevent infection," Nielsen said.

Larson sees great promise in the possible adoption of waterless, alcohol-based antimicrobial hand rubs, which are widely used in hospitals in Europe. She says studies show they are just as effective as hand washing but faster to use and gentler than soap and water.

And Dr. Maryanne McGuckin, a senior research investigator at the University of Pennsylvania School of Medicine, wants to turn her concentration from health care workers to the people who really care if the hands that touch them are contaminated: the patients. She has designed a program that gives information packages on the importance of hand washing to all patients being admitted to the hospital. Then the patients are instructed to ask each health care worker who comes into the room, "Did you wash your hands?"

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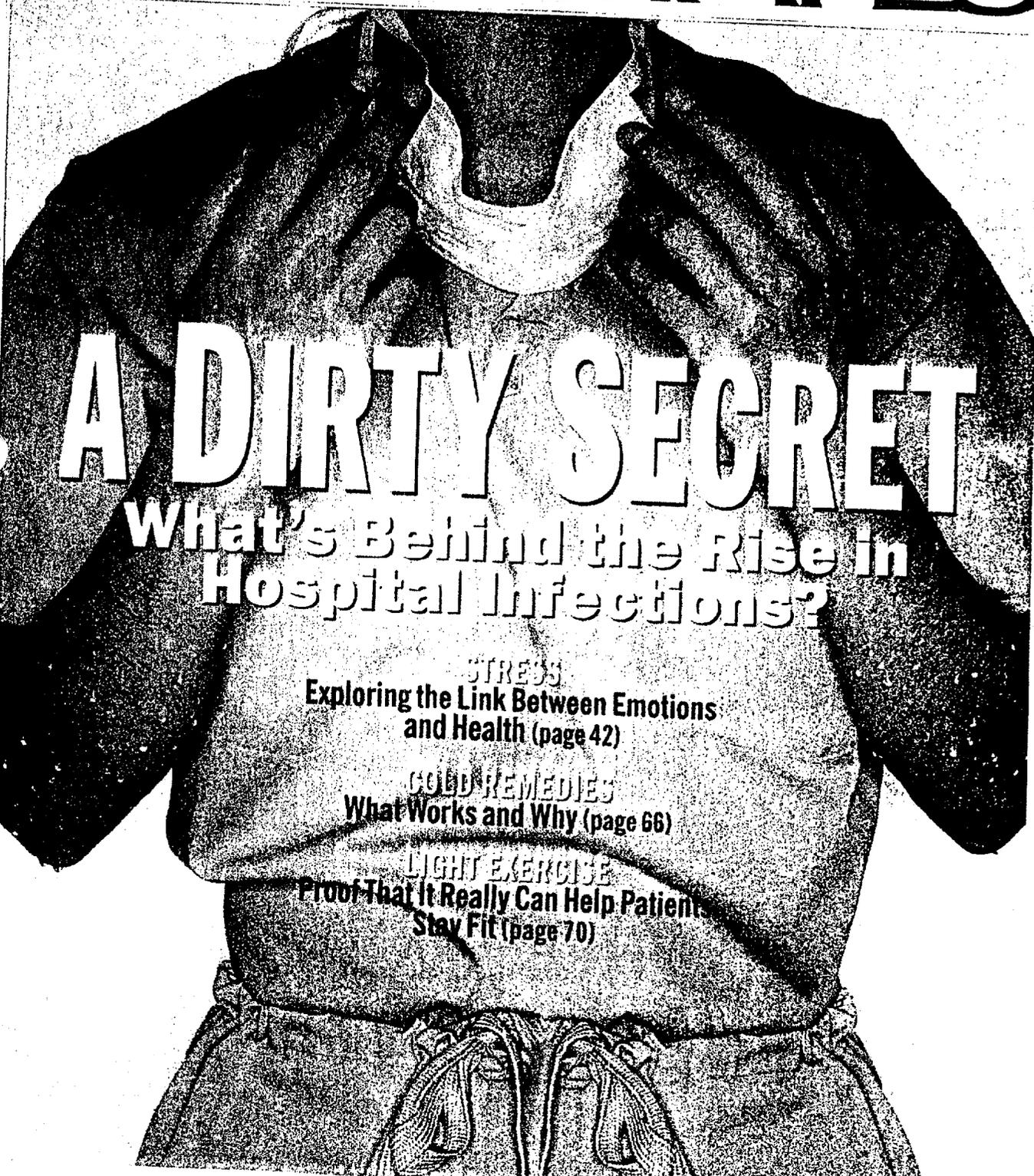
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FEBRUARY 1991

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HIPPOCRATES



A DIRTY SECRET

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HIPPOCRATES

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Editor's Note

A Crisis in the Making

W

hen Tom Morris, 33, started tiring easily, he knew it was time. Morris, the business manager of HIPPOCRATES, had a leaky valve in his heart, and the fatigue told him it needed to be replaced. He checked in to one of the country's leading medical centers. The operation went smoothly, and he was released in less than a week. He planned to return to work within the next five weeks—that is, until he was taken to the emergency room four days after his release with a high fever, his heart racing and his chest congested with fluid, thanks to a staphylococcal infection he'd picked up at the hospital. Morris had to be cut open again and was soon fighting for his life.

Morris was lucky. He survived. As staff writer Katherine Griffin reports in our cover story ("They Should Have Washed Their Hands"), many Americans are not as fortunate. Between 5 and 10 percent of the people admitted to a hospital each year contract an infection during their stay; of those, 80,000 to 150,000 die. That's more than the annual number of deaths from auto accidents and homicides combined. Only heart disease, stroke, and cancer cause more fatalities a year. And the problem may be getting worse. Turn to page 50 to find out the reasons and some possible solutions.

In this issue you can also discover why one remarkable physician continues to practice on an American Indian reservation. Author Chip Thomas, M.D., has lived and worked among the Navajo people for nine years. His photo-essay begins on page 58. Also focusing on eloquent images is HIPPOCRATES' new department, Medical Moments (page 78). This month photographer and contributing editor Max Aguilera-Hellweg offers an extraordinary look at an organ harvest and pays tribute to the donor who made it possible. The woman's gift represents the best in medicine and humanity, he says.

Tom Morris feels the same way about the operation that allows his heart to pump normally again. Back at work now, he is more likely to crack a joke about his close call at the hospital than to complain about his ordeal. But he also knows firsthand how critical a good infection control program is for a hospital—and its patients.

TEO FURTADO
Editor

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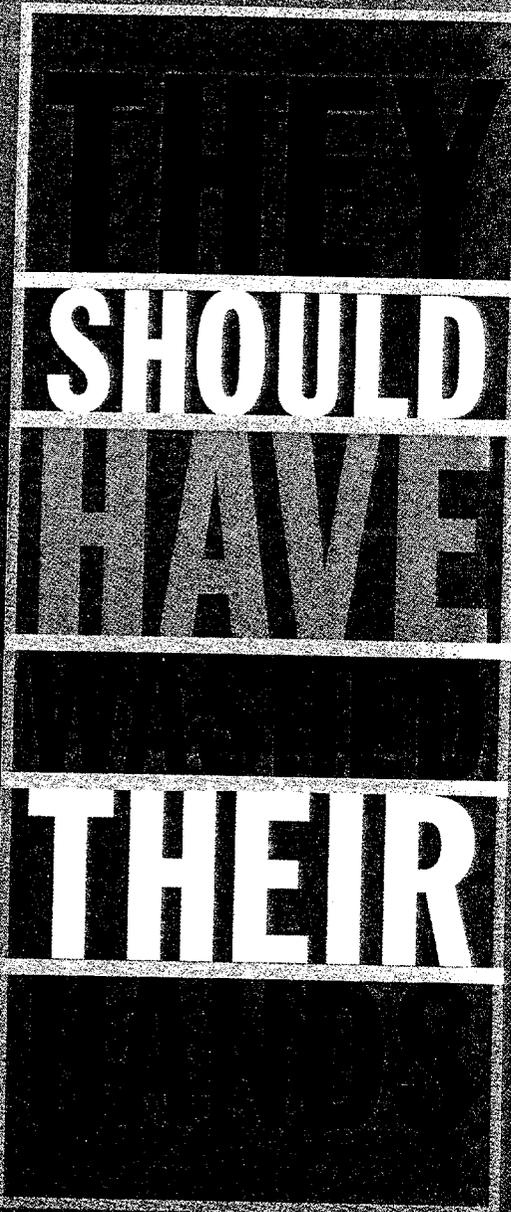
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By Katherine Griffin

THE ZAHR'S TARISEIN began one crisp winter day while he and his wife, Irene, were out walking through their tree-lined Austin neighborhood. Lately Irene had been worried about Ted. He'd fallen a few weeks earlier and on this walk she noticed that his long stride had shortened and he stumbled occasionally. The changes were subtle, but Irene had always been vigilant about her husband's movements. In the days following the fall, they found the changes more pronounced. Irene was sure that Ted was slipping on the sidewalk. She'd been watching him for weeks when he fell. "I don't know what happened," she said. "I was walking with him and he just fell. I didn't see it happen."

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hospital for many years. "He felt loyalty to the place," says his nephew, Charles Hafer.

The choice was typical of Zahra, a man whose life was marked by a faith in institutions. He had put in 33 years working for the postal service in Austin, where he earned numerous awards for coming up with bright ideas. He was an active member of his Lutheran church and an enthusiastic booster of the University of Texas sports teams. Zahra lived in an orderly universe, one in which, if you did your part, you could count on the people and organizations around you to do theirs.

In the first days after the surgery, it looked as though Zahra, who in the hospital was joined by doctors, removed the growth, which was indeed benign. And while Irene hovered by his bed in Brackenridge's intensive care unit, Ted was alert and able to sit up for ever longer periods. Since the surgery had gone so well, his family was confident he'd soon be back at home.

But on the sixth day of the ICU, Zahra began to have some trouble moving his arms and legs, and developed a fever. By the next day he was back in the ICU. The doctors removed the original diagnosis of a benign tumor. "More damage than expected" is the diagnosis of Zahra's doctor. The brain tumor, a special kind of glioma, was more intractable. The wound was a large one, with the incision spreading from Zahra's head into his neck, following his spine and triggering a stroke. One week after his surgery, a vessel that was causing him to tremble occasionally, Zahra found himself paralyzed from the neck down. What went wrong? Sometime during Zahra's recovery, a type

PHOTOGRAPHS BY MARY AGUIRRA HELLWEG



MORE AMERICANS DIE FROM HOSPITAL INFECTIONS EVERY YEAR
THAN FROM CAR WRECKS AND HOMICIDES COMBINED.
MANY OF THESE TRAGEDIES COULD BE AVOIDED—
IF TRIED-AND-TRUE INFECTION CONTROL PRACTICES WERE USED.



of bacteria that was circulating in the hospital hitchhiked into Zahr's surgical wound. And it got there, his lawyer later charged in a lawsuit against the hospital, on the unwashed hands of a nurse or doctor. Zahr's family was stunned. "You go to the hospital, you think you're going to get well," says Hafer. "This was on nobody's mind."

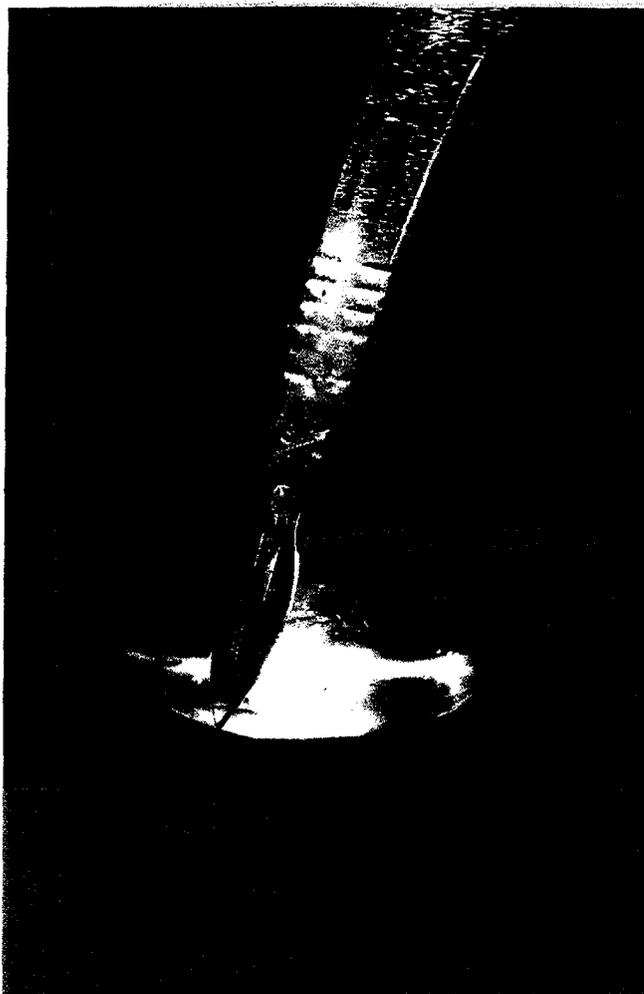
WHY HOSPITALS ARE

GETTING MORE DANGEROUS

What with outbreaks of Ebola virus in Africa, cholera in Latin America, and tuberculosis in America's cities, the notion that science might be able to vanquish infectious microbes now looks hopelessly naive. Still, we would at least like to think that we're safe from scary bacteria and viruses when we're inside hospitals, which, after all, portray themselves as bastions of cleanliness, order, and the best that modern medicine has to offer.

In fact, though hospitals don't like to talk about it, the chances that a patient or a loved one will get infected during a hospital stay are alarmingly high. Between 5 and 10 percent of hospitalized patients pick up infections, according to the Centers for Disease Control and Prevention. That's between 1.75 and 3.5 million people each year. At greatest risk are the very old, the very young, and the very sick, particularly those with weakened immune systems. But under the right conditions, microbes can attack anyone in a hospital. Sometimes, they can kill.

Every year at least 80,000 and perhaps as many as 150,000 people die from infections they didn't have before they entered the hospital. That's more than the number who die in homicides and auto accidents combined. After heart disease, stroke, and cancer, hospital-acquired infections are the nation's next biggest cause of death. The most common infections, those of the urinary tract, are not life-threatening. But those that do kill include pneumonia, contaminated surgical wounds, and bloodstream infections. Patients who survive these can expect to be hospitalized for several extra days and possibly a month or more—



often without anyone telling them that what slowed their recovery was an infection they got in the hospital.

Many experts believe the problem is growing more serious. "The numbers are probably going up," says William Jarvis, chief of investigation and prevention for the CDC's hospital infections program. "The proportion that leads to death is probably increasing." Jarvis can't give precise figures because there is no nationwide system for tracking hospital infections. But studies show that the number of the dangerous bloodstream infections, in which bacteria are transported throughout the body, doubled or tripled in many large institutions during the 1980s.

Given the direction of medicine today, some increase in hospital-acquired infections may be unavoidable. First of all, no one can eliminate microbes from hospitals—which, after all, are full of sick people. And these days hospital patients, as a group, are weaker than they used to be. Medical advances spare many who would have died 20 years ago, and cost-cutting pressures push relatively healthy people out the door more quickly. As a result,

a greater proportion of the patients in hospitals are susceptible to infections. Plus, treatments today are more likely to include catheters, intravenous devices, and tracheal tubes, creating more portals through which microbes can enter the body. Maryanne McGuckin, an infection control expert at the University of Pennsylvania, estimates it's impossible to prevent at least half of all hospital infections.

But what's disturbing is how many infections *could* be prevented. Even while infections have become more common and potentially catastrophic, breaches in the fire wall that should exist between patients and microbes are occurring every day, at hospitals large and small. The breaches include everything from hiring too few infection control specialists to leaving catheters in too long to neglecting to enforce prescribed hand washing procedures among doctors and nurses. CDC officials estimate that the failure to follow tried-and-true infection control practices causes a full *one-third* of hospital-acquired infections.

"The way hospitals have dealt with this problem has been to throw antibiotics at it," says Charles Inlander of the People's Medical Society, a national consumer group based in Allentown, Pennsylvania. "The attitude internally was, as long as we have a drug that works, there's nothing to worry about. As a result, infection control is abominable, and hospitals have never had to be accountable."

Relying on antibiotics doesn't just allow hospitals to bypass prevention. It makes the bugs themselves more dangerous. The more exposure microorganisms have to antibiotic drugs, the more likely they are to mutate into forms that resist those drugs. For years a chorus of Cassandra has warned that the overuse of antibiotics would create a class of microbes against which all known drugs would be useless. Inside hospitals, the first act of that scenario is under way: Perhaps half of infections are now caused by organisms that don't respond to an antibiotic that once killed them, and germs are developing new resistances at a staggering pace. For example, 14 percent

of enterococcal infections among patients in intensive care units now resist vancomycin, the drug of last resort in the antibiotic arsenal. That's a 20-fold increase in just seven years.

Luckily, though such infections are extremely difficult to treat, they're rare, and the people most likely to be attacked are already beyond help. Not so with a monster looming on the horizon: a strain of vancomycin-resistant staphylococcus that could kill tens of thousands of people. Staph infections are far more common and deadly than enterococcus, and they can strike people who are in good physical condition.

"We're looking at a very serious public health problem," says Richard Wenzel, who chairs the department of internal medicine at the Medical College of Virginia in Richmond. Adds Bryan Simmons, an epidemiologist who is medical director of infection control at Methodist Hospitals in Memphis, Tennessee, "Some people who come in for a minor procedure will get staph, and they will have a very tough time."

Already 25 percent of the staphylococcus found in hospitals is impervious to every drug except vancomycin. Four years ago researchers discovered that when enterococcus and staph bacteria are in proximity, they can swap genes, including the gene that codes for resistance to vancomycin. Most of the experts believe it's only a matter of time before a vancomycin-resistant staph—the first true superbug—makes hospitals extremely hazardous places to be.

THE TERRIBLE TRUTH ABOUT UNWASHED HANDS

It's impossible to know what measures Brackenridge Hospital was taking to curb infections at the time Zahr was there, because neither the city of Austin, which owns the hospital and managed it in 1990, or Seton Network, which manages it now, will comment. But in the opinion of McGuckin, the expert witness in a lawsuit Zahr has filed against the city, "This guy's case should have been prevented. It's obvious to me that this was spread by contact."

Normally such certainty is hard to come by, because hospitals, citing patient confidentiality, keep critical information behind closed doors. That's why successful hospital infection lawsuits are so rare. But in this case a judge granted Zahr's attorney, Ron Weddington, permission to

send a nurse into the hospital to review the ICU's records for a three-month period that included Zahr's hospitalization. It's from this data that McGuckin makes her case. Among 335 patients in the unit during that period, 118 were infected—a rate of 35 percent, a high proportion even for an intensive care unit full of complicated cases, she says. What's more, 12 patients, including Zahr, were infected with the same strain of a bacterium known as klebsiella, and they did not all pass through the same operating room. That means, she says, all of those patients picked up the bug in the ICU. The hospital, she believes, should have detected the ICU's problems before Zahr was admitted and taken steps to isolate patients and otherwise limit infections.

As McGuckin sees it, there is little mystery in how klebsiella, normally found in the human gastrointestinal tract, could infect so many people. The organism usually gets into the hospital environment courtesy of a patient who's careless about bathroom hygiene. After that, the most common way the bug manages to move from patient to patient is by way of doctors and nurses who fail to wash their hands.

Study after study has concluded that hospital workers are shockingly lax about keeping their hands clean. Hand washing has been the first line of defense against hospital infections since 1847, when an Austrian doctor named Ignaz Semmelweis first made doctors aware that they were infecting their own patients. When he bucked convention by getting doctors to wash up after dissecting cadavers, the change cut maternity ward deaths by more than 90 percent.

Hospital workers today are supposed to wash their hands vigorously for two minutes before starting each shift and then for ten to 15 seconds before every contact with a patient, even if they're going to put on surgical gloves. By now you'd think the practice would have become second nature. But it hasn't. "Experts in infection control coax, cajole, threaten, and plead," railed a recent editorial in the *New England Journal of Medicine*, "and still their colleagues neglect to wash their hands."

In a comprehensive review of 37 studies on hand washing, epidemiologist Elaine Larson of the Georgetown University School of Nursing found that doctors and nurses typically washed their hands only 40 percent of the time. That figure held true even in intensive care

units, with their mix of highly vulnerable patients and virulent bugs. And in some of these studies the health care workers *knew* they were being watched.

The reasons for negligence vary. Often workers simply don't realize that they're not washing up properly. One study found that nurses estimated they washed their hands correctly 90 percent of the time. But when observers followed them around, the nurses followed hand washing protocol less than 30 percent of the time. Sometimes they didn't wash at all; sometimes they washed for only three or four seconds, not long enough to get rid of bacteria. (And doctors, Larson says, are generally less likely than nurses to keep their hands clean.)

When asked, doctors and nurses say they don't wash as they should because they're too busy and because washing 40 or 50 times a shift irritates their hands. "Yes, people are busy," says Larson. "And yes, it does hurt your skin. But those are excuses." In studies where researchers provided a milder soap, hand washing behavior didn't change much. Hospital workers simply don't make the connection, Larson concludes, between how often they wash their hands and how often patients get infected.

McGuckin agrees. "This isn't rocket science," she says. "It's a basic concept we teach kids. But somehow people don't truly believe that dirty hands can be a vehicle for infection."

WHAT HAPPENS WHEN NO ONE IS WATCHING

The problem goes beyond hand washing, as Sandra Penner of Glendale, Arizona, learned the hard way. In April 1994, her mother, 67-year-old Wynona Barnette, was admitted to Scottsdale Memorial Hospital for treatment of pancreatitis and respiratory problems. Barnette improved steadily until May 1, when she began hallucinating. By the time her doctors did a blood culture, four days later, they discovered that she had a form of staph that was resistant to every drug but vancomycin. They treated her with the antibiotic, but it was too late; she died from the infection on May 8.

Penner is convinced her mother's infection was caused by sloppy practices at the hospital. Penner spent most days at her mother's side, and one day asked a respiratory therapist why she was putting on special sterile gloves to suction the bronchial catheter in Barnette's chest;

many times Penner had seen the nurses who usually looked after the catheter wearing unsterile gloves they pulled from an open box. "We're going down into her lungs," the therapist said. "We're supposed to do this." She told Penner to speak up if she ever again saw a nurse ignore this rule, because using an unsterile pair raises the chances of infection.

After her mother died, Penner took a look at the hospital bill. She found charges for 155 bronchial catheters but only 22 pairs of sterile gloves. That means, she says, that her mother was put at increased risk for infection at least 80 percent of the times nurses tended to her catheter.

The hospital disputes Penner's allegation, saying that gloves are sometimes included in the bill with catheters; they aren't always itemized separately. Penner says there's no explaining away what she saw at her mother's bedside. "Hospital administrators do not enforce sanitary protocols that are already established. I find this outrageous."

Indeed, hospitals aren't following many practices proven to lower infection rates, researchers say. A 1987 report from the General Accounting Office found that only 20 percent of hospitals routinely let surgeons know how many of their patients develop wound infections, which CDC research has shown to be an effective way to prompt surgeons to increase their vigilance. Another study found that Universal Precautions, a set of sanitary practices intended to protect patients and guard health workers against bloodborne diseases like AIDS, are followed only 55 percent of the time.

Hospitals do little or nothing to stop such sloppiness because no one is watching. To be certified by the Joint Commission on Accreditation of Health Care Organizations, a hospital must show that it has certain infection control policies and procedures in place. But in 1992, 99 percent of the hospitals evaluated by the commission passed that test and earned full accreditation even though half were found to *not* have effective infection con-



trol, according to internal commission documents publicized by the watchdog group Public Citizen. Despite recent signs that the commission's inspections are getting tougher, critics say, the regulator doesn't go nearly far enough.

"In every single case we've investigated," says the CDC's Jarvis, "the hospital may have had the correct policy in place, but the Joint Commission hasn't been able to take it to the next step to see how much of the policies were being followed. We're always amazed. In practice, the right thing was not being done."

It doesn't help that, just as the infection threat grows more frightening, hospitals are under intense financial pressure. Insurers are forcing patients to go home as soon as possible, and steering many to outpatient centers. Since 1987 more than 600 of the nation's hospitals have shut their doors. Scores of others are losing money. Increasingly hospital administrators are squeezed to turn a quick profit by pursuing "revenue generation" above all

else. "If you're an administrator," says Jarvis, "and someone comes to you and says, 'If we hire another heart surgeon we can do three more bypasses each day at \$200,000 a pop,' you're going to spend money on that rather than on infection control."

Such short-term thinking is even driving some institutions to make cuts in infection control. They are reducing staffs, which means fewer people to take cultures, monitor trouble spots, and keep the pressure on about washing hands.

Nurses, too, are being laid off, which researchers now know raises the risk of infection further. In one study, at the Veterans Affairs Medical Center in Tucson, Arizona, the CDC linked the hospital's outbreak of bloodstream infections among patients with chest catheters to cutbacks in the nursing staff. Nurses who kept their jobs were stretched thin, with less time for washing their hands and cleaning the area around each patient's catheter. In another study, bloodstream infections rose at a Southwestern hospital that had cut the number of nurses who worked exclusively in the

ICU and rotated in others from elsewhere in the hospital. The researchers' conclusion: Fewer experienced ICU nurses translated into a greater number of infections for patients.

The irony is that, in this era of managed care, more attention to infection control would save hospitals money. "Fifteen years ago hospitals made money off infections," says epidemiologist Bryan Simmons. That's because insurers paid the bills for longer stays without asking questions. Now, with health plans typically paying only a flat fee for every enrollee, hospitals must pay the extra costs to treat patients who develop complications. As a result, studies show, a strong program will more than pay for itself.

"You have to say, the people who aren't doing good infection control now are stupid businessmen," Simmons says. "And there are stupid businessmen out there."

To be fair, some hospitals understand the economics and are working to curb infections. Some of them have joined the

CDC's National Nosocomial Infections Surveillance System, a group of 200-odd hospitals that volunteer to anonymously report infections to the agency.

Many of these hospitals and others with effective programs have installed sophisticated computer systems to analyze infection rates throughout their facilities. Many limit the prescribing of certain antibiotics in order to stem the growth of drug-resistant organisms. They are also likely to have at least one full-time infection control practitioner for every 200 beds—a ratio that allows the specialists to be highly visible and, when an outbreak occurs, to act quickly.

For example, in 1988, when the Iowa City Veterans Affairs Medical Center experienced stubbornly high rates of a staph infection that didn't respond to any antibiotic but vancomycin, infection control experts teamed with doctors and nurses to increase reminders to wash hands. At staff meetings, doctors' hands were cultured as a vivid reminder that they carry bacteria. When a new case occurred, the patient's doctor received a letter pointing out the link between this type of infection and hand washing. Infection rates were soon cut in half.

The problem for physicians and their patients is that it's nearly impossible to distinguish responsible institutions from those that cut corners. Hospitals don't have to reveal what they do—or don't do—to protect the people they treat.

WHAT HOSPITALS KNOW AND DON'T TELL PATIENTS

Two years ago Karen Burton, a retired computer consultant in Iowa City, called the University of Iowa Hospital, where she planned to go for an elective ear operation. "I just naively asked to see their hospital-acquired infection rates," she says. "I got transferred around and around until I hit a brick wall."

The hospital's attorney told her that the hospital does gather data internally on infection rates, as required by the Joint Commission on Accreditation. But, like virtually all hospitals, it does not make the information public.

"There was a certain arrogance that piqued my interest," Burton says. "It irritated me that such an important public body isn't accountable to the public."

Eventually Burton hired an attorney and sued the hospital for release of the data under the Iowa Open Records Act. Last spring she won a summary judg-

ment. But because the university plans to appeal, she has yet to see the data.

Hospitals say they don't want the public to know their infection rates because different hospitals gather them differently, leaving no accurate way for consumers to compare. The hospitals have a point: Some institutions adjust their figures to take into account the severity of patients' illnesses, while others do not. Big-city public hospitals or university medical centers, with their higher proportion of complicated cases, will probably have higher rates of infection than private hospitals whose patients tend to be



INFECTED WHILE IN INTENSIVE CARE, ZAHR (WITH NEPHEW CHARLES HAFER) IS NOW WHEELCHAIR-BOUND FOR LIFE.

healthier. And any hospital with a conscientious surveillance program will turn up higher numbers of infections than a less vigilant institution.

"Infection rates can look very good when no one is looking," says Ann Kobs, of the department of standards at the Joint Commission on Accreditation. Until hospitals start to crunch their numbers similarly, making fair comparisons will be difficult.

Nevertheless, consumer advocates say, mandatory release of infection rates is the only way to bring change. There's evidence from elsewhere in medicine that making "quality of care" data available benefits patients. Since 1989 New York State officials have released standardized data on deaths from heart surgery, and some doctors whose patients had high death rates have stopped practicing surgery. As of 1993 the mortality rate from such surgery had dropped from 4.17 to 2.56 per 100 patients.

"Why shouldn't a consumer of health care be able to walk into a facility that's licensed and regulated by the state, that's taxpayer supported and has exclusive power to do things no other institution can do, with the information to know

whether that's a safe place?" says Charles Inlander of the People's Medical Society. "It never hurts to have the light of day shine in." The group is pushing for state legislation requiring hospitals to make infection rates public.

McGuckin would like to see a hospital in the midst of a flare-up notify patients about it before they come in for elective surgery. Brackenridge, for instance, could have told Ted Zahr that lots of infections were surfacing in the unit where he would be recovering, and that he could schedule his operation for a later time, when the staff had the problem in check.

But the kind of forthrightness she advocates is so rare as to be nonexistent.

"You're making someone sign a consent form saying they understand the risks of surgery," McGuckin says. "But you're leaving out that you're having a problem with infections."

Ted Zahr signed such a form, and now he's confined to a wheelchair for life. He spent the first months after his stroke in a rehabilitation center, his wife at his side, feeding and encouraging him through

the grueling physical therapy that helped him regain use of his upper body. Irene's goal was to get him well enough to come home to the low-slung brick house where they'd lived together since 1956.

After almost a year of effort, the couple succeeded. But less than a month after that, Irene died of cancer.

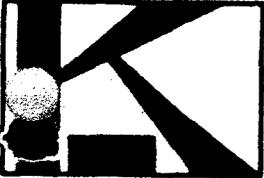
Since her death, Ted has lived in the Buckner Villa Siesta nursing home. He still keeps up with University of Texas sports teams, but nowadays it's via the newspaper and television. A photograph of him with Irene is prominently displayed on top of the TV set.

It's likely that Zahr, who comes from a long-lived family, will survive many more years. But he'll spend those years inside the walls of the nursing home. He'll never walk again, or swim, or putter in his yard, or do any of the other small but significant things that, for him, added up to an independent life.

Zahr sometimes gets upset when he thinks about what happened to him in the hospital, so he tries not to dwell on it. But he will tell a visitor, "They should have washed their hands." ■

Katherine Griffin is a staff writer.

TAB 2



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STUDY TITLE

MODIFIED TIME KILL STUDY

REPORT TITLE

ILTC Pure Rx Antimicrobial Product

PROTOCOL NUMBER

Laboratory Number 171314

AUTHOR

Dr. Peter J. Kmieck
Director, Kappa Laboratories, Inc.

STUDY COMPLETED ON

January 25, 2000

PERFORMING LABORATORY

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2577 N.W. 74th Avenue
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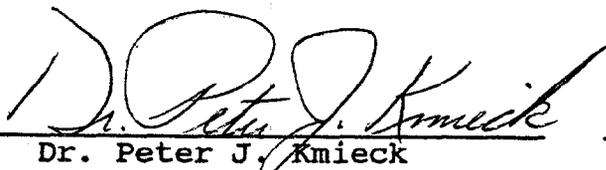
GOOD LABORATORY PRACTICE STATEMENT

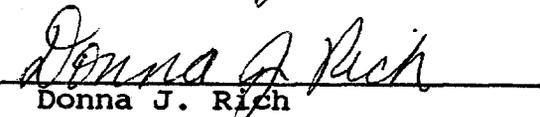
The study referenced in this report was conducted in compliance with U.S. Food and Drug Administration, Good Laboratory Practice (GLP) regulations set forth in 21 CFR Part. 58.

The studies not performed by or under the direction of Kappa Laboratories, Inc. are exempt from this Good Laboratory Practice Statement and include: characterization and stability of the compound(s).

Submitter: Int. Lab. Tech. Corp. Date: February 5, 1999
Sponsor: David Mall, President Date: February 5, 1999
Study Director Peter J. Kmieck, Ph.D. Date: February 5, 1999

ACCEPTANCE:

Project Director:  01/25/00
Dr. Peter J. Kmieck Date

Study Manager:  1/25/00
Donna J. Rich Date

Lab Associate:  1/25/00
Juana R. Rodriguez Date

Q/A Officer:  1/25/00
Denise M. Kmieck Date

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Microbiological Organisms - Stock Culture Log

25 Required Organisms and at least 25 Isolates:

CFR, Vol 59, No.116, Section 333.470

Testing of health-care antiseptic drug products.

Microbiological Organisms - Stock Culture Log

Staphylococcus aureus	(ATCC No.6538)
Escherichia coli	(ATCC No.25922)
Pseudomonas aeruginosa	(ATCC No.15442)
Enterobacter aerogenes	(ATCC No.13048)
Enterococcus faecalis	(ATCC No.29212)
Candida albicans	(ATCC No.10231)
Candida glabrata	(ATCC No. 2001)
Klebsiella oxytoca	(ATCC No.33496)
Escherichia coli	(ATCC No.11229)
Acinetobacter sp.	(ATCC No.49139)
Klebsiella pneumoniae	(ATCC No.13882)
Pseudomonas aeruginosa	(ATCC No.27858)
Proteus mirabilis	(ATCC No.7002)
Serratia marcescens	(ATCC No.14756)
Staphylococcus hominis	(ATCC No.27844)
Staph. epidermidis	(ATCC No.1228)
Staphylococcus aureus	(ATCC No.29213)
Enterococcus faecium	(ATCC No.27270)
Streptococcus pyogenes	(ATCC No.12384)
Strep. saprophyticus	(ATCC No.15305)
Streptococcus pneumoniae	(ATCC No.6303)
Staph. haemolyticus	(ATCC No.29970)
Haemophilus influenza	(ATCC No.35540)
Bacterioides fragilis	(ATCC No.23745)
Micrococcus luteus	(ATCC No.9341)

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25 Additional Isolates:

CFR, Vol 59, No.116, Section 333.470

Testing of health-care antiseptic drug products.

Serratia liquefaciens	(ATCC No.27592)
Enterobacter cloacae	(ATCC No.13047)
Bordetella bronchiseptica	(ATCC No.10580)
Micrococcus luteus	(ATCC No.10240)
Salmonella typhi	(ATCC No.6539)
Listeria monocytogenes	(Ch4, Smp113)
Burkholderia cepacia	(ATCC No.25416)
Edwardsiella tarda	(ATCC No.15947)
Enterococcus avium	(ATCC No.14025)
Enterobacter gergoviae	(ATCC No.3328)
Shigella flexneri	(ATCC No.9199)
Streptococcus bovis	(ATCC No.9809)
Proteus vulgaris	(ATCC No.6896)
Providencia stuartii	(ATCC No.33672)
Staphylococcus capitis	(ATCC No.35661)
Escherichia coli	(ATCC No.8739)
Pseudomonas aeruginosa	(ATCC No.9027)
Salmonella typhimurium	(ATCC No.14028)
Klebsiella pneumoniae	(ATCC No.4352)
Enterococcus durans	(ATCC No.49135)
Streptococcus agalactiae	(ATCC No.12386)
Acinetobacter baumannii	(ATCC No.19606)
Salmonella choleraesuis	(ATCC No.10708)
Listeria monocytogenes	Mills Jennings
Streptococcus mutans	(ATCC No.35668)

Kappa Laboratories - Crossreferenced Materials:

Thermometer Records/Incubation Temperature Log
Test Record/Notes - Sample Log Book (SpecMic)/Laboratory Worksheets
Media Log Book: Dated per analysis with Media production records.
Media Logbook: Lethen broths and buffer solutions per date/lot#.
Sterilization Log: according to date/indicator strip verification.
Media Validation performed per Lot - recorded Worksheet.

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METHOD AND RESULTS SUMMARY

Modified Time Kill Study Assay:

Quality Assurance Unit:

The objective of the Quality Assurance Unit is to monitor the conduct and reporting of nonclinical laboratory studies. These studies have been performed under Good Laboratory Practice regulations (21 CFR Part 58) and in accordance to standard operating procedures and standard protocols. The Quality Assurance Unit maintains copies of study protocols and standard operating procedures and has inspected this study on the date(s) listed below. Studies are inspected at time intervals to assure the integrity of the study. The findings of these inspections have been reported to management and the Study Director.

Phase Inspected: (Phases inspected each procedure / Addendum) Study Review - Worksheet Information

Test Set up - MTK Study	Date: Test Date
Platings/transfer MTK Study	Date: Test Date
Platings/readings MTK Study	Date: 24 to 48 Hours
Final Report	Date: 01/12/00 DR/PJK
Study Director Review	Date: 01/20/00 PJK
Management Review	Date: 01/20/00 DMK
Report Date	Date: 01/25/00 PJK/DMK

Professional personnel involved:

- Laboratory Director: Peter J. Kmieck, Ph.D.
- Study Director: Peter J. Kmieck, Ph.D.
- Laboratory Supervisor: Jacqueline Marchal, B.S.
- Research Assistant: Donna Rich, M.S.
- Quality Assurance Director: Denise M. Kmieck, B.A.

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PROJECT: Modified Time Kill Study - ILTC Pure Rx Product
Antibacterial Handwash.

REPORT DATE: January 25, 2000

SPONSOR:

International Laboratory Technology, Corp. (ILTC)
3389 Sheridan Street, Suite #149
Hollywood, Florida 33021

DATA RETENTION

A certified copy of the original final report and all raw data pertinent to this study will be stored at Kappa Laboratories, Inc., 2577 N. W. 74 Avenue, Miami, Florida 33132. The test substance will be discarded per Sponsor's request following study completion.

TEST MATERIAL: ILTC Pure Rx Product Antibacterial Handwash with an active ingredient of Benzalkonium chloride Lot #304 at 1422 PPM concentration and Lot #450 at 1167 PPM concentration.

CONTROL MATERIAL: Experimental Controls per Method

CHARACTERIZATION

The identity, strength, stability, solubility, purity and chemical composition were not provided to Kappa Laboratories, Inc. by Sponsor.

OBJECTIVE

The objective of this study was to evaluate the Time Kill Kinetics of antimicrobial activity of the ILTC Pure Rx Antibacterial Handwash with an active ingredient of Benzalkonium chloride against Gram Positive and Gram Negative bacterial test organisms and others as specified in the CFR, Vol 59, No.116, Section 333.470 Testing of health-care antiseptic drug products.

TEST FACILITY: Kappa Laboratories, Inc.
2577 N. W. 74 Avenue
Miami, Florida 33122

STUDY INITIATION DATE:	02/05/99	
DATE SAMPLE RECEIVED:	07/12/99 - X304	11/15/99 - X450
EXPERIMENTAL START DATE:	10/28/99 - X304	11/23/99 - X450
STUDY COMPLETION DATE:	01/12/00	

REFERENCES

Time Kill Study and Modified Time Kill Study protocol supplied by ECOLAB, MS022-05.
Federal Register/ Volume 59, No.116, Section 333.470, "Testing of Health Care Antiseptic Drug Products".

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METHOD AND RESULTS SUMMARY

EXPERIMENTAL DESIGN

CULTURE MEDIA

1. Trypticase Soy Broth (BBL-211768):

Prepare according to manufacturer's directions. Dispense 10 ml quantities into 20X150 mm test tubes and cap. Autoclave for 20 minutes at 121 degrees C.

2. Trypticase Soy Agar (BBL-211043):

Prepare according to manufacturer's directions. Dispense 10 ml quantities into 20X150 mm test tubes and cap. Autoclave for 20 minutes at 121 degrees C. Slant until cooled and solidified.

SUBCULTURE MEDIA

1. Trypticase Soy Agar (BBL-211043):

Prepare according to manufacturer's directions. Dispense in quantities suitable for easy handling and aseptic technique. Autoclave for 20 minutes at 121 degrees C.

2. Lethen Broth (BBL):

Prepare according to manufacturer's directions. Dispense 9 ml quantities into 20 X 150 mm test tubes (modified procedure). Autoclave for 20 minutes at 121 degrees C.

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REAGENTS AND APPARATUS

1. Phosphate Buffer Stock (0.25M)

Dissolve 34.0 g KH_2PO_4 in 500 ml of purified De-ionized water. Adjust to pH 7.2 with 1N NaOH and dilute to 1L.

2. Phosphate Buffer Dilution Water

Add 1.25 ml of 0.25M phosphate buffer stock to 1L of purified De-ionized water and mix. Dispense in 99 ml portions in media dilution bottles and 9 ml into 20 X 150ml test tubes. Autoclave for 20 minutes at 121 degrees C.

3. Glassware

30 ml beakers with magnetic stir bars. Cover with aluminum foil and sterilize for 20 minutes at 121 degrees C.

4. Petri Dishes

Sterile disposable petri dishes, 15 x 100mm.

5. Pipets

Sterile disposable 1ml and 5ml pipets.

6. Transfer Loops

Sterile plastic 10 microliter transfer loop

7. Magnetic Stir Plate.

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TEST SYSTEM: Microorganism Preparation

Microorganisms are maintained on Trypticase Soy agar slants by quarterly transfers. Slants are stored at 4 degrees C. From the stock culture inoculate a tube of Trypticase Soy broth and make at least 3 consecutive 24 hour transfers in Trypticase Soy broth incubated at 35 degrees \pm 2 degrees C before using culture for testing. (If only one daily transfer has been missed, it is not necessary to repeat the 3 consecutive transfers). Use 22-26 hour broth culture of organism grown in Trypticase Soy broth at 35 degrees C \pm 2 degrees C. Vortex and let settle for 15 minutes prior to testing.

OPERATING TECHNIQUE - MODIFIED TIME KILL STUDY

1. Place 10 ml of antibacterial test product in 30 ml beaker and place on magnetic stir plate. Adjust speed of mixer for rapid mixing without creating air bubbles.
2. Add 0.2 ml of test organism to antibacterial test product.
3. After each desired exposed time (30 seconds, 1, 5, 10 and 15 minutes), remove 1.0 ml of inoculated antibacterial test product and subculture into 9 ml of Lethen Broth. This represents a 10 to the (-1) dilution. After a 1 minute exposure to Lethen broth transfer is made of 1ml into 9ml and 1ml into 99ml of Phosphate buffer. These represent a 10 (-2) and 10 (-3) dilution.
4. From the 10 (-2) dilution pipet in triplicate 1ml portions to petri dishes and from the 10 (-3) dilution pipet in triplicate 1ml to petri dishes. The plates are poured with 15ml to 20ml of Trypticase Soy Agar into each dish, swirled to mix and allowed to harden. The plates were incubated at 35 degrees C \pm 2 degrees.
5. For each test organism tested, initial test organism numbers must be determined. Serial dilutions were carried out on test organisms in both letheen and phosphate buffer. A 0.2ml aliquot of test organism culture was used as the initial inoculum with sequential dilutions to yield a 10 (-5) concentration. The final 10 (-5) dilution was plated in triplicate to derive initial organism count. Each lot of letheen broth was verified for initial counts and compared to phosphate buffer initial counts.

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CALCULATION

I = Initial Bacterial Suspension Count

S = Survivors (Test Substance) Count

$$\%R = I-S/I \times 100$$

Results should be reported as a % reduction in relationship to exposure time. To be an effective antimicrobial according to this test procedure, >99.99% reduction should be achieved.

CONTROLS

1. Neutralization Method: Perform this procedure in triplicate.
For the Modified Time Kill Study:

Inoculate the following solutions with 0.1 ml of a 10 to the -4 dilution of the test system:

- a. 8.9 ml neutralizer + 1 ml test substance use-solution
- b. 9.9 ml neutralizer
- c. 9.9 ml sterile Phosphate Buffer Dilution Water
- d. 8.9 ml Phosphate Buffer + 1ml Test Substance at Use Dilution.

After a 1 minute contact time, enumerate the bacteria using serial dilutions and spread plate technique. Incubate the plates at 35 degrees C for 24 hours to 48 hours, (or whatever temperature is appropriate for growth of the test system).

The data obtained will show the neutralizer to be effective if a=b. The neutralizer will be observed not to be detrimental to the test system is b=c. If d < c neutralization is indicated.

2. Positive Control of 0.1ml of test culture in a Trypticase Soy Agar pour plate or appropriate media for organism being tested.
3. Sterile Lethen Broth
Plate 1 ml of letheen broth used in the test.
4. Sterile Phosphate Buffer Dilution Water
Plate 1 ml of sterile phosphate buffer used in the test.

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PROJECT: Modified Time Kill Assay - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS
Staphylococcus aureus (ATCC No.6538)

Percent Reduction indicated for test time points.
Note: NG = No Growth Detected at 48 Hours Incubation
G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 600,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: Modified Time Kill Assay - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS
Enterobacter aerogenes (ATCC No.13048)

Percent Reduction indicated for test time points.
Note: NG = No Growth Detected at 48 Hours Incubation
G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 150,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Enterococcus faecalis (ATCC No.29212)

Percent Reduction indicated for test time points.

Note: NG = No Growth Detected at 48 Hours Incubation

G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 410,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Candida albicans (ATCC No.10231)

Percent Reduction indicated for test time points.

Note: NG = No Growth Detected at 48 Hours Incubation

G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 380,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	<99.99%	<99.99%	<99.99%	<99.99%
60 Seconds	>99.99%	>99.99%	<99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - Pure Rx Antibacterial Handwash,
Lot #304, with an active ingredient of Benzalkonium chloride at 1422
PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Klebsiella oxytoca (ATCC No.33496)

Percent Reduction indicated for test time points.

Note: NG = No Growth Detected at 48 Hours Incubation

G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 470,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2)
separate analytical procedures performed in triplicate for the
determination of the Bacteriocidal Kinetics.

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PROJECT: Modified Time Kill Assay - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS
Escherichia coli (ATCC No.11229)

Percent Reduction indicated for test time points.
Note: NG = No Growth Detected at 48 Hours Incubation
G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 750,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS Escherichia coli (ATCC No.25922)

Percent Reduction indicated for test time points.
Note: NG = No Growth Detected at 48 Hours Incubation
G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 670,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS Acinetobacter sp. (ATCC No.49139)

Percent Reduction indicated for test time points.
Note: NG = No Growth Detected at 48 Hours Incubation
G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 100,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - Pure Rx Antibacterial Handwash,
Lot #304, with an active ingredient of Benzalkonium chloride at 1422
PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Klebsiella pneumoniae (ATCC No.13882)

Percent Reduction indicated for test time points.

Note: NG = No Growth Detected at 48 Hours Incubation

G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 650,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2)
separate analytical procedures performed in triplicate for the
determination of the Bacteriocidal Kinetics.

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PROJECT: Modified Time Kill Assay - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS
Pseudomonas aeruginosa (ATCC No.27858)

Percent Reduction indicated for test time points.

Note: NG = No Growth Detected at 48 Hours Incubation

G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 620,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS Proteus mirabilis (ATCC No.7002)

Percent Reduction indicated for test time points.
Note: NG = No Growth Detected at 48 Hours Incubation
G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 460,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Pseudomonas aeruginosa (ATCC No.15442)

Percent Reduction indicated for test time points.

Note: NG = No Growth Detected at 48 Hours Incubation

G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 550,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Serratia marcescens (ATCC No.14756)

Percent Reduction indicated for test time points.

Note: NG = No Growth Detected at 48 Hours Incubation

G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 520,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: Modified Time Kill Assay - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS
Staphylococcus hominis (ATCC No.27844)

Percent Reduction indicated for test time points.
Note: NG = No Growth Detected at 48 Hours Incubation
G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 100,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Staphylococcus aureus (ATCC No.29213)

Percent Reduction indicated for test time points.

Note: NG = No Growth Detected at 48 Hours Incubation

G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 520,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Staphylococcus epidermidis (ATCC No.12228)

Percent Reduction indicated for test time points.

Note: NG = No Growth Detected at 48 Hours Incubation

G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 520,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS Candida glabrata (ATCC No.2001)

Percent Reduction indicated for test time points.

Note: NG = No Growth Detected at 48 Hours Incubation

G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 360,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: Modified Time Kill Assay - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Enterococcus faecium (ATCC No.27270)

Percent Reduction indicated for test time points.

Note: NG = No Growth Detected at 48 Hours Incubation

G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 620,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS Streptococcus pyogenes (ATCC No.12384)

Percent Reduction indicated for test time points.
Note: NG = No Growth Detected at 48 Hours Incubation
G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 180,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS Streptococcus saprophyticus (ATCC No.15305)

Percent Reduction indicated for test time points.
Note: NG = No Growth Detected at 48 Hours Incubation
G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 77,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Streptococcus pneumoniae (ATCC No.6303)

Percent Reduction indicated for test time points.
Note: NG = No Growth Detected at 48 Hours Incubation
G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 67,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: Modified Time Kill Assay - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS Staphylococcus haemolyticus (ATCC No.29970)

Percent Reduction indicated for test time points.

Note: NG = No Growth Detected at 48 Hours Incubation

G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 65,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS Micrococcus luteus (ATCC No.9341)

Percent Reduction indicated for test time points.
Note: NG = No Growth Detected at 48 Hours Incubation
G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 110,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Bacteroides fragilis (ATCC No.23745)

Percent Reduction indicated for test time points.

Note: NG = No Growth Detected at 48 Hours Incubation

G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 900,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - Pure RX Antibacterial Handwash,
Lot #304, with an active ingredient of Benzalkonium chloride at 1422
PPM concentration.

REPORT DATE: January 25, 2000

RESULTS Haemophilus influenza (ATCC No.35540)

Percent Reduction indicated for test time points.
Note: NG = No Growth Detected at 48 Hours Incubation
G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 1,300,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2)
separate analytical procedures performed in triplicate for the
determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - Pure Rx Antibacterial Handwash,
Lot #304, with an active ingredient of Benzalkonium chloride at 1422
PPM concentration.

REPORT DATE: January 25, 2000

RESULTS
Salmonella typhimurium (ATCC No.14028)

Percent Reduction indicated for test time points.
Note: NG = No Growth Detected at 48 Hours Incubation
G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 450,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2)
separate analytical procedures performed in triplicate for the
determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Pseudomonas aeruginosa (ATCC No.9027)

Percent Reduction indicated for test time points.

Note: NG = No Growth Detected at 48 Hours Incubation

G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 600,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS Escherichia coli (ATCC No.8739)

Percent Reduction indicated for test time points.
Note: NG = No Growth Detected at 48 Hours Incubation
G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 380,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Serratia liquefaciens (ATCC No.27592)

Percent Reduction indicated for test time points.

Note: NG = No Growth Detected at 48 Hours Incubation

G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 700,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Enterobacter cloacae (ATCC No.13047)

Percent Reduction indicated for test time points.

Note: NG = No Growth Detected at 48 Hours Incubation

G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 1,800,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Bordetella bronchiseptica (ATCC No.10580)

Percent Reduction indicated for test time points.
Note: NG = No Growth Detected at 48 Hours Incubation
G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 380,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Micrococcus luteus (ATCC No.10240)

Percent Reduction indicated for test time points.

Note: NG = No Growth Detected at 48 Hours Incubation

G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 680,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS Salmonella typhi (ATCC No.6539)

Percent Reduction indicated for test time points.
Note: NG = No Growth Detected at 48 Hours Incubation
G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 51,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Listeria monocytogenes (Lab No. Ch. 4, Smpl 13)

Percent Reduction indicated for test time points.

Note: NG = No Growth Detected at 48 Hours Incubation

G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 420,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Burkholderia cepacia (ATCC No.25416)

Percent Reduction indicated for test time points.
Note: NG = No Growth Detected at 48 Hours Incubation
G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 220,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Edwardsiella tarda (ATCC No.15947)

Percent Reduction indicated for test time points.
Note: NG = No Growth Detected at 48 Hours Incubation
G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 650,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Enterococcus avium (ATCC No.14025)

Percent Reduction indicated for test time points.

Note: NG = No Growth Detected at 48 Hours Incubation

G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 880,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Enterobacter gergoviae (ATCC No.3328)

Percent Reduction indicated for test time points.
Note: NG = No Growth Detected at 48 Hours Incubation
G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 180,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Shigella flexneri (ATCC No.9199)

Percent Reduction indicated for test time points.
Note: NG = No Growth Detected at 48 Hours Incubation
G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 880,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #304, with an active ingredient of Benzalkonium chloride at 1422 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Streptococcus bovis (ATCC No.9809)

Percent Reduction indicated for test time points.

Note: NG = No Growth Detected at 48 Hours Incubation

G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 9,200,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #450, with an active ingredient of Benzalkonium chloride at 1167 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Proteus vulgaris (ATCC No.6896)

Percent Reduction indicated for test time points.

Note: NG = No Growth Detected at 48 Hours Incubation

G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 300,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #450, with an active ingredient of Benzalkonium chloride at 1167 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Providencia stuartii (ATCC No.33672)

Percent Reduction indicated for test time points.
Note: NG = No Growth Detected at 48 Hours Incubation
G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 440,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #450, with an active ingredient of Benzalkonium chloride at 1167 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Staphylococcus capitis (ATCC No.35661)

Percent Reduction indicated for test time points.

Note: NG = No Growth Detected at 48 Hours Incubation

G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 720,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #450, with an active ingredient of Benzalkonium chloride at 1167 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Klebsiella pneumoniae (ATCC No.4352)

Percent Reduction indicated for test time points.
Note: NG = No Growth Detected at 48 Hours Incubation
G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 750,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #450, with an active ingredient of Benzalkonium chloride at 1167 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Enterococcus durans (ATCC No.49135)

Percent Reduction indicated for test time points.

Note: NG = No Growth Detected at 48 Hours Incubation

G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 110,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #450, with an active ingredient of Benzalkonium chloride at 1167 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Streptococcus agalactiae (ATCC No.12386)

Percent Reduction indicated for test time points.

Note: NG = No Growth Detected at 48 Hours Incubation

G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 720,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #450, with an active ingredient of Benzalkonium chloride at 1167 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Acinetobacter baumannii (ATCC No.19606)

Percent Reduction indicated for test time points.
Note: NG = No Growth Detected at 48 Hours Incubation
G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 260,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #450, with an active ingredient of Benzalkonium chloride at 1167 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS Salmonella choleraesuis (ATCC No.10708)

Percent Reduction indicated for test time points.

Note: NG = No Growth Detected at 48 Hours Incubation

G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 540,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #450, with an active ingredient of Benzalkonium chloride at 1167 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Listeria monocytogenes (Lab No. Mills Jennings)

Percent Reduction indicated for test time points.

Note: NG = No Growth Detected at 48 Hours Incubation

G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 3,500,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - ILTC Pure Rx Antibacterial Handwash, Lot #450, with an active ingredient of Benzalkonium chloride at 1167 PPM concentration.

REPORT DATE: January 25, 2000

RESULTS

Streptococcus mutans (ATCC No.35668)

Percent Reduction indicated for test time points.

Note: NG = No Growth Detected at 48 Hours Incubation

G = Growth Detected at 48 Hours Incubation

Average Initial Bacterial Counts = 510,000,000 cts. per 0.2 ml.

<u>Time Point</u>	<u>Percent Reduction</u>			
30 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
60 Seconds	>99.99%	>99.99%	>99.99%	>99.99%
5 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
10 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
15 Minutes	>99.99%	>99.99%	>99.99%	>99.99%
Positive Controls	G	G	G	G
Negative Controls	NG	NG	NG	NG

Note: Time Kill Value represents the average value of two (2) separate analytical procedures performed in triplicate for the determination of the Bacteriocidal Kinetics.

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PROJECT: MODIFIED TIME KILL ASSAY - Pure Rx Antibacterial Handwash, Lot #450, with an active ingredient of Benzalkonium chloride at 1167 PPM concentration.

REPORT DATE: January 25, 2000

SUMMARY:

The ILTC Pure Rx product appeared to be consistently effective in exerting Bacteriocidal Activity at >99.99% level of kill on the Gram Positive organisms, Gram Negative organisms and Yeast cells assayed at time exposures of less than one (1) minute.

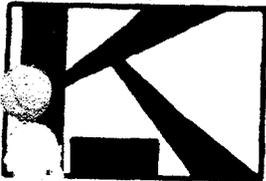
CONTROLS

Negative Controls for all medias were performed by incubation of uninoculated media. Positive Controls were performed for all organisms by plating directly onto the appropriate media employed for the assay. Broths were tested for Positive growth by inoculation with the appropriate test organism.

TEST FACILITY: Kappa Laboratories, Inc.
2577 N. W. 74 Avenue
Miami, Florida 33122

Kappa Laboratories has been inspected and has been Recognized by the U.S. Department of Agriculture (USDA Microbiology-#0093) formerly (USDA Chemistry - #1282); Certified by the Florida Dept. of Health and Rehabilitative Services, Drinking Water, including Microbiology, Pesticides, PCB's and Group I Unregulated Contaminants (HRS-#86260); Environmental Certification in Pesticides, Herbicides, PCB's (HPLC) (HRS #E86515); Registered with the U.S. Food and Drug Administration (FDA-#1039389) and is an FDA Accepted Laboratory for Import Testing. Kappa Laboratories is currently a Contract Laboratory to the U.S. Centers for Disease Control (CDC), Atlanta, Georgia for the Vessell Sanitation Program. Contract Laboratory to the Department of the Interior, National Parks System, Everglades District for Drinking Water and Environmental Water.

signed: 
Dr. Peter J. Kmiec
Director, Kappa Laboratories, Inc.



KAPPA LABORATORIES, INC.

2577 N.W. 74th Avenue, Miami, Florida 33122

Phone (305) 599-0199 • Fax (305) 532-1224

LABORATORY REPORT

I.L.T.C.

David Moll, President
3389 Sheridan Street
Suite #149
Hollywood, Florida 33021

September 15, 1999

Re: High Pressure Liquid Chromatography (HPLC) Analysis of one (1) sample of ILTC Pure RX Antibacterial Handwash with an active ingredient of Benzalkonium chloride at 1167 PPM concentration, Batch No. X450. The Sample was delivered to Kappa Laboratories, Inc., 2577 N.W. 74th Avenue, Miami, Fla 33122 on September 7, 1999. Analysis performed for ILTC, Hollywood, Florida

The samples were contained in a white plastic bottles, sealed, labelled:

Product: Pure RX Antibacterial Handwash
R&D Batch: Batch X450
Mfg. Date: 07/28/99

Standard BTC 50 Solution was manufactured by Stepan Chemical Co., and samples provided by Hydrox Labs, 825-B Tollgate Road, Elgin, Illinois 60123. BTC 50 is a 50% active solution of:

1) n-Alkyl (50% C-12, 30% C-14, 17% C-16, 3% C-18) Dimethyl Benzyl Ammonium Chloride	50%
2) Inert Ingredients:	50%

	100%

Preliminary Data as of 03/07/00
 Product #1 - Pure.Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
1	<i>Acinetobacter</i> spp. (ATCC #9957)	1 : 4,096	0.3462 ppm
2	<i>Acinetobacter</i> sp. (ATCC #11171)	1 : 1024	1.3848 ppm
3	<i>Acinetobacter</i> sp. (ATCC #33305)	1 : 256	5.5391 ppm
4	<i>Acinetobacter</i> sp. (ATCC #33306)	1 : 1024	1.3848 ppm
5	<i>Acinetobacter</i> sp. (ATCC #9955)	1 : 128	11.0781 ppm
6	<i>Acinetobacter</i> sp. (ATCC #33969)	1 : 2,048	0.6924 ppm
7	<i>Acinetobacter</i> sp. (ATCC #49137)	1 : 64	22.1563 ppm
8	<i>Acinetobacter</i> sp. (ATCC #49139)	1 : 256	5.5391 ppm
9	<i>Acinetobacter</i> sp. (ATCC #49466)	1 : 128	11.0781 ppm
10	<i>Acinetobacter</i> sp. (ATCC #17976)	1 : 4,096	0.3462 ppm
11	<i>Acinetobacter</i> sp. (ATCC #49468)	1 : 64	22.1563 ppm
12	<i>Acinetobacter</i> sp. (ATCC #17978)	1 : 128	11.0781 ppm
13	<i>Acinetobacter</i> sp. (ATCC #51550)	1 : 256	5.5391 ppm
14	<i>A. baumannii</i> (ATCC #19003)	1 : 128	11.0781 ppm
15	<i>A. baumannii</i> (ATCC #19606)	1 : 128	11.0781 ppm
16	<i>A. calcoaceticus</i> (ATCC #14987)	1 : 256	5.5391 ppm
17	<i>A. calcoaceticus</i> (ATCC #23055)	1 : 1024	1.3848 ppm
18	<i>A. calcoaceticus</i> (ATCC #51432)	1 : 128	11.0781 ppm
19	<i>A. haemolyticus</i> (ATCC #17906)	1 : 128	11.0781 ppm
20	<i>A. haemolyticus</i> (ATCC #19002)	1 : 128	11.0781 ppm
21	<i>A. johnsonii</i> (ATCC #17909)	1 : 512	2.7695 ppm
22	<i>A. junii</i> (ATCC #17908)	1 : 512	2.7695 ppm
23	<i>A. lwoffii</i> (ATCC #15309)	1 : 2,048	0.6924 ppm
24	<i>A. lwoffii</i> (ATCC #17925)	1 : 2,048	0.6924 ppm
25	<i>A. radioresistens</i> (ATCC #43998)	1 : 8,192	0.1731 ppm

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure-Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
26	<i>Acinetobacter</i> sp. (Clinical Isolate - BSLI #081399Abc)	1 : 128	11.0781
27	<i>Acinetobacter</i> sp. (Clinical Isolate - BSLI #071499Ab)	1 : 128	11.0781
28	<i>Acinetobacter</i> sp. (Clinical Isolate - BSLI #121699Asp)	1 : 64	22.1563 ppm
29	<i>Acinetobacter</i> sp. (Clinical Isolate - BSLI #121799Asp1)	1 : 16	88.6250 ppm
30	<i>Acinetobacter</i> sp. (Clinical Isolate - BSLI #121799Asp2)	1 : 128	11.0781 ppm
31	<i>Acinetobacter</i> sp. (Clinical Isolate - BSLI #121799Asp3)	1 : 128	11.0781 ppm
32	<i>Acinetobacter</i> sp. (Clinical Isolate - BSLI #121799Asp4)	1 : 128	11.0781 ppm
33	<i>Acinetobacter</i> sp. (Clinical Isolate - BSLI #121799Asp5)	1 : 256	5.5391 ppm
34	<i>Acinetobacter</i> sp. (Clinical Isolate - 010500Asp)	1 : 512	2.7695 ppm
35	<i>Acinetobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
36	<i>Acinetobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
37	<i>Acinetobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
38	<i>Acinetobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
39	<i>Acinetobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
40	<i>Acinetobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
41	<i>Acinetobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
42	<i>Acinetobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
43	<i>Acinetobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
44	<i>Acinetobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
45	<i>Acinetobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
46	<i>Acinetobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
47	<i>Acinetobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
48	<i>Acinetobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
49	<i>Acinetobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
50	<i>Acinetobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
51	<i>B. fragilis</i> (ATCC #23745)	1 : 4,096	0.3462 ppm
52	<i>B. fragilis</i> (ATCC #25285)	1 : 1024	1.3848 ppm
53	<i>B. fragilis</i> (ATCC #29762)	*	Testing not completed as of 3/6/00
54	<i>B. fragilis</i> (ATCC #29763)	1 : 4,096	0.3462 ppm
55	<i>B. fragilis</i> (ATCC #29764)	1 : 4,096	0.3462 ppm
56	<i>B. fragilis</i> (ATCC #29765)	1 : 4,096	0.3462 ppm
57	<i>B. fragilis</i> (ATCC #29766)	1 : 4,096	0.3462 ppm
58	<i>B. fragilis</i> (ATCC #29767)	1 : 4,096	0.3462 ppm
59	<i>B. fragilis</i> (ATCC #29768)	1 : 2,048	0.6924 ppm
60	<i>B. fragilis</i> (ATCC #29769)	1 : 2,048	0.6924 ppm
61	<i>B. fragilis</i> (ATCC #29770)	1 : 2,048	0.6924 ppm
62	<i>B. fragilis</i> (ATCC #29771)	1 : 2,048	0.6924 ppm
63	<i>B. fragilis</i> (ATCC #43858)	*	Testing not completed as of 3/6/00
64	<i>B. fragilis</i> (ATCC #43859)	1 : 2,048	0.6924 ppm
65	<i>B. fragilis</i> (ATCC #43860)	1 : 2,048	0.6924 ppm
66	<i>B. fragilis</i> (ATCC #43935)	1 : 2,048	0.6924 ppm
67	<i>B. fragilis</i> (ATCC #43936)	1 : 2,048	0.6924 ppm
68	<i>B. fragilis</i> (ATCC #43937)	1 : 2,048	0.6924 ppm
69	<i>B. fragilis</i> (ATCC #51477)	1 : 2,048	0.6924 ppm
70	<i>Bacteroides</i> sp. (Clinical Isolate - BSLI #021000Bf1)	1 : 2,048	0.6924 ppm
71	<i>Bacteroides</i> sp. (Clinical Isolate - BSLI #021000Bf2)	1 : 2,048	0.6924 ppm
72	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
73	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
74	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
75	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
76	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
77	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
78	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
79	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
80	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
81	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
82	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
83	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
84	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
85	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
86	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
87	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
88	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
89	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
90	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
91	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
92	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
93	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
94	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
95	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
96	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
97	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
98	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
99	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
100	<i>Bacteroides</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
101	<i>E. aerogenes</i> (ATCC #13048)	1 : 64	22.1563 ppm
102	<i>E. aerogenes</i> (ATCC #15038)	1 : 32	44.3125 ppm
103	<i>E. aerogenes</i> (ATCC #29007)	1 : 64	22.1563 ppm
104	<i>E. aerogenes</i> (ATCC #29008)	1 : 64	22.1563 ppm
105	<i>E. aerogenes</i> (ATCC #29009)	1 : 64	22.1563 ppm
106	<i>E. aerogenes</i> (ATCC #29010)	1 : 64	22.1563 ppm
107	<i>E. aerogenes</i> (ATCC #29751)	1 : 64	22.1563 ppm
108	<i>E. aerogenes</i> (ATCC #35028)	1 : 32	44.3125 ppm
109	<i>E. aerogenes</i> (ATCC #35029)	1 : 64	22.1563 ppm
110	<i>E. aerogenes</i> (ATCC #49469)	1 : 64	22.1563 ppm
111	<i>E. aerogenes</i> (ATCC #49701)	1 : 32	44.3125 ppm
112	<i>E. aerogenes</i> (ATCC #51342)	1 : 64	22.1563 ppm
113	<i>E. aerogenes</i> (ATCC #51697)	1 : 64	22.1563 ppm
114	<i>E. cloacae</i> (ATCC #222)	1 : 64	22.1563 ppm
115	<i>E. cloacae</i> (ATCC #529)	1 : 64	22.1563 ppm
116	<i>E. cloacae</i> (ATCC #961)	1 : 64	22.1563 ppm
117	<i>E. cloacae</i> (ATCC #962)	1 : 64	22.1563 ppm
118	<i>E. cloacae</i> (ATCC #7256)	1 : 32	44.3125 ppm
119	<i>E. cloacae</i> (ATCC #13047)	1 : 32	44.3125 ppm
120	<i>E. cloacae</i> (ATCC #23355)	1 : 32	44.3125 ppm
121	<i>E. cloacae</i> (ATCC #33457)	1 : 32	44.3125 ppm
122	<i>E. cloacae</i> (ATCC #35030)	1 : 64	22.1563 ppm
123	<i>E. cloacae</i> (ATCC #35549)	1 : 128	11.0781
124	<i>E. cloacae</i> (ATCC #43091)	1 : 32	44.3125 ppm
125	<i>E. cloacae</i> (ATCC #49141)	1 : 16	88.6250 ppm

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
126	<i>E. cloacae</i> (Clinical Isolate - BSLI #081299EC)	1 : 32	44.3125 ppm
127	<i>Enterobacter</i> sp. (Clinical Isolate - BSLI #121799Ec11)	1 : 32	44.3125 ppm
128	<i>Enterobacter</i> sp. (Clinical Isolate - BSLI #121799Ec12)	1 : 32	44.3125 ppm
129	<i>Enterobacter</i> sp. (Clinical Isolate - BSLI #013100EA)	1 : 64	22.1563 ppm
130	<i>Enterobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
131	<i>Enterobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
132	<i>Enterobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
133	<i>Enterobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
134	<i>Enterobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
135	<i>Enterobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
136	<i>Enterobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
137	<i>Enterobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
138	<i>Enterobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
139	<i>Enterobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
140	<i>Enterobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
141	<i>Enterobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
142	<i>Enterobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
143	<i>Enterobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
144	<i>Enterobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
145	<i>Enterobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
146	<i>Enterobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
147	<i>Enterobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
148	<i>Enterobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
149	<i>Enterobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
150	<i>Enterobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
151	<i>E. faecalis</i> (ATCC #4082)	1 : 512	2.7695 ppm
152	<i>E. faecalis</i> (ATCC #4083)	1 : 1024	1.3848 ppm
153	<i>E. faecalis</i> (ATCC #4200)	1 : 512	2.7695 ppm
154	<i>E. faecalis</i> (ATCC #6055)	1 : 512	2.7695 ppm
155	<i>E. faecalis</i> (ATCC #7080)	1 : 512	2.7695 ppm
156	<i>E. faecalis</i> (ATCC #10100)	1 : 1024	1.3848 ppm
157	<i>E. faecalis</i> (ATCC #14506)	1 : 1024	1.3848 ppm
158	<i>E. faecalis</i> (ATCC #19433)	1 : 256	5.5391 ppm
159	<i>E. faecalis</i> (ATCC #29212)	1 : 512	2.7695 ppm
160	<i>E. faecalis</i> (ATCC #33012)	1 : 512	2.7695 ppm
161	<i>E. faecalis</i> (ATCC #33186)	1 : 512	2.7695 ppm
162	<i>E. faecalis</i> (ATCC #35038)	1 : 1024	1.3848 ppm
163	<i>E. faecalis</i> (ATCC #35550)	1 : 512	2.7695 ppm
164	<i>E. faecalis</i> (ATCC #49149)	1 : 512	2.7695 ppm
165	<i>E. faecalis</i> (ATCC #49332)	1 : 512	2.7695 ppm
166	<i>E. faecalis</i> (ATCC #49452)	1 : 512	2.7695 ppm
167	<i>E. faecalis</i> (ATCC #49474)	1 : 512	2.7695 ppm
168	<i>E. faecalis</i> (ATCC #49477)	1 : 512	2.7695 ppm
169	<i>E. faecalis</i> (ATCC #49478)	1 : 512	2.7695 ppm
170	<i>E. faecalis</i> (ATCC #49532)	1 : 512	2.7695 ppm
171	<i>E. faecalis</i> (ATCC #49533)	1 : 1024	1.3848 ppm
172	<i>E. faecalis</i> (ATCC #49761)	1 : 2,048	0.6924 ppm
173	<i>E. faecalis</i> (ATCC #51188)	1 : 256	5.5391 ppm
174	<i>E. faecalis</i> (ATCC #51299)	1 : 128	11.0781 ppm
175	<i>E. faecalis</i> (ATCC #51575)	1 : 256	5.5391 ppm

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
176	<i>E. faecalis</i> (Clinical Isolate - BSLI #080294VRE2)	1 : 256	5.5391 ppm
177	<i>E. faecalis</i> (Clinical Isolate - BSLI #080294VRE4)	1 : 256	5.5391 ppm
178	<i>E. faecalis</i> (Clinical Isolate - BSLI #080294VRE1)	1 : 256	5.5391 ppm
179	<i>E. faecalis</i> (Clinical Isolate - BSLI #121699Efs1)	1 : 512	2.7695 ppm
180	<i>E. faecalis</i> (Clinical Isolate - BSLI #121699Efs2)	1 : 512	2.7695 ppm
181	<i>E. faecalis</i> (Clinical Isolate - BSLI #010500Efs)	*	Testing not completed as of 3/6/00
182	<i>E. faecalis</i> (Clinical Isolate - BSLI #013100EFS)	1 : 512	2.7695 ppm
183	<i>E. faecalis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
184	<i>E. faecalis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
185	<i>E. faecalis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
186	<i>E. faecalis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
187	<i>E. faecalis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
188	<i>E. faecalis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
189	<i>E. faecalis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
190	<i>E. faecalis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
191	<i>E. faecalis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
192	<i>E. faecalis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
193	<i>E. faecalis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
194	<i>E. faecalis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
195	<i>E. faecalis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
196	<i>E. faecalis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
197	<i>E. faecalis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
198	<i>E. faecalis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
199	<i>E. faecalis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
200	<i>E. faecalis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
201	<i>E. faecium</i> (ATCC #349)	1 : 1024	1.3848 ppm
202	<i>E. faecium</i> (ATCC #882)	1 : 1024	1.3848 ppm
203	<i>E. faecium</i> (ATCC #6057)	1 : 1024	1.3848 ppm
204	<i>E. faecium</i> (ATCC #6569)	1 : 1024	1.3848 ppm
205	<i>E. faecium</i> (ATCC #8459)	1 : 1024	1.3848 ppm
206	<i>E. faecium</i> (ATCC #9756)	1 : 1024	1.3848 ppm
207	<i>E. faecium</i> (ATCC #12952)	1 : 512	2.7695 ppm
208	<i>E. faecium</i> (ATCC #19434)	1 : 256	5.5391 ppm
209	<i>E. faecium</i> (ATCC #19579)	1 : 1024	1.3848 ppm
210	<i>E. faecium</i> (ATCC #19580)	1 : 512	2.7695 ppm
211	<i>E. faecium</i> (ATCC #19581)	1 : 1024	1.3848 ppm
212	<i>E. faecium</i> (ATCC #19634)	1 : 1024	1.3848 ppm
213	<i>E. faecium</i> (ATCC #19950)	1 : 1024	1.3848 ppm
214	<i>E. faecium</i> (ATCC #19953)	1 : 2,048	0.6924 ppm
215	<i>E. faecium</i> (ATCC #23828)	*	Testing not completed as of 3/6/00
216	<i>E. faecium</i> (ATCC #25307)	1 : 1024	1.3848 ppm
217	<i>E. faecium</i> (ATCC #27270)	1 : 512	2.7695 ppm
218	<i>E. faecium</i> (ATCC #27273)	1 : 256	5.5391 ppm
219	<i>E. faecium</i> (ATCC #35667)	1 : 512	2.7695 ppm
220	<i>E. faecium</i> (ATCC #49032)	1 : 4,096	0.3462 ppm
221	<i>E. faecium</i> (ATCC #49224)	1 : 1024	1.3848 ppm
222	<i>E. faecium</i> (ATCC #49225)	1 : 1024	1.3848 ppm
223	<i>E. faecium</i> (ATCC #49624)	1 : 1024	1.3848 ppm
224	<i>E. faecium</i> (ATCC #51558)	1 : 512	2.7695 ppm
225	<i>E. faecium</i> (ATCC #51559)	1 : 256	5.5391 ppm

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
226	<i>E. faecium</i> (Clinical Isolate - BSLI #050499VRE)	1 : 256	5.5391 ppm
227	<i>E. faecium</i> (Clinical Isolate - BSLI #062599VRE)	1 : 256	5.5391 ppm
228	<i>E. faecium</i> (Clinical Isolate - BSLI #052999EF)	1 : 256	5.5391 ppm
229	<i>E. faecium</i> (Clinical Isolate - BSLI #080599VRE)	1 : 256	5.5391 ppm
230	<i>E. faecium</i> (Clinical Isolate - BSLI #072199VRE)	1 : 256	5.5391 ppm
231	<i>E. faecium</i> (Clinical Isolate - BSLI #071999VRE)	1 : 256	5.5391 ppm
232	<i>E. faecium</i> (Clinical Isolate - BSLI #062999VRE)	1 : 256	5.5391 ppm
233	<i>E. faecium</i> (Clinical Isolate - BSLI #071499VRE)	1 : 256	5.5391 ppm
234	<i>E. faecium</i> (Clinical Isolate - BSLI #010500Efm)	1 : 512	2.7695 ppm
235	<i>E. faecium</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
236	<i>E. faecium</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
237	<i>E. faecium</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
238	<i>E. faecium</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
239	<i>E. faecium</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
240	<i>E. faecium</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
241	<i>E. faecium</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
242	<i>E. faecium</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
243	<i>E. faecium</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
244	<i>E. faecium</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
245	<i>E. faecium</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
246	<i>E. faecium</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
247	<i>E. faecium</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
248	<i>E. faecium</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
249	<i>E. faecium</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
250	<i>E. faecium</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
251	<i>E. coli</i> (ATCC #4157)	1 : 256	5.5391 ppm
252	<i>E. coli</i> (ATCC #8677)	1 : 64	22.1563 ppm
253	<i>E. coli</i> (ATCC #8739)	1 : 64	22.1563 ppm
254	<i>E. coli</i> (ATCC #9637)	1 : 32	44.3125 ppm
255	<i>E. coli</i> (ATCC #10536)	1 : 256	5.5391 ppm
256	<i>E. coli</i> (ATCC #10798)	1 : 32	44.3125 ppm
257	<i>E. coli</i> (ATCC #11229)	1 : 64	22.1563 ppm
258	<i>E. coli</i> (ATCC #11303)	1 : 64	22.1563 ppm
259	<i>E. coli</i> (ATCC #11775)	1 : 128	11.0781 ppm
260	<i>E. coli</i> (ATCC #12435)	1 : 64	22.1563 ppm
261	<i>E. coli</i> (ATCC #13762)	1 : 64	22.1563 ppm
262	<i>E. coli</i> (ATCC #14948)	1 : 32	44.3125 ppm
263	<i>E. coli</i> (ATCC #15223)	1 : 128	11.0781 ppm
264	<i>E. coli</i> (ATCC #15224)	1 : 64	22.1563 ppm
265	<i>E. coli</i> (ATCC #15597)	1 : 64	22.1563 ppm
266	<i>E. coli</i> (ATCC #15939)	1 : 128	11.0781 ppm
267	<i>E. coli</i> (ATCC #23231)	1 : 128	11.0781 ppm
268	<i>E. coli</i> (ATCC #23558)	1 : 64	22.1563 ppm
269	<i>E. coli</i> (ATCC #23559)	1 : 64	22.1563 ppm
270	<i>E. coli</i> (ATCC #23588)	1 : 64	22.1563 ppm
271	<i>E. coli</i> (ATCC #25922)	1 : 128	11.0781 ppm
272	<i>E. coli</i> (ATCC #29194)	1 : 128	11.0781 ppm
273	<i>E. coli</i> (ATCC #35150)	1 : 64	22.1563 ppm
274	<i>E. coli</i> (ATCC #35218)	1 : 64	22.1563 ppm
275	<i>E. coli</i> (ATCC #43892)	1 : 256	5.5391 ppm

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
276	<i>E. coli</i> (Clinical Isolate - BSLI #060199EC)	1 : 64	22.1563 ppm
277	<i>E. coli</i> (Clinical Isolate - BSLI # 051599EC)	1 : 128	11.0781 ppm
278	<i>E. coli</i> (Clinical Isolate - BSLI #070399EC)	1 : 64	22.1563 ppm
279	<i>E. coli</i> (Clinical Isolate - BSLI #121699Ec2)	1 : 64	22.1563 ppm
280	<i>E. coli</i> (Clinical Isolate - BSLI #121699Ec1)	1 : 64	22.1563 ppm
281	<i>E. coli</i> (Clinical Isolate - BSLI #121799EC1)	1 : 64	22.1563 ppm
282	<i>E. coli</i> (Clinical Isolate - BSLI #121799EC2)	1 : 128	11.0781 ppm
283	<i>E. coli</i> (Clinical Isolate - BSLI #121799EC3)	1 : 64	22.1563 ppm
284	<i>E. coli</i> (Clinical Isolate - BSLI #010500Ec1)	1 : 128	11.0781 ppm
285	<i>E. coli</i> (Clinical Isolate - BSLI #010500Ec2)	1 : 128	11.0781 ppm
286	<i>E. coli</i> (Clinical Isolate - BSLI #010500Ec3)	1 : 64	22.1563 ppm
287	<i>E. coli</i> (Clinical Isolate - BSLI #010500Ec4)	1 : 128	11.0781 ppm
288	<i>E. coli</i> (Clinical Isolate - BSLI #010500Ec5)	1 : 128	11.0781 ppm
289	<i>E. coli</i> (Clinical Isolate - BSLI #010500Ec6)	1 : 32	44.3125 ppm
290	<i>E. coli</i> (Clinical Isolate - BSLI #010500Ec7)	1 : 128	11.0781 ppm
291	<i>E. coli</i> (Clinical Isolate - BSLI #010500Ec8)	1 : 128	11.0781 ppm
292	<i>E. coli</i> (Clinical Isolate - BSLI #010500Ec9)	1 : 128	11.0781 ppm
293	<i>E. coli</i> (Clinical Isolate - BSLI #013100EC1)	1 : 128	11.0781 ppm
294	<i>E. coli</i> (Clinical Isolate - BSLI #013100EC2)	1 : 128	11.0781 ppm
295	<i>E. coli</i> (Clinical Isolate - BSLI #013100EC3)	1 : 128	11.0781 ppm
296	<i>E. coli</i> (Clinical Isolate - BSLI #013100EC4)	1 : 128	11.0781 ppm
297	<i>E. coli</i> (Clinical Isolate - BSLI #013100EC5)	1 : 128	11.0781 ppm
298	<i>E. coli</i> (Clinical Isolate - BSLI #013100EC6)	1 : 128	11.0781 ppm
299	<i>E. coli</i> (Clinical Isolate - BSLI #013100EC7)	1 : 128	11.0781 ppm
300	<i>E. coli</i> (Clinical Isolate - BSLI #013100EC8)	1 : 64	22.1563 ppm

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
301	<i>H. influenzae</i> (ATCC #8142)	*	Testing not completed as of 3/6/00
302	<i>H. influenzae</i> (ATCC #8149)	*	Testing not completed as of 3/6/00
303	<i>H. influenzae</i> (ATCC #9006)	1 : 512	2.7695 ppm
304	<i>H. influenzae</i> (ATCC #9007)	*	Testing not completed as of 3/6/00
305	<i>H. influenzae</i> (ATCC #9008)	*	Testing not completed as of 3/6/00
306	<i>H. influenzae</i> (ATCC #9131)	*	Testing not completed as of 3/6/00
307	<i>H. influenzae</i> (ATCC #9795)	*	Testing not completed as of 3/6/00
308	<i>H. influenzae</i> (ATCC #9833)	*	Testing not completed as of 3/6/00
309	<i>H. influenzae</i> (ATCC #10211)	1 : 1024	1.3848 ppm
310	<i>H. influenzae</i> (ATCC #11116)	*	Testing not completed as of 3/6/00
311	<i>H. influenzae</i> (ATCC #19418)	1 : 1024	1.3848 ppm
312	<i>H. influenzae</i> (ATCC #33391)	*	Testing not completed as of 3/6/00
313	<i>H. influenzae</i> (ATCC #33533)	1 : 1024	1.3848 ppm
314	<i>H. influenzae</i> (ATCC #33930)	1 : 512	2.7695 ppm
315	<i>H. influenzae</i> (ATCC #35056)	1 : 512	2.7695 ppm
316	<i>H. influenzae</i> (ATCC #35540)	*	Testing not completed as of 3/6/00
317	<i>H. influenzae</i> (ATCC #43065)	1 : 1024	1.3848 ppm
318	<i>H. influenzae</i> (ATCC #43163)	1 : 512	2.7695 ppm
319	<i>H. influenzae</i> (ATCC #49144)	1 : 2,048	0.6924 ppm
320	<i>H. influenzae</i> (ATCC #49247)	*	Testing not completed as of 3/6/00
321	<i>H. influenzae</i> (ATCC #49401)	*	Testing not completed as of 3/6/00
322	<i>H. influenzae</i> (ATCC #49766)	1 : 1024	1.3848 ppm
323	<i>H. influenzae</i> (ATCC #49824)	*	Testing not completed as of 3/6/00
324	<i>H. influenzae</i> (ATCC #51654)	*	Testing not completed as of 3/6/00
325	<i>H. influenzae</i> (ATCC #51907)	*	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
326	<i>H. influenzae</i> (Clinical Isolate - BSLI #121699Hi2)	1 : 1024	1.3848 ppm
327	<i>H. influenzae</i> (Clinical Isolate - BSLI #121699Hi3)	1 : 512	2.7695 ppm
328	<i>H. influenzae</i> (Clinical Isolate - BSLI #121699Hi4)	1 : 512	2.7695 ppm
329	<i>H. influenzae</i> (Clinical Isolate - BSLI #121699Hi1)	1 : 1024	1.3848 ppm
330	<i>H. influenzae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
331	<i>H. influenzae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
332	<i>H. influenzae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
333	<i>H. influenzae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
334	<i>H. influenzae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
335	<i>H. influenzae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
336	<i>H. influenzae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
337	<i>H. influenzae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
338	<i>H. influenzae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
339	<i>H. influenzae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
340	<i>H. influenzae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
341	<i>H. influenzae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
342	<i>H. influenzae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
343	<i>H. influenzae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
344	<i>H. influenzae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
345	<i>H. influenzae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
346	<i>H. influenzae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
347	<i>H. influenzae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
348	<i>H. influenzae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
349	<i>H. influenzae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
350	<i>H. influenzae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
351	<i>K. oxytoca</i> (ATCC #8724)	1 : 32	44.3125 ppm
352	<i>K. oxytoca</i> (ATCC #12833)	*	Testing not completed as of 3/6/00
353	<i>K. oxytoca</i> (ATCC #13030)	1 : 32	44.3125 ppm
354	<i>K. oxytoca</i> (ATCC #13182)	1 : 64	22.1563 ppm
355	<i>K. oxytoca</i> (ATCC #13183)	1 : 64	22.1563 ppm
356	<i>K. oxytoca</i> (ATCC #15328)	1 : 16	88.6250 ppm
357	<i>K. oxytoca</i> (ATCC #15764)	1 : 64	22.1563 ppm
358	<i>K. oxytoca</i> (ATCC #29516)	1 : 64	22.1563 ppm
359	<i>K. oxytoca</i> (ATCC #31899)	1 : 32	44.3125 ppm
360	<i>K. oxytoca</i> (ATCC #33496)	1 : 128	11.0781 ppm
361	<i>K. oxytoca</i> (ATCC #35600)	1 : 64	22.1563 ppm
362	<i>K. oxytoca</i> (ATCC #43075)	1 : 16	88.6250 ppm
363	<i>K. oxytoca</i> (ATCC #43086)	1 : 64	22.1563 ppm
364	<i>K. oxytoca</i> (ATCC #43165)	1 : 64	22.1563 ppm
365	<i>K. oxytoca</i> (ATCC #43863)	1 : 32	44.3125 ppm
366	<i>K. oxytoca</i> (ATCC #49131)	1 : 128	11.0781 ppm
367	<i>K. oxytoca</i> (ATCC #49334)	1 : 64	22.1563 ppm
368	<i>K. oxytoca</i> (ATCC #49473)	1 : 64	22.1563 ppm
369	<i>K. oxytoca</i> (ATCC #68831)	1 : 64	22.1563 ppm
370	<i>K. planticola</i> (ATCC #8329)	1 : 64	22.1563 ppm
371	<i>K. planticola</i> (ATCC #15050)	1 : 128	11.0781 ppm
372	<i>K. planticola</i> (ATCC #21524)	1 : 64	22.1563 ppm
373	<i>K. planticola</i> (ATCC #21609)	1 : 256	5.5391 ppm
374	<i>K. planticola</i> (ATCC #33531)	1 : 64	22.1563 ppm
375	<i>K. planticola</i> (ATCC #43176)	1 : 128	11.0781 ppm

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
Product #1 - Pure Rx
Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
376	<i>K. oxytoca</i> (Clinical Isolate - BSLI #060199KO)	1 : 64	22.1563 ppm
377	<i>Klebsiella</i> sp. (Clinical Isolate - BSLI #121799KO)	1 : 64	22.1563 ppm
378	<i>Klebsiella</i> sp. (Clinical Isolate - BSLI #010500KO)	1 : 128	11.0781 ppm
379	<i>Klebsiella</i> sp. (Clinical Isolate - BSLI #010500Kp1)	*	Testing not completed as of 3/6/00
380	<i>Klebsiella</i> sp. (Clinical Isolate - BSLI #010500Kp2)	*	Testing not completed as of 3/6/00
381	<i>Klebsiella</i> sp. (Clinical Isolate - BSLI #010500Kp3)	*	Testing not completed as of 3/6/00
382	<i>Klebsiella</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
383	<i>Klebsiella</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
384	<i>Klebsiella</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
385	<i>Klebsiella</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
386	<i>Klebsiella</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
387	<i>Klebsiella</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
388	<i>Klebsiella</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
389	<i>Klebsiella</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
390	<i>Klebsiella</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
391	<i>Klebsiella</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
392	<i>Klebsiella</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
393	<i>Klebsiella</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
394	<i>Klebsiella</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
395	<i>Klebsiella</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
396	<i>Klebsiella</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
397	<i>Klebsiella</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
398	<i>Klebsiella</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
399	<i>Klebsiella</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
400	<i>Klebsiella</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00

NOTE
This information has not
yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
401	<i>K. pneumoniae</i> (ATCC #132)	1 : 64	22.1563 ppm
402	<i>K. pneumoniae</i> (ATCC #211)	1 : 64	22.1563 ppm
403	<i>K. pneumoniae</i> (ATCC #4208)	1 : 256	5.5391 ppm
404	<i>K. pneumoniae</i> (ATCC #4209)	1 : 512	2.7695 ppm
405	<i>K. pneumoniae</i> (ATCC #4211)	1 : 128	11.0781
406	<i>K. pneumoniae</i> (ATCC #4352)	1 : 256	5.5391 ppm
407	<i>K. pneumoniae</i> (ATCC #4727)	1 : 64	22.1563 ppm
408	<i>K. pneumoniae</i> (ATCC #8044)	1 : 256	5.5391 ppm
409	<i>K. pneumoniae</i> (ATCC #8045)	1 : 256	5.5391 ppm
410	<i>K. pneumoniae</i> (ATCC #8047)	1 : 256	5.5391 ppm
411	<i>K. pneumoniae</i> (ATCC #8308)	1 : 32	44.3125 ppm
412	<i>K. pneumoniae</i> (ATCC #9997)	1 : 256	5.5391 ppm
413	<i>K. pneumoniae</i> (ATCC #10031)	1 : 512	2.7695 ppm
414	<i>K. pneumoniae</i> (ATCC #11296)	1 : 256	5.5391 ppm
415	<i>K. pneumoniae</i> (ATCC #12657)	1 : 64	22.1563 ppm
416	<i>K. pneumoniae</i> (ATCC #13882)	1 : 256	5.5391 ppm
417	<i>K. pneumoniae</i> (ATCC #13883)	1 : 64	22.1563 ppm
418	<i>K. pneumoniae</i> (ATCC #27736)	1 : 64	22.1563 ppm
419	<i>K. pneumoniae</i> (ATCC #29665)	1 : 64	22.1563 ppm
420	<i>K. pneumoniae</i> (ATCC #33495)	1 : 64	22.1563 ppm
421	<i>K. pneumoniae</i> (ATCC #35555)	1 : 64	22.1563 ppm
422	<i>K. pneumoniae</i> (ATCC #35657)	1 : 256	5.5391 ppm
423	<i>K. pneumoniae</i> (ATCC #49472)	1 : 32	44.3125 ppm
424	<i>K. pneumoniae</i> (ATCC #51503)	1 : 32	44.3125 ppm
425	<i>K. pneumoniae</i> (ATCC #51504)	1 : 128	11.0781 ppm

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
Product #1 - Pure Rx
Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
426	<i>K. pneumoniae</i> (Clinical Isolate - BSLI #081599Kp)	1 : 16	88.6250 ppm
427	<i>K. pneumoniae</i> (Clinical Isolate - BSLI #121699Kp)	1 : 128	11.0781 ppm
428	<i>K. pneumoniae</i> (Clinical Isolate - BSLI #121799KP1)	1 : 64	22.1563 ppm
429	<i>K. pneumoniae</i> (Clinical Isolate - BSLI #121799KP2)	1 : 128	11.0781 ppm
430	<i>K. pneumoniae</i> (Clinical Isolate - BSLI #121799KP3)	1 : 64	22.1563 ppm
431	<i>K. pneumoniae</i> (Clinical Isolate - BSLI #010500Kp1)	1 : 32	44.3125 ppm
432	<i>K. pneumoniae</i> (Clinical Isolate - BSLI #010500Kp2)	1 : 32	44.3125 ppm
433	<i>K. pneumoniae</i> (Clinical Isolate - BSLI #010500Kp3)	1 : 32	44.3125 ppm
434	<i>K. pneumoniae</i> (Clinical Isolate - BSLI #013100KP1)	1 : 64	22.1563 ppm
435	<i>K. pneumoniae</i> (Clinical Isolate - BSLI #013100KP2)	1 : 64	22.1563 ppm
436	<i>K. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
437	<i>K. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
438	<i>K. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
439	<i>K. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
440	<i>K. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
441	<i>K. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
442	<i>K. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
443	<i>K. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
444	<i>K. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
445	<i>K. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
446	<i>K. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
447	<i>K. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
448	<i>K. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
449	<i>K. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
450	<i>K. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00

NOTE
This information has not
yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
451	<i>M. luteus</i> (ATCC #147)	*	Testing not completed as of 3/6/00
452	<i>M. luteus</i> (ATCC #272)	*	Testing not completed as of 3/6/00
453	<i>M. luteus</i> (ATCC #379)	*	Testing not completed as of 3/6/00
454	<i>M. luteus</i> (ATCC #381)	*	Testing not completed as of 3/6/00
455	<i>M. luteus</i> (ATCC #382)	*	Testing not completed as of 3/6/00
456	<i>M. luteus</i> (ATCC #383)	*	Testing not completed as of 3/6/00
457	<i>M. luteus</i> (ATCC #400)	*	Testing not completed as of 3/6/00
458	<i>M. luteus</i> (ATCC #533)	1 : 512	2.7695 ppm
459	<i>M. luteus</i> (ATCC #540)	*	Testing not completed as of 3/6/00
460	<i>M. luteus</i> (ATCC #4698)	1 : 512	2.7695 ppm
461	<i>M. luteus</i> (ATCC #7468)	1 : 256	5.5391 ppm
462	<i>M. luteus</i> (ATCC #7468D)	*	Testing not completed as of 3/6/00
463	<i>M. luteus</i> (ATCC #9273)	*	Testing not completed as of 3/6/00
464	<i>M. luteus</i> (ATCC #9341)	1 : 256	5.5391 ppm
465	<i>M. luteus</i> (ATCC #9341a)	1 : 512	2.7695 ppm
466	<i>M. luteus</i> (ATCC #9622)	*	Testing not completed as of 3/6/00
467	<i>M. luteus</i> (ATCC #10054)	*	Testing not completed as of 3/6/00
468	<i>M. luteus</i> (ATCC #10240)	1 : 2,048	0.6924 ppm
469	<i>M. luteus</i> (ATCC #10240a)	*	Testing not completed as of 3/6/00
470	<i>M. luteus</i> (ATCC #10240b)	*	Testing not completed as of 3/6/00
471	<i>M. luteus</i> (ATCC #14452)	*	Testing not completed as of 3/6/00
472	<i>M. luteus</i> (ATCC #15957)	1 : 512	2.7695 ppm
473	<i>M. luteus</i> (ATCC #27523)	*	Testing not completed as of 3/6/00
474	<i>M. luteus</i> (ATCC #49442)	*	Testing not completed as of 3/6/00
475	<i>M. luteus</i> (ATCC #49732)	1 : 1024	1.3848 ppm

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
476	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
477	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
478	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
479	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
480	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
481	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
482	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
483	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
484	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
485	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
486	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
487	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
488	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
489	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
490	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
491	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
492	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
493	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
494	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
495	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
496	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
497	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
498	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
499	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
500	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
501	<i>P. mirabilis</i> (ATCC #4630)	1 : 16	88.6250 ppm
502	<i>P. mirabilis</i> (ATCC #4675)	*	Testing not completed as of 3/6/00
503	<i>P. mirabilis</i> (ATCC #7002)	1 : 8	177.2500 ppm
504	<i>P. mirabilis</i> (ATCC #9240)	*	Testing not completed as of 3/6/00
505	<i>P. mirabilis</i> (ATCC #9921)	*	Testing not completed as of 3/6/00
506	<i>P. mirabilis</i> (ATCC #12453)	1 : 8	177.2500 ppm
507	<i>P. mirabilis</i> (ATCC #14153)	*	Testing not completed as of 3/6/00
508	<i>P. mirabilis</i> (ATCC #14273)	*	Testing not completed as of 3/6/00
509	<i>P. mirabilis</i> (ATCC #15363)	*	Testing not completed as of 3/6/00
510	<i>P. mirabilis</i> (ATCC #25933)	1 : 8	177.2500 ppm
511	<i>P. mirabilis</i> (ATCC #27035)	*	Testing not completed as of 3/6/00
512	<i>P. mirabilis</i> (ATCC #29245)	1 : 8	177.2500 ppm
513	<i>P. mirabilis</i> (ATCC #29512)	*	Testing not completed as of 3/6/00
514	<i>P. mirabilis</i> (ATCC #29852)	*	Testing not completed as of 3/6/00
515	<i>P. mirabilis</i> (ATCC #29854)	*	Testing not completed as of 3/6/00
516	<i>P. mirabilis</i> (ATCC #29855)	*	Testing not completed as of 3/6/00
517	<i>P. mirabilis</i> (ATCC #29856)	*	Testing not completed as of 3/6/00
518	<i>P. mirabilis</i> (ATCC #29857)	*	Testing not completed as of 3/6/00
519	<i>P. mirabilis</i> (ATCC #29906)	1 : 8	177.2500 ppm
520	<i>P. mirabilis</i> (ATCC #33583)	*	Testing not completed as of 3/6/00
521	<i>P. mirabilis</i> (ATCC #35659)	1 : 32	44.3125 ppm
522	<i>P. mirabilis</i> (ATCC #43071)	1 : 8	177.2500 ppm
523	<i>P. mirabilis</i> (ATCC #49995)	*	Testing not completed as of 3/6/00
524	<i>P. mirabilis</i> (ATCC #51286)	*	Testing not completed as of 3/6/00
525	<i>P. mirabilis</i> (ATCC #51393)	*	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
526	<i>P. mirabilis</i> (Clinical Isolate - BSLI #081299PM)	1 : 8	177.2500 ppm
527	<i>P. mirabilis</i> (Clinical Isolate - BSLI #121699Pm1)	1 : 8	177.2500 ppm
528	<i>P. mirabilis</i> (Clinical Isolate - BSLI #121699Pm2)	1 : 8	177.2500 ppm
529	<i>P. mirabilis</i> (Clinical Isolate - BSLI #010500PM)	1 : 8	177.2500 ppm
530	<i>P. mirabilis</i> (Clinical Isolate - BSLI #013100PM)	1 : 16	88.6250 ppm
531	<i>P. mirabilis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
532	<i>P. mirabilis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
533	<i>P. mirabilis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
534	<i>P. mirabilis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
535	<i>P. mirabilis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
536	<i>P. mirabilis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
537	<i>P. mirabilis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
538	<i>P. mirabilis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
539	<i>P. mirabilis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
540	<i>P. mirabilis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
541	<i>P. mirabilis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
542	<i>P. mirabilis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
543	<i>P. mirabilis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
544	<i>P. mirabilis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
545	<i>P. mirabilis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
546	<i>P. mirabilis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
547	<i>P. mirabilis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
548	<i>P. mirabilis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
549	<i>P. mirabilis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
550	<i>P. mirabilis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
551	<i>P. aeruginosa</i> (ATCC #7700)	1 : 16	88.6250 ppm
552	<i>P. aeruginosa</i> (ATCC #9027)	1 : 16	88.6250 ppm
553	<i>P. aeruginosa</i> (ATCC #9721)	1 : 32	44.3125 ppm
554	<i>P. aeruginosa</i> (ATCC #10145)	1 : 16	88.6250 ppm
555	<i>P. aeruginosa</i> (ATCC #13388)	1 : 16	88.6250 ppm
556	<i>P. aeruginosa</i> (ATCC #14207)	1 : 16	88.6250 ppm
557	<i>P. aeruginosa</i> (ATCC #14502)	1 : 16	88.6250 ppm
558	<i>P. aeruginosa</i> (ATCC #14885)	1 : 16	88.6250 ppm
559	<i>P. aeruginosa</i> (ATCC #15442)	1 : 16	88.6250 ppm
560	<i>P. aeruginosa</i> (ATCC #15692)	1 : 16	88.6250 ppm
561	<i>P. aeruginosa</i> (ATCC #17934)	1 : 32	44.3125 ppm
562	<i>P. aeruginosa</i> (ATCC #19429)	1 : 32	44.3125 ppm
563	<i>P. aeruginosa</i> (ATCC #19660)	1 : 16	88.6250 ppm
564	<i>P. aeruginosa</i> (ATCC #25619)	1 : 16	88.6250 ppm
565	<i>P. aeruginosa</i> (ATCC #27312)	1 : 16	88.6250 ppm
566	<i>P. aeruginosa</i> (ATCC #27313)	1 : 32	44.3125 ppm
567	<i>P. aeruginosa</i> (ATCC #27315)	1 : 16	88.6250 ppm
568	<i>P. aeruginosa</i> (ATCC #27853)	1 : 16	88.6250 ppm
569	<i>P. aeruginosa</i> (ATCC #29336)	1 : 32	44.3125 ppm
570	<i>P. aeruginosa</i> (ATCC #33584)	1 : 16	88.6250 ppm
571	<i>P. aeruginosa</i> (ATCC #35032)	1 : 16	88.6250 ppm
572	<i>P. aeruginosa</i> (ATCC #35422)	1 : 16	88.6250 ppm
573	<i>P. aeruginosa</i> (ATCC #35554)	1 : 16	88.6250 ppm
574	<i>P. aeruginosa</i> (ATCC #43088)	1 : 16	88.6250 ppm
575	<i>P. aeruginosa</i> (ATCC #51447)	1 : 16	88.6250 ppm

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
Product #1 - Pure Rx
Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
576	<i>P. aeruginosa</i> (Clinical Isolate - BSLI #052299Pa)	1 : 16	88.6250 ppm
577	<i>P. aeruginosa</i> (Clinical Isolate - BSLI #053099Pa)	1 : 16	88.6250 ppm
578	<i>P. aeruginosa</i> (Clinical Isolate - BSLI #070199Pa)	1 : 16	88.6250 ppm
579	<i>P. aeruginosa</i> (Clinical Isolate - BSLI #121699Pa3)	1 : 16	88.6250 ppm
580	<i>P. aeruginosa</i> (Clinical Isolate - BSLI #121699Pa2)	1 : 16	88.6250 ppm
581	<i>P. aeruginosa</i> (Clinical Isolate - BSLI #121699Pa1)	1 : 16	88.6250 ppm
582	<i>P. aeruginosa</i> (Clinical Isolate - BSLI #010500Pa1)	1 : 16	88.6250 ppm
583	<i>P. aeruginosa</i> (Clinical Isolate - BSLI #010500Pa2)	1 : 16	88.6250 ppm
584	<i>P. aeruginosa</i> (Clinical Isolate - BSLI #013100PA1)	1 : 16	88.6250 ppm
585	<i>P. aeruginosa</i> (Clinical Isolate - BSLI #013100PA2)	1 : 16	88.6250 ppm
586	<i>P. aeruginosa</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
587	<i>P. aeruginosa</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
588	<i>P. aeruginosa</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
589	<i>P. aeruginosa</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
590	<i>P. aeruginosa</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
591	<i>P. aeruginosa</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
592	<i>P. aeruginosa</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
593	<i>P. aeruginosa</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
594	<i>P. aeruginosa</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
595	<i>P. aeruginosa</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
596	<i>P. aeruginosa</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
597	<i>P. aeruginosa</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
598	<i>P. aeruginosa</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
599	<i>P. aeruginosa</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
600	<i>P. aeruginosa</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00

NOTE
This information has not
yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
601	<i>S. marcescens</i> (ATCC #60)	1 : 16	88.6250 ppm
602	<i>S. marcescens</i> (ATCC #93)	1 : 16	88.6250 ppm
603	<i>S. marcescens</i> (ATCC #264)	1 : 16	88.6250 ppm
604	<i>S. marcescens</i> (ATCC #274)	1 : 16	88.6250 ppm
605	<i>S. marcescens</i> (ATCC #275)	1 : 16	88.6250 ppm
606	<i>S. marcescens</i> (ATCC #990)	1 : 16	88.6250 ppm
607	<i>S. marcescens</i> (ATCC #4002)	1 : 16	88.6250 ppm
608	<i>S. marcescens</i> (ATCC #4003)	1 : 16	88.6250 ppm
609	<i>S. marcescens</i> (ATCC #4180)	1 : 64	22.1563 ppm
610	<i>S. marcescens</i> (ATCC #6065)	1 : 16	88.6250 ppm
611	<i>S. marcescens</i> (ATCC #6911)	1 : 16	88.6250 ppm
612	<i>S. marcescens</i> (ATCC #7316)	*	Testing not completed as of 3/6/00
613	<i>S. marcescens</i> (ATCC #8100)	1 : 32	44.3125 ppm
614	<i>S. marcescens</i> (ATCC #8101)	1 : 16	88.6250 ppm
615	<i>S. marcescens</i> (ATCC #8195)	1 : 16	88.6250 ppm
616	<i>S. marcescens</i> (ATCC #9103)	1 : 16	88.6250 ppm
617	<i>S. marcescens</i> (ATCC #13880)	1 : 16	88.6250 ppm
618	<i>S. marcescens</i> (ATCC #14041)	1 : 16	88.6250 ppm
619	<i>S. marcescens</i> (ATCC #14756)	1 : 16	88.6250 ppm
620	<i>S. marcescens</i> (ATCC #29632)	1 : 16	88.6250 ppm
621	<i>S. marcescens</i> (ATCC #29633)	1 : 16	88.6250 ppm
622	<i>S. marcescens</i> (ATCC #29634)	1 : 16	88.6250 ppm
623	<i>S. marcescens</i> (ATCC #29635)	1 : 16	88.6250 ppm
624	<i>S. marcescens</i> (ATCC #43861)	1 : 16	88.6250 ppm
625	<i>S. marcescens</i> (ATCC #43862)	1 : 16	88.6250 ppm

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
626	<i>S. marcescens</i> (Clinical Isolate - BSLI #081499SM)	1 : 16	88.6250 ppm
627	<i>S. marcescens</i> (Clinical Isolate - BSLI #121799SM1)	1 : 16	88.6250 ppm
628	<i>S. marcescens</i> (Clinical Isolate - BSLI #121799SM2)	1 : 16	88.6250 ppm
629	<i>S. marcescens</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
630	<i>S. marcescens</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
631	<i>S. marcescens</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
632	<i>S. marcescens</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
633	<i>S. marcescens</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
634	<i>S. marcescens</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
635	<i>S. marcescens</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
636	<i>S. marcescens</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
637	<i>S. marcescens</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
638	<i>S. marcescens</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
639	<i>S. marcescens</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
640	<i>S. marcescens</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
641	<i>S. marcescens</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
642	<i>S. marcescens</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
643	<i>S. marcescens</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
644	<i>S. marcescens</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
645	<i>S. marcescens</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
646	<i>S. marcescens</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
647	<i>S. marcescens</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
648	<i>S. marcescens</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
649	<i>S. marcescens</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
650	<i>S. marcescens</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
651	<i>S. aureus</i> (ATCC #6538)	1 : 512	2.7695 ppm
652	<i>S. aureus</i> (ATCC #6538P)	1 : 1024	1.3848 ppm
653	<i>S. aureus</i> (ATCC #10832)	*	Testing not completed as of 3/6/00
654	<i>S. aureus</i> (ATCC #11632)	1 : 1024	1.3848 ppm
655	<i>S. aureus</i> (ATCC #12598)	*	Testing not completed as of 3/6/00
656	<i>S. aureus</i> (ATCC #12600)	*	Testing not completed as of 3/6/00
657	<i>S. aureus</i> (ATCC #13301)	*	Testing not completed as of 3/6/00
658	<i>S. aureus</i> (ATCC #25923)	1 : 2,048	0.6924 ppm
659	<i>S. aureus</i> (ATCC #27217)	1 : 2,048	0.6924 ppm
660	<i>S. aureus</i> (ATCC #29737)	1 : 2,048	0.6924 ppm
661	<i>S. aureus</i> (ATCC #33862)	1 : 1024	1.3848 ppm
662	<i>S. aureus</i> (ATCC #27690)	*	Testing not completed as of 3/6/00
663	<i>S. aureus</i> (ATCC #27691)	*	Testing not completed as of 3/6/00
664	<i>S. aureus</i> (ATCC #27694)	*	Testing not completed as of 3/6/00
665	<i>S. aureus</i> (ATCC #27696)	*	Testing not completed as of 3/6/00
666	<i>S. aureus</i> (ATCC #27697)	*	Testing not completed as of 3/6/00
667	<i>S. aureus</i> (ATCC #27698)	*	Testing not completed as of 3/6/00
668	<i>S. aureus</i> (ATCC #29213)	1 : 128	11.0781 ppm
669	<i>S. aureus</i> (ATCC #33591)	1 : 512	2.7695 ppm
670	<i>S. aureus</i> (ATCC #33592)	1 : 2,048	0.6924 ppm
671	<i>S. aureus</i> (ATCC #33593)	1 : 2,048	0.6924 ppm
672	<i>S. aureus</i> (ATCC #43300)	1 : 1024	1.3848 ppm
673	<i>S. aureus</i> (ATCC #49444)	1 : 512	2.7695 ppm
674	<i>S. aureus</i> (ATCC #49476)	1 : 1024	1.3848 ppm
675	<i>S. aureus</i> (ATCC #51153)	1 : 512	2.7695 ppm

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
Product #1 - Pure Rx
Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
676	<i>S. aureus</i> (Clinical Isolate - BSLI #051599 MRSA)	1 : 1024	1.3848 ppm
677	<i>S. aureus</i> (Clinical Isolate - BSLI #062799 MRSA)	1 : 2,048	0.6924 ppm
678	<i>S. aureus</i> (Clinical Isolate - BSLI #060799 MRSA)	1 : 512	2.7695 ppm
679	<i>S. aureus</i> (Clinical Isolate - BSLI #080599 MRSA)	1 : 2,048	0.6924 ppm
680	<i>S. aureus</i> (Clinical Isolate - BSLI #071999 MRSA)	1 : 512	2.7695 ppm
681	<i>S. aureus</i> (Clinical Isolate - BSLI #070499 MRSA)	1 : 1024	1.3848 ppm
682	<i>S. aureus</i> (Clinical Isolate - BSLI #072199 MRSA)	1 : 1024	1.3848 ppm
683	<i>S. aureus</i> (Clinical Isolate - BSLI #082594 MRSA1)	1 : 2,048	0.6924 ppm
684	<i>S. aureus</i> (Clinical Isolate - BSLI #071499 MRSA)	1 : 512	2.7695 ppm
685	<i>S. aureus</i> (Clinical Isolate - BSLI #082494 MRSA2)	1 : 2,048	0.6924 ppm
686	<i>S. aureus</i> (Clinical Isolate - BSLI #121699SA1)	1 : 2,048	0.6924 ppm
687	<i>S. aureus</i> (Clinical Isolate - BSLI #121699SA2)	1 : 2,048	0.6924 ppm
688	<i>S. aureus</i> (Clinical Isolate - BSLI #121699SA3)	1 : 2,048	0.6924 ppm
689	<i>S. aureus</i> (Clinical Isolate - BSLI #121699SA4)	1 : 2,048	0.6924 ppm
690	<i>S. aureus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
691	<i>S. aureus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
692	<i>S. aureus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
693	<i>S. aureus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
694	<i>S. aureus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
695	<i>S. aureus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
696	<i>S. aureus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
697	<i>S. aureus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
698	<i>S. aureus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
699	<i>S. aureus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
700	<i>S. aureus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00

NOTE
This information has not
yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure-Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
701	<i>S. epidermidis</i> (ATCC #146)	*	Testing not completed as of 3/6/00
702	<i>S. epidermidis</i> (ATCC #9491)	*	Testing not completed as of 3/6/00
703	<i>S. epidermidis</i> (ATCC #12228)	1 : 4,096	0.3462 ppm
704	<i>S. epidermidis</i> (ATCC #13518)	*	Testing not completed as of 3/6/00
705	<i>S. epidermidis</i> (ATCC #14852)	*	Testing not completed as of 3/6/00
706	<i>S. epidermidis</i> (ATCC #14990)	1 : 4,096	0.3462 ppm
707	<i>S. epidermidis</i> (ATCC #19654)	*	Testing not completed as of 3/6/00
708	<i>S. epidermidis</i> (ATCC #29641)	*	Testing not completed as of 3/6/00
709	<i>S. epidermidis</i> (ATCC #29886)	*	Testing not completed as of 3/6/00
710	<i>S. epidermidis</i> (ATCC #29887)	*	Testing not completed as of 3/6/00
711	<i>S. epidermidis</i> (ATCC #29997)	*	Testing not completed as of 3/6/00
712	<i>S. epidermidis</i> (ATCC #31874)	*	Testing not completed as of 3/6/00
713	<i>S. epidermidis</i> (ATCC #33501)	*	Testing not completed as of 3/6/00
714	<i>S. epidermidis</i> (ATCC #35547)	*	Testing not completed as of 3/6/00
715	<i>S. epidermidis</i> (ATCC #35983)	*	Testing not completed as of 3/6/00
716	<i>S. epidermidis</i> (ATCC #35984)	*	Testing not completed as of 3/6/00
717	<i>S. epidermidis</i> (ATCC #49134)	1 : 16,384	0.0865 ppm
718	<i>S. epidermidis</i> (ATCC #49461)	1 : 1024	1.3748 ppm
719	<i>S. epidermidis</i> (ATCC #49741)	*	Testing not completed as of 3/6/00
720	<i>S. epidermidis</i> (ATCC #51624)	1 : 1024	1.3748 ppm
721	<i>S. epidermidis</i> (ATCC #51625)	1 : 8,192	0.1791 ppm
722	<i>S. epidermidis</i> (ATCC #55133)	*	Testing not completed as of 3/6/00
723	<i>S. epidermidis</i> (Clinical Isolate - BSLI #010500Se1)	1 : 2,048	0.6924 ppm
724	<i>S. epidermidis</i> (Clinical Isolate - BSLI #010500Se2)	1 : 512	2.7695 ppm
725	<i>S. epidermidis</i> (Clinical Isolate - BSLI #013100SE)	1 : 4,096	0.3462 ppm

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure-Rx.
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
726	<i>S. epidermidis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
727	<i>S. epidermidis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
728	<i>S. epidermidis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
729	<i>S. epidermidis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
730	<i>S. epidermidis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
731	<i>S. epidermidis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
732	<i>S. epidermidis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
733	<i>S. epidermidis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
734	<i>S. epidermidis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
735	<i>S. epidermidis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
736	<i>S. epidermidis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
737	<i>S. epidermidis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
738	<i>S. epidermidis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
739	<i>S. epidermidis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
740	<i>S. epidermidis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
741	<i>S. epidermidis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
742	<i>S. epidermidis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
743	<i>S. epidermidis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
744	<i>S. epidermidis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
745	<i>S. epidermidis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
746	<i>S. epidermidis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
747	<i>S. epidermidis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
748	<i>S. epidermidis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
749	<i>S. epidermidis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
750	<i>S. epidermidis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
751	<i>S. haemolyticus</i> (ATCC #15796)	1 : 4,096	0.3462 ppm
752	<i>S. haemolyticus</i> (ATCC #29968)	1 : 2,048	0.6924 ppm
753	<i>S. haemolyticus</i> (ATCC #29969)	1 : 4,096	0.3462 ppm
754	<i>S. haemolyticus</i> (ATCC #29970)	1 : 4,096	0.3462 ppm
755	<i>S. haemolyticus</i> (ATCC #43252)	1 : 4,096	0.3462 ppm
756	<i>S. haemolyticus</i> (ATCC #43253)	1 : 4,096	0.3462 ppm
757	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
758	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
759	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
760	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
761	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
762	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
763	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
764	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
765	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
766	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
767	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
768	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
769	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
770	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
771	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
772	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
773	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
774	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
775	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
776	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
777	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
778	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
779	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
780	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
781	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
782	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
783	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
784	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
785	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
786	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
787	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
788	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
789	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
790	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
791	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
792	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
793	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
794	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
795	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
796	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
797	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
798	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
799	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
800	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product.#1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
801	<i>S. hominis</i> (ATCC #25615)	*	Testing not completed as of 3/6/00
802	<i>S. hominis</i> (ATCC #27844)	1 : 4,096	0.3462 ppm
803	<i>S. hominis</i> (ATCC #27845)	1 : 4,096	0.3462 ppm
804	<i>S. hominis</i> (ATCC #27846)	1 : 4,096	0.3462 ppm
805	<i>S. hominis</i> (ATCC #27847)	1 : 512	2.7695 ppm
806	<i>S. hominis</i> (ATCC #29885)	*	Testing not completed as of 3/6/00
807	<i>S. hominis</i> (ATCC #35981)	1 : 512	2.7695 ppm
808	<i>S. hominis</i> (ATCC #35982)	1 : 256	5.5391 ppm
809	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
810	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
811	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
812	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
813	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
814	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
815	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
816	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
817	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
818	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
819	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
820	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
821	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
822	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
823	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
824	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
825	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
826	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
827	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
828	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
829	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
830	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
831	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
832	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
833	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
834	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
835	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
836	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
837	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
838	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
839	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
840	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
841	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
842	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
843	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
844	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
845	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
846	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
847	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
848	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
849	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
850	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
851	<i>S. saprophyticus</i> (ATCC #15305)	1 : 4,096	0.3462 ppm
852	<i>S. saprophyticus</i> (ATCC #35552)	*	Testing not completed as of 3/6/00
853	<i>S. saprophyticus</i> (ATCC #43867)	*	Testing not completed as of 3/6/00
854	<i>S. saprophyticus</i> (ATCC #49453)	1 : 1024	1.3848 ppm
855	<i>S. saprophyticus</i> (ATCC #49907)	*	Testing not completed as of 3/6/00
856	<i>S. saprophyticus</i> (Clinical Isolate - BSLI #081399SS)	1 : 256	5.5391 ppm
857	<i>S. saprophyticus</i> (Clinical Isolate - BSLI #121699SS1)	*	Testing not completed as of 3/6/00
858	<i>S. saprophyticus</i> (Clinical Isolate - BSLI #121699SS2)	1 : 512	2.7695 ppm
859	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
860	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
861	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
862	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
863	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
864	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
865	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
866	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
867	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
868	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
869	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
870	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
871	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
872	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
873	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
874	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
875	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
876	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
877	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
878	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
879	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
880	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
881	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
882	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
883	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
884	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
885	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
886	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
887	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
888	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
889	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
890	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
891	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
892	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
893	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
894	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
895	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
896	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
897	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
898	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
899	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
900	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
901	<i>S. pneumoniae</i> (ATCC #6301)	*	Testing not completed as of 3/6/00
902	<i>S. pneumoniae</i> (ATCC #6302)	*	Testing not completed as of 3/6/00
903	<i>S. pneumoniae</i> (ATCC #6303)	*	Testing not completed as of 3/6/00
904	<i>S. pneumoniae</i> (ATCC #6304)	*	Testing not completed as of 3/6/00
905	<i>S. pneumoniae</i> (ATCC #6305)	*	Testing not completed as of 3/6/00
906	<i>S. pneumoniae</i> (ATCC #6306)	*	Testing not completed as of 3/6/00
907	<i>S. pneumoniae</i> (ATCC #6307)	*	Testing not completed as of 3/6/00
908	<i>S. pneumoniae</i> (ATCC #6308)	*	Testing not completed as of 3/6/00
909	<i>S. pneumoniae</i> (ATCC #6309)	*	Testing not completed as of 3/6/00
910	<i>S. pneumoniae</i> (ATCC #6310)	*	Testing not completed as of 3/6/00
911	<i>S. pneumoniae</i> (ATCC #6311)	*	Testing not completed as of 3/6/00
912	<i>S. pneumoniae</i> (ATCC #6314)	*	Testing not completed as of 3/6/00
913	<i>S. pneumoniae</i> (ATCC #9163)	*	Testing not completed as of 3/6/00
914	<i>S. pneumoniae</i> (ATCC #10015)	*	Testing not completed as of 3/6/00
915	<i>S. pneumoniae</i> (ATCC #10813)	*	Testing not completed as of 3/6/00
916	<i>S. pneumoniae</i> (ATCC #11733)	*	Testing not completed as of 3/6/00
917	<i>S. pneumoniae</i> (ATCC #12213)	*	Testing not completed as of 3/6/00
918	<i>S. pneumoniae</i> (ATCC #27336)	*	Testing not completed as of 3/6/00
919	<i>S. pneumoniae</i> (ATCC #29514)	*	Testing not completed as of 3/6/00
920	<i>S. pneumoniae</i> (ATCC #33400)	*	Testing not completed as of 3/6/00
921	<i>S. pneumoniae</i> (ATCC #35088)	*	Testing not completed as of 3/6/00
922	<i>S. pneumoniae</i> (ATCC #49136)	*	Testing not completed as of 3/6/00
923	<i>S. pneumoniae</i> (ATCC #49150)	*	Testing not completed as of 3/6/00
924	<i>S. pneumoniae</i> (ATCC #49619)	*	Testing not completed as of 3/6/00
925	<i>S. pneumoniae</i> (ATCC #51422)	*	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
926	<i>S. pneumoniae</i> (Clinical Isolate - BSLI #121699Spn1)	1 : 1024	1.3848 ppm
927	<i>S. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
928	<i>S. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
929	<i>S. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
930	<i>S. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
931	<i>S. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
932	<i>S. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
933	<i>S. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
934	<i>S. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
935	<i>S. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
936	<i>S. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
937	<i>S. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
938	<i>S. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
939	<i>S. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
940	<i>S. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
941	<i>S. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
942	<i>S. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
943	<i>S. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
944	<i>S. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
945	<i>S. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
946	<i>S. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
947	<i>S. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
948	<i>S. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
949	<i>S. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
950	<i>S. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
951	<i>S. pyogenes</i> (ATCC #4543)	*	Testing not completed as of 3/6/00
952	<i>S. pyogenes</i> (ATCC #8058)	*	Testing not completed as of 3/6/00
953	<i>S. pyogenes</i> (ATCC #8668)	*	Testing not completed as of 3/6/00
954	<i>S. pyogenes</i> (ATCC #8669)	*	Testing not completed as of 3/6/00
955	<i>S. pyogenes</i> (ATCC #8670)	*	Testing not completed as of 3/6/00
956	<i>S. pyogenes</i> (ATCC #10389)	*	Testing not completed as of 3/6/00
957	<i>S. pyogenes</i> (ATCC #12202)	*	Testing not completed as of 3/6/00
958	<i>S. pyogenes</i> (ATCC #12203)	*	Testing not completed as of 3/6/00
959	<i>S. pyogenes</i> (ATCC #12204)	*	Testing not completed as of 3/6/00
960	<i>S. pyogenes</i> (ATCC #12344)	*	Testing not completed as of 3/6/00
961	<i>S. pyogenes</i> (ATCC #12351)	*	Testing not completed as of 3/6/00
962	<i>S. pyogenes</i> (ATCC #12384)	*	Testing not completed as of 3/6/00
963	<i>S. pyogenes</i> (ATCC #12385)	*	Testing not completed as of 3/6/00
964	<i>S. pyogenes</i> (ATCC #14289)	*	Testing not completed as of 3/6/00
965	<i>S. pyogenes</i> (ATCC #14918)	*	Testing not completed as of 3/6/00
966	<i>S. pyogenes</i> (ATCC #14919)	*	Testing not completed as of 3/6/00
967	<i>S. pyogenes</i> (ATCC #19615)	*	Testing not completed as of 3/6/00
968	<i>S. pyogenes</i> (ATCC #27762)	*	Testing not completed as of 3/6/00
969	<i>S. pyogenes</i> (ATCC #49117)	*	Testing not completed as of 3/6/00
970	<i>S. pyogenes</i> (ATCC #49399)	*	Testing not completed as of 3/6/00
971	<i>S. pyogenes</i> (ATCC #51339)	*	Testing not completed as of 3/6/00
972	<i>S. pyogenes</i> (ATCC #51500)	*	Testing not completed as of 3/6/00
973	<i>S. pyogenes</i> (ATCC #51574)	*	Testing not completed as of 3/6/00
974	<i>S. pyogenes</i> (ATCC #51877)	*	Testing not completed as of 3/6/00
975	<i>S. pyogenes</i> (ATCC #51878)	*	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
976	<i>S. pyogenes</i> (Clinical Isolate - BSLI #121699Spy1)	1 : 2,048	0.6924 ppm
977	<i>S. pyogenes</i> (Clinical Isolate - BSLI #121699Spy2)	1 : 2,048	0.6924 ppm
978	<i>S. pyogenes</i> (Clinical Isolate - BSLI #121699Spy3)	1 : 1024	1.3848 ppm
979	<i>S. pyogenes</i> (Clinical Isolate - BSLI #121699Spy4)	1 : 4,096	0.3462 ppm
980	<i>S. pyogenes</i> (Clinical Isolate - BSLI #121699Spy5)	1 : 4,096	0.3462 ppm
981	<i>S. pyogenes</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
982	<i>S. pyogenes</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
983	<i>S. pyogenes</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
984	<i>S. pyogenes</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
985	<i>S. pyogenes</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
986	<i>S. pyogenes</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
987	<i>S. pyogenes</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
988	<i>S. pyogenes</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
989	<i>S. pyogenes</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
990	<i>S. pyogenes</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
991	<i>S. pyogenes</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
992	<i>S. pyogenes</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
993	<i>S. pyogenes</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
994	<i>S. pyogenes</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
995	<i>S. pyogenes</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
996	<i>S. pyogenes</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
997	<i>S. pyogenes</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
998	<i>S. pyogenes</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
999	<i>S. pyogenes</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
1000	<i>S. pyogenes</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
1001	<i>C. glabrata</i> (ATCC #2001)	1 : 1024	1.3848 ppm
1002	<i>C. glabrata</i> (ATCC #15545)	*	Testing not completed as of 3/6/00
1003	<i>C. glabrata</i> (ATCC #32554)	*	Testing not completed as of 3/6/00
1004	<i>C. glabrata</i> (ATCC #66032)	1 : 512	2.7695 ppm
1005	<i>C. guilliermondii</i> (ATCC #6260)	*	Testing not completed as of 3/6/00
1006	<i>C. guilliermondii</i> (ATCC #34134)	*	Testing not completed as of 3/6/00
1007	<i>C. guilliermondii</i> (ATCC #56822)	*	Testing not completed as of 3/6/00
1008	<i>C. krusei</i> (ATCC #6258)	*	Testing not completed as of 3/6/00
1009	<i>C. krusei</i> (ATCC #14243)	1 : 512	2.7695 ppm
1010	<i>C. krusei</i> (ATCC #34135)	*	Testing not completed as of 3/6/00
1011	<i>C. krusei</i> (ATCC #44507)	*	Testing not completed as of 3/6/00
1012	<i>C. lusitaniae</i> (ATCC #42720)	*	Testing not completed as of 3/6/00
1013	<i>C. lusitaniae</i> (ATCC #64125)	*	Testing not completed as of 3/6/00
1014	<i>C. lusitaniae</i> (ATCC #66035)	*	Testing not completed as of 3/6/00
1015	<i>C. parapsilosis</i> (ATCC #7330)	*	Testing not completed as of 3/6/00
1016	<i>C. parapsilosis</i> (ATCC #22019)	*	Testing not completed as of 3/6/00
1017	<i>C. parapsilosis</i> (ATCC #60548)	*	Testing not completed as of 3/6/00
1018	<i>C. tropicalis</i> (ATCC #750)	1 : 256	5.5391 ppm
1019	<i>C. tropicalis</i> (ATCC #13803)	1 : 1024	1.3848 ppm
1020	<i>C. tropicalis</i> (ATCC #14056)	*	Testing not completed as of 3/6/00
1021	<i>C. tropicalis</i> (ATCC #18526)	*	Testing not completed as of 3/6/00
1022	<i>C. tropicalis</i> (ATCC #34139)	*	Testing not completed as of 3/6/00
1023	<i>C. kefyr</i> (ATCC #2512)	1 : 1024	1.3848 ppm
1024	<i>C. kefyr</i> (ATCC #66028)	1 : 512	2.7695 ppm
1025	<i>C. tropicalis</i> (ATCC #66029)	1 : 512	2.7695 ppm

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
1026	<i>Candida</i> sp. (Clinical Isolate - BSLI #121699CG)	1 : 512	2.7695 ppm
1027	<i>Candida</i> sp. (Clinical Isolate - BSLI #121799Ct)	1 : 512	2.7695 ppm
1028	<i>Candida</i> sp. (Clinical Isolate - BSLI #121799Cg1)	1 : 128	11.0781 ppm
1029	<i>Candida</i> sp. (Clinical Isolate - BSLI #121799Cg2)	1 : 256	5.5391 ppm
1030	<i>Candida</i> sp. (Clinical Isolate - BSLI #121799Cg3)	1 : 4,096	0.3462 ppm
1031	<i>Candida</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
1032	<i>Candida</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
1033	<i>Candida</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
1034	<i>Candida</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
1035	<i>Candida</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
1036	<i>Candida</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
1037	<i>Candida</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
1038	<i>Candida</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
1039	<i>Candida</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
1040	<i>Candida</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
1041	<i>Candida</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
1042	<i>Candida</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
1043	<i>Candida</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
1044	<i>Candida</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
1045	<i>Candida</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
1046	<i>Candida</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
1047	<i>Candida</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
1048	<i>Candida</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
1049	<i>Candida</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
1050	<i>Candida</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #1 - Pure Rx
 Batch #X450

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
1076	<i>C. albicans</i> (Clinical Isolate - BSLI #081599CA)	1 : 256	5.5391 ppm
1077	<i>C. albicans</i> (Clinical Isolate - BSLI #121699Ca)	1 : 256	5.5391 ppm
1078	<i>C. albicans</i> (Clinical Isolate - BSLI #121799Ca1)	1 : 1024	1.3848 ppm
1079	<i>C. albicans</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
1080	<i>C. albicans</i> (Clinical Isolate - BSLI #121799Ca3)	1 : 512	2.7695 ppm
1081	<i>C. albicans</i> (Clinical Isolate - BSLI #121799Ca4)	1 : 256	5.5391 ppm
1082	<i>C. albicans</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
1083	<i>C. albicans</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
1084	<i>C. albicans</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
1085	<i>C. albicans</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
1086	<i>C. albicans</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
1087	<i>C. albicans</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
1088	<i>C. albicans</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
1089	<i>C. albicans</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
1090	<i>C. albicans</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
1091	<i>C. albicans</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
1092	<i>C. albicans</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
1093	<i>C. albicans</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
1094	<i>C. albicans</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
1095	<i>C. albicans</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
1096	<i>C. albicans</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
1097	<i>C. albicans</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
1098	<i>C. albicans</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
1099	<i>C. albicans</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
1100	<i>C. albicans</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #2 - Pure Rx Vehicle
 Batch #426

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration - Dilution
7	<i>Acinetobacter</i> sp. (ATCC #49137)	1 : 8
15	<i>A. baumannii</i> (ATCC #19606)	1 : 8
16	<i>A. calcoaceticus</i> (ATCC #14987)	1 : 8
20	<i>A. haemolyticus</i> (ATCC #19002)	1 : 8
23	<i>A. lwoffii</i> (ATCC #15309)	1 : 16
26	<i>Acinetobacter</i> sp. (Clinical Isolate - BSLI #081399Abc)	1 : 4
27	<i>Acinetobacter</i> sp. (Clinical Isolate - BSLI #071499Ab)	1 : 8
28	<i>Acinetobacter</i> sp. (Clinical Isolate - BSLI #121699Asp)	1 : 8
29	<i>Acinetobacter</i> sp. (Clinical Isolate - BSLI #121799Asp1)	1 : 8
30	<i>Acinetobacter</i> sp. (Clinical Isolate - BSLI #121799Asp2)	1 : 8
51	<i>B. fragilis</i> (ATCC #23745)	1 : 32
52	<i>B. fragilis</i> (ATCC #25285)	1 : 16
53	<i>B. fragilis</i> (ATCC #29762)	Testing not completed as of 3/6/00
63	<i>B. fragilis</i> (ATCC #43858)	Testing not completed as of 3/6/00
67	<i>B. fragilis</i> (ATCC #43936)	1 : 16
70	<i>Bacteroides</i> sp. (Clinical Isolate - BSLI #021000Bf1)	1 : 16
71	<i>Bacteroides</i> sp. (Clinical Isolate - BSLI #021000Bf2)	1 : 16
72	<i>Bacteroides</i> sp. (Clinical Isolate)	Testing not completed as of 3/6/00
73	<i>Bacteroides</i> sp. (Clinical Isolate)	Testing not completed as of 3/6/00
74	<i>Bacteroides</i> sp. (Clinical Isolate)	Testing not completed as of 3/6/00
101	<i>E. aerogenes</i> (ATCC #13048)	1 : 4
102	<i>E. aerogenes</i> (ATCC #15038)	1 : 4
108	<i>E. aerogenes</i> (ATCC #35028)	1 : 4
119	<i>E. cloacae</i> (ATCC #13047)	1 : 4
120	<i>E. cloacae</i> (ATCC #23355)	1 : 8

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #2 - Pure Rx Vehicle
 Batch #426

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration - Dilution
126	<i>E. cloacae</i> (Clinical Isolate - BSLI #081299EC)	1 : 4
127	<i>Enterobacter</i> sp. (Clinical Isolate - BSLI #121799Ec1)	1 : 8
128	<i>Enterobacter</i> sp. (Clinical Isolate - BSLI #121799Ec2)	1 : 8
129	<i>Enterobacter</i> sp. (Clinical Isolate - BSLI #013100EA)	< 1 : 8
130	<i>Enterobacter</i> sp. (Clinical Isolate)	Testing not completed as of 3/6/00
158	<i>E. faecalis</i> (ATCC #19433)	1 : 16
159	<i>E. faecalis</i> (ATCC #29212)	1 : 16
160	<i>E. faecalis</i> (ATCC #33012)	1 : 8
174	<i>E. faecalis</i> (ATCC #51299)	1 : 16
175	<i>E. faecalis</i> (ATCC #51575)	1 : 16
176	<i>E. faecalis</i> (Clinical Isolate - BSLI #080294VRE2)	1 : 16
177	<i>E. faecalis</i> (Clinical Isolate - BSLI #080294VRE4)	1 : 16
178	<i>E. faecalis</i> (Clinical Isolate - BSLI #080294VRE1)	1 : 32
179	<i>E. faecalis</i> (Clinical Isolate - BSLI #121699Efs1)	1 : 16
180	<i>E. faecalis</i> (Clinical Isolate - BSLI #121699Efs2)	1 : 8
208	<i>E. faecium</i> (ATCC #19434)	1 : 8
225	<i>E. faecium</i> (ATCC #51559)	1 : 32
226	<i>E. faecium</i> (Clinical Isolate - BSLI #050499VRE)	1 : 32
227	<i>E. faecium</i> (Clinical Isolate - BSLI #062599VRE)	1 : 32
228	<i>E. faecium</i> (Clinical Isolate - BSLI #052999EF)	1 : 64
229	<i>E. faecium</i> (Clinical Isolate - BSLI #080599VRE)	1 : 32
230	<i>E. faecium</i> (Clinical Isolate - BSLI #072199VRE)	1 : 32
231	<i>E. faecium</i> (Clinical Isolate - BSLI #071999VRE)	1 : 32
232	<i>E. faecium</i> (Clinical Isolate - BSLI #062999VRE)	1 : 64
233	<i>E. faecium</i> (Clinical Isolate - BSLI #071499VRE)	1 : 16

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #2 - Pure Rx Vehicle
 Batch #426

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration - Dilution
253	<i>E. coli</i> (ATCC #8739)	1 : 16
257	<i>E. coli</i> (ATCC #11229)	1 : 8
271	<i>E. coli</i> (ATCC #25922)	1 : 4
273	<i>E. coli</i> (ATCC #35150)	1 : 8
275	<i>E. coli</i> (ATCC #43892)	1 : 4
276	<i>E. coli</i> (Clinical Isolate - BSLI #060199EC)	1 : 8
277	<i>E. coli</i> (Clinical Isolate - BSLI # 051599EC)	1 : 8
278	<i>E. coli</i> (Clinical Isolate - BSLI #070399EC)	1 : 8
279	<i>E. coli</i> (Clinical Isolate - BSLI #121699Ec2)	1 : 4
280	<i>E. coli</i> (Clinical Isolate - BSLI #121699Ec1)	1 : 4
307	<i>H. influenzae</i> (ATCC #9795)	Testing not completed as of 3/6/00
308	<i>H. influenzae</i> (ATCC #9833)	Testing not completed as of 3/6/00
311	<i>H. influenzae</i> (ATCC #19418)	1 : 16
316	<i>H. influenzae</i> (ATCC #35540)	Testing not completed as of 3/6/00
321	<i>H. influenzae</i> (ATCC #49401)	Testing not completed as of 3/6/00
326	<i>H. influenzae</i> (Clinical Isolate - BSLI #121699Hi2)	1 : 16
327	<i>H. influenzae</i> (Clinical Isolate - BSLI #121699Hi3)	1 : 32
328	<i>H. influenzae</i> (Clinical Isolate - BSLI #121699Hi4)	1 : 16
329	<i>H. influenzae</i> (Clinical Isolate - BSLI #121699Hi1)	1 : 128
330	<i>H. influenzae</i> (Clinical Isolate)	Testing not completed as of 3/6/00
357	<i>K. oxytoca</i> (ATCC #15764)	1 : 8
364	<i>K. oxytoca</i> (ATCC #43165)	1 : 4
365	<i>K. oxytoca</i> (ATCC #43863)	1 : 4
367	<i>K. oxytoca</i> (ATCC #49334)	1 : 8

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
Product #2 - Pure Rx Vehicle
Batch #426

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration - Dilution
368	<i>K. oxytoca</i> (ATCC #49473)	1 : 8
376	<i>K. oxytoca</i> (Clinical Isolate - BSLI #060199K0)	1 : 4
377	<i>Klebsiella</i> sp. (Clinical Isolate - BSLI #121799KO)	1 : 4
378	<i>Klebsiella</i> sp. (Clinical Isolate - BSLI #010500KO)	1 : 8
379	<i>Klebsiella</i> sp. (Clinical Isolate - BSLI #010500Kp1)	1 : 8
380	<i>Klebsiella</i> sp. (Clinical Isolate - BSLI #010500Kp2)	1 : 4
412	<i>K. pneumoniae</i> (ATCC #9997)	1 : 4
413	<i>K. pneumoniae</i> (ATCC #10031)	1 : 8
414	<i>K. pneumoniae</i> (ATCC #11296)	1 : 8
417	<i>K. pneumoniae</i> (ATCC #13883)	1 : 4
418	<i>K. pneumoniae</i> (ATCC #27736)	1 : 8
426	<i>K. pneumoniae</i> (Clinical Isolate - BSLI #081599Kp)	1 : 4
427	<i>K. pneumoniae</i> (Clinical Isolate - BSLI #121699Kp)	1 : 4
428	<i>K. pneumoniae</i> (Clinical Isolate - BSLI #121799KP1)	1 : 4
429	<i>K. pneumoniae</i> (Clinical Isolate - BSLI #121799KP2)	1 : 4
430	<i>K. pneumoniae</i> (Clinical Isolate - BSLI #121799KP3)	1 : 4
454	<i>M. luteus</i> (ATCC #381)	Testing not completed as of 3/6/00
460	<i>M. luteus</i> (ATCC #4698)	1 : 32
461	<i>M. luteus</i> (ATCC #7468)	1 : 64
471	<i>M. luteus</i> (ATCC #14452)	Testing not completed as of 3/6/00
473	<i>M. luteus</i> (ATCC #27523)	Testing not completed as of 3/6/00
476	<i>Micrococcus</i> sp. (Clinical Isolate)	Testing not completed as of 3/6/00
477	<i>Micrococcus</i> sp. (Clinical Isolate)	Testing not completed as of 3/6/00
478	<i>Micrococcus</i> sp. (Clinical Isolate)	Testing not completed as of 3/6/00
479	<i>Micrococcus</i> sp. (Clinical Isolate)	Testing not completed as of 3/6/00

NOTE
This information has not
yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #2 - Pure Rx Vehicle
 Batch #426

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration - Dilution
480	<i>Micrococcus</i> sp. (Clinical Isolate)	Testing not completed as of 3/6/00
501	<i>P. mirabilis</i> (ATCC #4630)	1 : 4
503	<i>P. mirabilis</i> (ATCC #7002)	1 : 4
507	<i>P. mirabilis</i> (ATCC #14153)	Testing not completed as of 3/6/00
510	<i>P. mirabilis</i> (ATCC #25933)	1 : 4
520	<i>P. mirabilis</i> (ATCC #33583)	Testing not completed as of 3/6/00
526	<i>P. mirabilis</i> (Clinical Isolate - BSLI #081299PM)	1 : 4
527	<i>P. mirabilis</i> (Clinical Isolate - BSLI #121699Pm1)	1 : 4
528	<i>P. mirabilis</i> (Clinical Isolate - BSLI #121699Pm2)	1 : 4
529	<i>P. mirabilis</i> (Clinical Isolate - BSLI #010500PM)	1 : 4
530	<i>P. mirabilis</i> (Clinical Isolate - BSLI #013100PM)	< 1 : 8
552	<i>P. aeruginosa</i> (ATCC #9027)	1 : 8
553	<i>P. aeruginosa</i> (ATCC #9721)	1 : 8
556	<i>P. aeruginosa</i> (ATCC #14207)	1 : 8
559	<i>P. aeruginosa</i> (ATCC #15442)	1 : 8
568	<i>P. aeruginosa</i> (ATCC #27853)	1 : 8
576	<i>P. aeruginosa</i> (Clinical Isolate - BSLI #052299Pa)	1 : 8
577	<i>P. aeruginosa</i> (Clinical Isolate - BSLI #053099Pa)	1 : 8
578	<i>P. aeruginosa</i> (Clinical Isolate - BSLI #070199Pa)	1 : 8
579	<i>P. aeruginosa</i> (Clinical Isolate - BSLI #121699Pa3)	1 : 8
580	<i>P. aeruginosa</i> (Clinical Isolate - BSLI #121699Pa2)	1 : 8
581	<i>P. aeruginosa</i> (Clinical Isolate - BSLI #121699Pa1)	1 : 8
613	<i>S. marcescens</i> (ATCC #8100)	1 : 8
617	<i>S. marcescens</i> (ATCC #13880)	1 : 4
619	<i>S. marcescens</i> (ATCC #14756)	1 : 8
620	<i>S. marcescens</i> (ATCC #29632)	1 : 8

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #2 - Pure Rx Vehicle
 Batch #426

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration - Dilution
625	<i>S. marcescens</i> (ATCC #43862)	1 : 8
626	<i>S. marcescens</i> (Clinical Isolate - BSLI #081499SM)	1 : 8
627	<i>S. marcescens</i> (Clinical Isolate - BSLI #121799SM1)	1 : 8
628	<i>S. marcescens</i> (Clinical Isolate - BSLI #121799SM2)	1 : 8
629	<i>S. marcescens</i> (Clinical Isolate)	Testing not completed as of 3/6/00
630	<i>S. marcescens</i> (Clinical Isolate)	Testing not completed as of 3/6/00
660	<i>S. aureus</i> (ATCC #29737)	1 : 8
661	<i>S. aureus</i> (ATCC #33862)	< 1 : 8
676	<i>S. aureus</i> (Clinical Isolate - BSLI #051599 MRSA)	1 : 8
677	<i>S. aureus</i> (Clinical Isolate - BSLI #062799 MRSA)	1 : 8
678	<i>S. aureus</i> (Clinical Isolate - BSLI #060799 MRSA)	1 : 8
679	<i>S. aureus</i> (Clinical Isolate - BSLI #080599 MRSA)	1 : 8
680	<i>S. aureus</i> (Clinical Isolate - BSLI #071999 MRSA)	1 : 4
681	<i>S. aureus</i> (Clinical Isolate - BSLI #070499 MRSA)	1 : 8
682	<i>S. aureus</i> (Clinical Isolate - BSLI #072199 MRSA)	1 : 8
683	<i>S. aureus</i> (Clinical Isolate - BSLI #082594 MRSA1)	1 : 8
684	<i>S. aureus</i> (Clinical Isolate - BSLI #071499 MRSA)	1 : 8
685	<i>S. aureus</i> (Clinical Isolate - BSLI #082494 MRSA2)	1 : 4
703	<i>S. epidermidis</i> (ATCC #12228)	< 1 : 8
706	<i>S. epidermidis</i> (ATCC #14990)	1 : 8
714	<i>S. epidermidis</i> (ATCC #35547)	Testing not completed as of 3/6/00
720	<i>S. epidermidis</i> (ATCC #51624)	1 : 8
721	<i>S. epidermidis</i> (ATCC #51625)	1 : 8
723	<i>S. epidermidis</i> (Clinical Isolate - BSLI #010500Se1)	1 : 4
724	<i>S. epidermidis</i> (Clinical Isolate - BSLI #010500Se2)	1 : 4

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #2 - Pure Rx Vehicle
 Batch #426

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration - Dilution
725	<i>S. epidermidis</i> (Clinical Isolate - BSLI #013100SE)	< 1 : 8
726	<i>S. epidermidis</i> (Clinical Isolate)	Testing not completed as of 3/6/00
727	<i>S. epidermidis</i> (Clinical Isolate)	Testing not completed as of 3/6/00
751	<i>S. haemolyticus</i> (ATCC #15796)	1 : 8
752	<i>S. haemolyticus</i> (ATCC #29968)	1 : 8
753	<i>S. haemolyticus</i> (ATCC #29969)	< 1 : 8
754	<i>S. haemolyticus</i> (ATCC #29970)	1 : 8
755	<i>S. haemolyticus</i> (ATCC #43252)	1 : 8
757	<i>S. haemolyticus</i> (Clinical Isolate)	Testing not completed as of 3/6/00
758	<i>S. haemolyticus</i> (Clinical Isolate)	Testing not completed as of 3/6/00
759	<i>S. haemolyticus</i> (Clinical Isolate)	Testing not completed as of 3/6/00
760	<i>S. haemolyticus</i> (Clinical Isolate)	Testing not completed as of 3/6/00
761	<i>S. haemolyticus</i> (Clinical Isolate)	Testing not completed as of 3/6/00
801	<i>S. hominis</i> (ATCC #25615)	Testing not completed as of 3/6/00
802	<i>S. hominis</i> (ATCC #27844)	1 : 8
803	<i>S. hominis</i> (ATCC #27845)	1 : 8
804	<i>S. hominis</i> (ATCC #27846)	1 : 8
805	<i>S. hominis</i> (ATCC #27847)	1 : 16
809	<i>S. hominis</i> (Clinical Isolate)	Testing not completed as of 3/6/00
810	<i>S. hominis</i> (Clinical Isolate)	Testing not completed as of 3/6/00
811	<i>S. hominis</i> (Clinical Isolate)	Testing not completed as of 3/6/00
812	<i>S. hominis</i> (Clinical Isolate)	Testing not completed as of 3/6/00
813	<i>S. hominis</i> (Clinical Isolate)	Testing not completed as of 3/6/00
851	<i>S. saprophyticus</i> (ATCC #15305)	1 : 8
852	<i>S. saprophyticus</i> (ATCC #35552)	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #2 - Pure Rx Vehicle
 Batch #426

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration - Dilution
853	<i>S. saprophyticus</i> (ATCC #43867)	Testing not completed as of 3/6/00
854	<i>S. saprophyticus</i> (ATCC #49453)	1 : 8
855	<i>S. saprophyticus</i> (ATCC #49907)	Testing not completed as of 3/6/00
856	<i>S. saprophyticus</i> (Clinical Isolate - BSLI #081399SS)	1 : 8
857	<i>S. saprophyticus</i> (Clinical Isolate - BSLI #121699SS1)	Testing not completed as of 3/6/00
858	<i>S. saprophyticus</i> (Clinical Isolate - BSLI #121699SS2)	1 : 8
859	<i>S. saprophyticus</i> (Clinical Isolate)	Testing not completed as of 3/6/00
860	<i>S. saprophyticus</i> (Clinical Isolate)	Testing not completed as of 3/6/00
903	<i>S. pneumoniae</i> (ATCC #6303)	Testing not completed as of 3/6/00
913	<i>S. pneumoniae</i> (ATCC #9163)	Testing not completed as of 3/6/00
914	<i>S. pneumoniae</i> (ATCC #10015)	Testing not completed as of 3/6/00
920	<i>S. pneumoniae</i> (ATCC #33400)	Testing not completed as of 3/6/00
921	<i>S. pneumoniae</i> (ATCC #35088)	Testing not completed as of 3/6/00
926	<i>S. pneumoniae</i> (Clinical Isolate - BSLI #121699Spn1)	1 : 32
927	<i>S. pneumoniae</i> (Clinical Isolate)	Testing not completed as of 3/6/00
928	<i>S. pneumoniae</i> (Clinical Isolate)	Testing not completed as of 3/6/00
929	<i>S. pneumoniae</i> (Clinical Isolate)	Testing not completed as of 3/6/00
930	<i>S. pneumoniae</i> (Clinical Isolate)	Testing not completed as of 3/6/00
952	<i>S. pyogenes</i> (ATCC #8058)	Testing not completed as of 3/6/00
961	<i>S. pyogenes</i> (ATCC #F2351)	Testing not completed as of 3/6/00
964	<i>S. pyogenes</i> (ATCC #14289)	Testing not completed as of 3/6/00
967	<i>S. pyogenes</i> (ATCC #19615)	Testing not completed as of 3/6/00
971	<i>S. pyogenes</i> (ATCC #51339)	Testing not completed as of 3/6/00
976	<i>S. pyogenes</i> (Clinical Isolate - BSLI #121699Spy1)	1 : 16
977	<i>S. pyogenes</i> (Clinical Isolate - BSLI #121699Spy2)	1 : 16

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #2 - Pure Rx Vehicle
 Batch #426

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration - Dilution
853	<i>S. saprophyticus</i> (ATCC #43867)	Testing not completed as of 3/6/00
854	<i>S. saprophyticus</i> (ATCC #49453)	1 : 8
855	<i>S. saprophyticus</i> (ATCC #49907)	Testing not completed as of 3/6/00
856	<i>S. saprophyticus</i> (Clinical Isolate - BSLI #081399SS)	1 : 8
857	<i>S. saprophyticus</i> (Clinical Isolate - BSLI #121699SS1)	Testing not completed as of 3/6/00
858	<i>S. saprophyticus</i> (Clinical Isolate - BSLI #121699SS2)	1 : 8
859	<i>S. saprophyticus</i> (Clinical Isolate)	Testing not completed as of 3/6/00
860	<i>S. saprophyticus</i> (Clinical Isolate)	Testing not completed as of 3/6/00
903	<i>S. pneumoniae</i> (ATCC #6303)	Testing not completed as of 3/6/00
913	<i>S. pneumoniae</i> (ATCC #9163)	Testing not completed as of 3/6/00
914	<i>S. pneumoniae</i> (ATCC #10015)	Testing not completed as of 3/6/00
920	<i>S. pneumoniae</i> (ATCC #33400)	Testing not completed as of 3/6/00
921	<i>S. pneumoniae</i> (ATCC #35088)	Testing not completed as of 3/6/00
926	<i>S. pneumoniae</i> (Clinical Isolate - BSLI #121699Spn1)	1 : 32
927	<i>S. pneumoniae</i> (Clinical Isolate)	Testing not completed as of 3/6/00
928	<i>S. pneumoniae</i> (Clinical Isolate)	Testing not completed as of 3/6/00
929	<i>S. pneumoniae</i> (Clinical Isolate)	Testing not completed as of 3/6/00
930	<i>S. pneumoniae</i> (Clinical Isolate)	Testing not completed as of 3/6/00
952	<i>S. pyogenes</i> (ATCC #8058)	Testing not completed as of 3/6/00
961	<i>S. pyogenes</i> (ATCC #12351)	Testing not completed as of 3/6/00
964	<i>S. pyogenes</i> (ATCC #14289)	Testing not completed as of 3/6/00
967	<i>S. pyogenes</i> (ATCC #19615)	Testing not completed as of 3/6/00
971	<i>S. pyogenes</i> (ATCC #51339)	Testing not completed as of 3/6/00
976	<i>S. pyogenes</i> (Clinical Isolate - BSLI #121699Spy1)	1 : 16
977	<i>S. pyogenes</i> (Clinical Isolate - BSLI #121699Spy2)	1 : 16

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #3 - Hibiclens®
 Lot #3204B

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
126	<i>E. cloacae</i> (Clinical Isolate - BSLI #081299EC)	1 : 8,192	4.8828 ppm
127	<i>Enterobacter</i> sp. (Clinical Isolate - BSLI #121799Ecl1)	1 : 32,768	1.2207 ppm
128	<i>Enterobacter</i> sp. (Clinical Isolate - BSLI #121799Ecl2)	1 : 32,768	1.2207 ppm
129	<i>Enterobacter</i> sp. (Clinical Isolate - BSLI #013100EA)	1 : 32,768	1.2207 ppm
130	<i>Enterobacter</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
158	<i>E. faecalis</i> (ATCC #19433)	1 : 16,384	2.4414 ppm
159	<i>E. faecalis</i> (ATCC #29212)	1 : 8,192	4.8828 ppm
160	<i>E. faecalis</i> (ATCC #33012)	1 : 8,192	4.8828 ppm
174	<i>E. faecalis</i> (ATCC #51299)	1 : 4,096	9.7656 ppm
175	<i>E. faecalis</i> (ATCC #51575)	1 : 8,192	4.8828 ppm
176	<i>E. faecalis</i> (Clinical Isolate - BSLI #080294VRE2)	1 : 8,192	4.8828 ppm
177	<i>E. faecalis</i> (Clinical Isolate - BSLI #080294VRE4)	1 : 8,192	4.8828 ppm
178	<i>E. faecalis</i> (Clinical Isolate - BSLI #080294VRE1)	1 : 16,384	2.4414 ppm
179	<i>E. faecalis</i> (Clinical Isolate - BSLI #121699Efs1)	1 : 4,096	9.7656 ppm
180	<i>E. faecalis</i> (Clinical Isolate - BSLI #121699Efs2)	1 : 8,192	4.8828 ppm
208	<i>E. faecium</i> (ATCC #19434)	1 : 8,192	4.8828 ppm
225	<i>E. faecium</i> (ATCC #51559)	1 : 16,384	2.4414 ppm
226	<i>E. faecium</i> (Clinical Isolate - BSLI #050499VRE)	1 : 16,384	2.4414 ppm
227	<i>E. faecium</i> (Clinical Isolate - BSLI #062599VRE)	1 : 16,384	2.4414 ppm
228	<i>E. faecium</i> (Clinical Isolate - BSLI #052999EF)	1 : 16,384	2.4414 ppm
229	<i>E. faecium</i> (Clinical Isolate - BSLI #080599VRE)	1 : 16,384	2.4414 ppm
230	<i>E. faecium</i> (Clinical Isolate - BSLI #072199VRE)	1 : 16,384	2.4414 ppm
231	<i>E. faecium</i> (Clinical Isolate - BSLI #071999VRE)	1 : 16,384	2.4414 ppm
232	<i>E. faecium</i> (Clinical Isolate - BSLI #062999VRE)	1 : 16,384	2.4414 ppm
233	<i>E. faecium</i> (Clinical Isolate - BSLI #071499VRE)	1 : 16,384	2.4414 ppm

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #3 - Hibiclens[®]
 Lot #3204B

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
253	<i>E. coli</i> (ATCC #8739)	1 : 32,768	1.2207 ppm
257	<i>E. coli</i> (ATCC #11229)	1 : 32,768	1.2207 ppm
271	<i>E. coli</i> (ATCC #25922)	1 : 32,768	1.2207 ppm
273	<i>E. coli</i> (ATCC #35150)	1 : 32,768	1.2207 ppm
275	<i>E. coli</i> (ATCC #43892)	1 : 32,768	1.2207 ppm
276	<i>E. coli</i> (Clinical Isolate - BSLI #060199EC)	1 : 16,384	2.4414 ppm
277	<i>E. coli</i> (Clinical Isolate - BSLI # 051599EC)	1 : 32,768	1.2207 ppm
278	<i>E. coli</i> (Clinical Isolate - BSLI #070399EC)	1 : 16,384	2.4414 ppm
279	<i>E. coli</i> (Clinical Isolate - BSLI #121699Ec2)	1 : 16,384	2.4414 ppm
280	<i>E. coli</i> (Clinical Isolate - BSLI #121699Ec1)	< 1 : 65,536	> 0.6104 ppm
307	<i>H. influenzae</i> (ATCC #9795)	*	Testing not completed as of 3/6/00
308	<i>H. influenzae</i> (ATCC #9833)	*	Testing not completed as of 3/6/00
311	<i>H. influenzae</i> (ATCC #19418)	1 : 32,768	1.2207 ppm
316	<i>H. influenzae</i> (ATCC #35540)	*	Testing not completed as of 3/6/00
321	<i>H. influenzae</i> (ATCC #49401)	*	Testing not completed as of 3/6/00
326	<i>H. influenzae</i> (Clinical Isolate - BSLI #121699Hi2)	< 1 : 65,536	> 0.6104 ppm
327	<i>H. influenzae</i> (Clinical Isolate - BSLI #121699Hi3)	< 1 : 65,536	> 0.6104 ppm
328	<i>H. influenzae</i> (Clinical Isolate - BSLI #121699Hi4)	< 1 : 65,536	> 0.6104 ppm
329	<i>H. influenzae</i> (Clinical Isolate - BSLI #121699Hi1)	< 1 : 65,536	> 0.6104 ppm
330	<i>H. influenzae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
357	<i>K. oxytoca</i> (ATCC #15764)	1 : 16,384	2.4414 ppm
364	<i>K. oxytoca</i> (ATCC #43165)	1 : 8,192	4.8828 ppm
365	<i>K. oxytoca</i> (ATCC #43863)	1 : 8,192	4.8828 ppm
367	<i>K. oxytoca</i> (ATCC #49334)	1 : 8,192	4.8828 ppm

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #3 - Hibiclens®
 Lot #3204B

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
368	<i>K. oxytoca</i> (ATCC #49473)	1 : 4,096	9.7656 ppm
376	<i>K. oxytoca</i> (Clinical Isolate - BSLI #060199K0)	1 : 8,192	4.8828 ppm
377	<i>Klebsiella</i> sp. (Clinical Isolate - BSLI #121799KO)	1 : 8,192	4.8828 ppm
378	<i>Klebsiella</i> sp. (Clinical Isolate - BSLI #010500KO)	1 : 16,384	2.4414 ppm
379	<i>Klebsiella</i> sp. (Clinical Isolate - BSLI #010500Kp1)	1 : 4,096	9.7656 ppm
380	<i>Klebsiella</i> sp. (Clinical Isolate - BSLI #010500Kp2)	1 : 16,384	2.4414 ppm
412	<i>K. pneumoniae</i> (ATCC #9997)	1 : 32,768	1.2207 ppm
413	<i>K. pneumoniae</i> (ATCC #10031)	1 : 32,768	1.2207 ppm
414	<i>K. pneumoniae</i> (ATCC #11296)	< 1 : 65,536	> 0.6104 ppm
417	<i>K. pneumoniae</i> (ATCC #13883)	1 : 16,384	2.4414 ppm
418	<i>K. pneumoniae</i> (ATCC #27736)	1 : 8,192	4.8828 ppm
426	<i>K. pneumoniae</i> (Clinical Isolate - BSLI #081599Kp)	1 : 4,096	9.7656 ppm
427	<i>K. pneumoniae</i> (Clinical Isolate - BSLI #121699Kp)	1 : 16,384	2.4414 ppm
428	<i>K. pneumoniae</i> (Clinical Isolate - BSLI #121799KP1)	1 : 32,768	1.2207 ppm
429	<i>K. pneumoniae</i> (Clinical Isolate - BSLI #121799KP2)	1 : 32,768	1.2207 ppm
430	<i>K. pneumoniae</i> (Clinical Isolate - BSLI #121799KP3)	1 : 8,192	4.8828 ppm
454	<i>M. luteus</i> (ATCC #381)	*	Testing not completed as of 3/6/00
460	<i>M. luteus</i> (ATCC #4698)	1 : 8	5,000.0000 ppm
461	<i>M. luteus</i> (ATCC #7468)	1 : 64	625.0000 ppm
471	<i>M. luteus</i> (ATCC #14452)	*	Testing not completed as of 3/6/00
473	<i>M. luteus</i> (ATCC #27523)	*	Testing not completed as of 3/6/00
476	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
477	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
478	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
479	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #3 - Hibiclens®
 Lot #3204B

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
480	<i>Micrococcus</i> sp. (Clinical Isolate)	*	Testing not completed as of 3/6/00
501	<i>P. mirabilis</i> (ATCC #4630)	1 : 8,192	4.8828 ppm
503	<i>P. mirabilis</i> (ATCC #7002)	1 : 4,096	9.7656 ppm
507	<i>P. mirabilis</i> (ATCC #14153)	*	Testing not completed as of 3/6/00
510	<i>P. mirabilis</i> (ATCC #25933)	1 : 1024	39.0625 ppm
520	<i>P. mirabilis</i> (ATCC #33583)	*	Testing not completed as of 3/6/00
526	<i>P. mirabilis</i> (Clinical Isolate - BSLI #081299PM)	1 : 4,096	9.7656 ppm
527	<i>P. mirabilis</i> (Clinical Isolate - BSLI #121699Pm1)	1 : 1024	39.0625 ppm
528	<i>P. mirabilis</i> (Clinical Isolate - BSLI #121699Pm2)	1 : 256	156.2500 ppm
529	<i>P. mirabilis</i> (Clinical Isolate - BSLI #010500PM)	1 : 2,048	19.5313 ppm
530	<i>P. mirabilis</i> (Clinical Isolate - BSLI #013100PM)	1 : 8,192	4.8828 ppm
552	<i>P. aeruginosa</i> (ATCC #9027)	1 : 4,096	9.7656 ppm
553	<i>P. aeruginosa</i> (ATCC #9721)	1 : 4,096	9.7656 ppm
556	<i>P. aeruginosa</i> (ATCC #14207)	1 : 4,096	9.7656 ppm
559	<i>P. aeruginosa</i> (ATCC #15442)	1 : 2,048	19.5313 ppm
568	<i>P. aeruginosa</i> (ATCC #27853)	1 : 8,192	4.8828 ppm
576	<i>P. aeruginosa</i> (Clinical Isolate - BSLI #052299Pa)	1 : 2,048	19.5313 ppm
577	<i>P. aeruginosa</i> (Clinical Isolate - BSLI #053099Pa)	1 : 4,096	9.7656 ppm
578	<i>P. aeruginosa</i> (Clinical Isolate - BSLI #070199Pa)	1 : 4,096	9.7656 ppm
579	<i>P. aeruginosa</i> (Clinical Isolate - BSLI #121699Pa3)	1 : 4,096	9.7656 ppm
580	<i>P. aeruginosa</i> (Clinical Isolate - BSLI #121699Pa2)	1 : 4,096	9.7656 ppm
581	<i>P. aeruginosa</i> (Clinical Isolate - BSLI #121699Pa1)	1 : 4,096	9.7656 ppm
613	<i>S. marcescens</i> (ATCC #8100)	1 : 1024	39.0625 ppm
617	<i>S. marcescens</i> (ATCC #13880)	*	Testing not completed as of 3/6/00
619	<i>S. marcescens</i> (ATCC #14756)	1 : 2,048	19.5313 ppm
620	<i>S. marcescens</i> (ATCC #29632)	*	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #3 - Hibiclens®
 Lot #3204B

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
625	<i>S. marcescens</i> (ATCC #43862)	1 : 2,048	19.5313 ppm
626	<i>S. marcescens</i> (Clinical Isolate - BSLI #081499SM)	1 : 2,048	19.5313 ppm
627	<i>S. marcescens</i> (Clinical Isolate - BSLI #121799SM1)	1 : 8,192	4.8828 ppm
628	<i>S. marcescens</i> (Clinical Isolate - BSLI #121799SM2)	1 : 4,096	9.7656 ppm
629	<i>S. marcescens</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
630	<i>S. marcescens</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
660	<i>S. aureus</i> (ATCC #29737)	< 1 : 65,536	> 0.6104 ppm
661	<i>S. aureus</i> (ATCC #33862)	< 1 : 65,536	> 0.6104 ppm
676	<i>S. aureus</i> (Clinical Isolate - BSLI #051599 MRSA)	< 1 : 65,536	> 0.6104 ppm
677	<i>S. aureus</i> (Clinical Isolate - BSLI #062799 MRSA)	< 1 : 65,536	> 0.6104 ppm
678	<i>S. aureus</i> (Clinical Isolate - BSLI #060799 MRSA)	< 1 : 65,536	> 0.6104 ppm
679	<i>S. aureus</i> (Clinical Isolate - BSLI #080599 MRSA)	< 1 : 65,536	> 0.6104 ppm
680	<i>S. aureus</i> (Clinical Isolate - BSLI #071999 MRSA)	< 1 : 65,536	> 0.6104 ppm
681	<i>S. aureus</i> (Clinical Isolate - BSLI #070499 MRSA)	< 1 : 65,536	> 0.6104 ppm
682	<i>S. aureus</i> (Clinical Isolate - BSLI #072199 MRSA)	< 1 : 65,536	> 0.6104 ppm
683	<i>S. aureus</i> (Clinical Isolate - BSLI #082594 MRSA1)	< 1 : 65,536	> 0.6104 ppm
684	<i>S. aureus</i> (Clinical Isolate - BSLI #071499 MRSA)	< 1 : 65,536	> 0.6104 ppm
685	<i>S. aureus</i> (Clinical Isolate - BSLI #082494 MRSA2)	< 1 : 65,536	> 0.6104 ppm
703	<i>S. epidermidis</i> (ATCC #12228)	< 1 : 65,536	> 0.6104 ppm
706	<i>S. epidermidis</i> (ATCC #14990)	< 1 : 65,536	> 0.6104 ppm
714	<i>S. epidermidis</i> (ATCC #35547)	*	Testing not completed as of 3/6/00
720	<i>S. epidermidis</i> (ATCC #51624)	< 1 : 65,536	> 0.6104 ppm
721	<i>S. epidermidis</i> (ATCC #51625)	< 1 : 65,536	> 0.6104 ppm
723	<i>S. epidermidis</i> (Clinical Isolate - BSLI #010500Se1)	< 1 : 65,536	> 0.6104 ppm
724	<i>S. epidermidis</i> (Clinical Isolate - BSLI #010500Se2)	< 1 : 65,536	> 0.6104 ppm

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #3 - Hibiclens[®]
 Lot #3204B

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
725	<i>S. epidermidis</i> (Clinical Isolate - BSLI #013100SE)	< 1 : 65,536	> 0.6104 ppm
726	<i>S. epidermidis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
727	<i>S. epidermidis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
751	<i>S. haemolyticus</i> (ATCC #15796)	< 1 : 65,536	> 0.6104 ppm
752	<i>S. haemolyticus</i> (ATCC #29968)	< 1 : 65,536	> 0.6104 ppm
753	<i>S. haemolyticus</i> (ATCC #29969)	< 1 : 65,536	> 0.6104 ppm
754	<i>S. haemolyticus</i> (ATCC #29970)	< 1 : 65,536	> 0.6104 ppm
755	<i>S. haemolyticus</i> (ATCC #43252)	1 : 32,768	1.2207 ppm
757	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
758	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
759	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
760	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
761	<i>S. haemolyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
801	<i>S. hominis</i> (ATCC #25615)	*	Testing not completed as of 3/6/00
802	<i>S. hominis</i> (ATCC #27844)	< 1 : 65,536	> 0.6104 ppm
803	<i>S. hominis</i> (ATCC #27845)	< 1 : 65,536	> 0.6104 ppm
804	<i>S. hominis</i> (ATCC #27846)	< 1 : 65,536	> 0.6104 ppm
805	<i>S. hominis</i> (ATCC #27847)	< 1 : 65,536	> 0.6104 ppm
809	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
810	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
811	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
812	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
813	<i>S. hominis</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
851	<i>S. saprophyticus</i> (ATCC #15305)	< 1 : 65,536	> 0.6104 ppm
852	<i>S. saprophyticus</i> (ATCC #35552)	*	Testing not completed as of 3/6/00

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
Product #3 - Hibiclens®
Lot #3204B

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
853	<i>S. saprophyticus</i> (ATCC #43867)	*	Testing not completed as of 3/6/00
854	<i>S. saprophyticus</i> (ATCC #49453)	< 1 : 65,536	> 0.6104 ppm
855	<i>S. saprophyticus</i> (ATCC #49907)	*	Testing not completed as of 3/6/00
856	<i>S. saprophyticus</i> (Clinical Isolate - BSLI #081399SS)	< 1 : 65,536	> 0.6104 ppm
857	<i>S. saprophyticus</i> (Clinical Isolate - BSLI #121699SS1)	*	Testing not completed as of 3/6/00
858	<i>S. saprophyticus</i> (Clinical Isolate - BSLI #121699SS2)	1 : 8,192	4.8828 ppm
859	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
860	<i>S. saprophyticus</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
903	<i>S. pneumoniae</i> (ATCC #6303)	*	Testing not completed as of 3/6/00
913	<i>S. pneumoniae</i> (ATCC #9163)	*	Testing not completed as of 3/6/00
914	<i>S. pneumoniae</i> (ATCC #10015)	*	Testing not completed as of 3/6/00
920	<i>S. pneumoniae</i> (ATCC #33400)	*	Testing not completed as of 3/6/00
921	<i>S. pneumoniae</i> (ATCC #35088)	*	Testing not completed as of 3/6/00
926	<i>S. pneumoniae</i> (Clinical Isolate - BSLI #121699Spn1)	1 : 16,384	2.4414 ppm
927	<i>S. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
928	<i>S. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
929	<i>S. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
930	<i>S. pneumoniae</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
952	<i>S. pyogenes</i> (ATCC #8058)	*	Testing not completed as of 3/6/00
961	<i>S. pyogenes</i> (ATCC #12351)	*	Testing not completed as of 3/6/00
964	<i>S. pyogenes</i> (ATCC #14289)	*	Testing not completed as of 3/6/00
967	<i>S. pyogenes</i> (ATCC #19615)	*	Testing not completed as of 3/6/00
971	<i>S. pyogenes</i> (ATCC #51339)	*	Testing not completed as of 3/6/00
976	<i>S. pyogenes</i> (Clinical Isolate - BSLI #121699Spy1)	1 : 32,768	1.2207 ppm
977	<i>S. pyogenes</i> (Clinical Isolate - BSLI #121699Spy2)	< 1 : 65,536	> 0.6104 ppm

NOTE
This information has not
yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #3 - Hibiclens®
 Lot #3204B

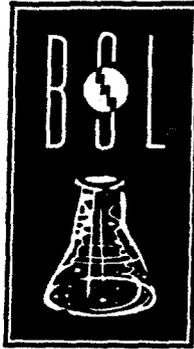
No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration	
		Dilution	Parts per Million (ppm) of Active Ingredient
978	<i>S. pyogenes</i> (Clinical Isolate - BSLI #121699Spy3)	< 1 : 65,536	> 0.6104 ppm
979	<i>S. pyogenes</i> (Clinical Isolate - BSLI #121699Spy4)	1 : 32,768	1.2207 ppm
980	<i>S. pyogenes</i> (Clinical Isolate - BSLI #121699Spy5)	< 1 : 65,536	> 0.6104 ppm
1001	<i>C. glabrata</i> (ATCC #2001)	1 : 8,192	4.8828 ppm
1005	<i>C. guilliermondii</i> (ATCC #6260)	*	Testing not completed as of 3/6/00
1008	<i>C. krusei</i> (ATCC #6258)	*	Testing not completed as of 3/6/00
1012	<i>C. lusitaniae</i> (ATCC #42720)	*	Testing not completed as of 3/6/00
1018	<i>C. tropicalis</i> (ATCC #750)	1 : 16,384	2.4414 ppm
1023	<i>C. kefyr</i> (ATCC #2512)	< 1 : 65,536	> 0.6104 ppm
1024	<i>C. kefyr</i> (ATCC #66028)	1 : 2,048	19.5313 ppm
1026	<i>Candida</i> sp. (Clinical Isolate - BSLI #121699CG)	1 : 256	156.2500 ppm
1027	<i>Candida</i> sp. (Clinical Isolate - BSLI #121799Ct)	1 : 4	10,000.0000 ppm
1028	<i>Candida</i> sp. (Clinical Isolate - BSLI #121799Cg1)	1 : 4,096	9.7656 ppm
1029	<i>Candida</i> sp. (Clinical Isolate - BSLI #121799Cg2)	1 : 4	10,000.0000 ppm
1030	<i>Candida</i> sp. (Clinical Isolate - BSLI #121799Cg3)	1 : 8,192	4.8828 ppm
1052	<i>C. albicans</i> (ATCC #10231)	1 : 16	2,500.0000 ppm
1056	<i>C. albicans</i> (ATCC #14053)	1 : 4	10,000.0000 ppm
1058	<i>C. albicans</i> (ATCC #18804)	1 : 8	5,000.0000 ppm
1059	<i>C. albicans</i> (ATCC #24433)	1 : 4	10,000.0000 ppm
1066	<i>C. albicans</i> (ATCC #36232)	*	Testing not completed as of 3/6/00
1076	<i>C. albicans</i> (Clinical Isolate - BSLI #081599CA)	1 : 16	2,500.0000 ppm
1077	<i>C. albicans</i> (Clinical Isolate - BSLI #121699Ca)	1 : 4	10,000.0000 ppm
1078	<i>C. albicans</i> (Clinical Isolate - BSLI #121799Ca1)	1 : 4	10,000.0000 ppm
1079	<i>C. albicans</i> (Clinical Isolate)	*	Testing not completed as of 3/6/00
1080	<i>C. albicans</i> (Clinical Isolate - BSLI #121799Ca3)	1 : 8	5,000.0000 ppm

NOTE
 This information has not
 yet been QA-reviewed

Preliminary Data as of 03/07/00
 Product #2 - Pure Rx Vehicle
 Batch #426

No.	Microorganism (ATCC # or BSLI #)	Minimum Inhibitory Concentration - Dilution
978	<i>S. pyogenes</i> (Clinical Isolate - BSLI #121699Spy3)	1 : 32
979	<i>S. pyogenes</i> (Clinical Isolate - BSLI #121699Spy4)	1 : 32
980	<i>S. pyogenes</i> (Clinical Isolate - BSLI #121699Spy5)	1 : 16
1001	<i>C. glabrata</i> (ATCC #2001)	1 : 16
1005	<i>C. guilliermondii</i> (ATCC #6260)	Testing not completed as of 3/6/00
1008	<i>C. krusei</i> (ATCC #6258)	Testing not completed as of 3/6/00
1012	<i>C. lusitaniae</i> (ATCC #42720)	Testing not completed as of 3/6/00
1018	<i>C. tropicalis</i> (ATCC #750)	1 : 32
1023	<i>C. kefyr</i> (ATCC #2512)	< 1 : 32
1024	<i>C. kefyr</i> (ATCC #66028)	< 1 : 32
1026	<i>Candida</i> sp. (Clinical Isolate - BSLI #121699CG)	1 : 32
1027	<i>Candida</i> sp. (Clinical Isolate - BSLI #121799Ct)	1 : 16
1028	<i>Candida</i> sp. (Clinical Isolate - BSLI #121799Cg1)	1 : 8
1029	<i>Candida</i> sp. (Clinical Isolate - BSLI #121799Cg2)	1 : 16
1030	<i>Candida</i> sp. (Clinical Isolate - BSLI #121799Cg3)	1 : 8
1052	<i>C. albicans</i> (ATCC #10231)	1 : 32
1056	<i>C. albicans</i> (ATCC #14053)	1 : 16
1058	<i>C. albicans</i> (ATCC #18804)	1 : 4
1059	<i>C. albicans</i> (ATCC #24433)	1 : 16
1066	<i>C. albicans</i> (ATCC #36232)	Testing not completed as of 3/6/00
1076	<i>C. albicans</i> (Clinical Isolate - BSLI #081599CA)	1 : 32
1077	<i>C. albicans</i> (Clinical Isolate - BSLI #121699Ca)	1 : 64
1078	<i>C. albicans</i> (Clinical Isolate - BSLI #121799Ca1)	1 : 16
1079	<i>C. albicans</i> (Clinical Isolate)	Testing not completed as of 3/6/00
1080	<i>C. albicans</i> (Clinical Isolate - BSLI #121799Ca3)	1 : 16

NOTE
 This information has not
 yet been QA-reviewed



BIO SCIENCE
LABORATORIES-INC

March 7, 2000

FINAL REPORT #990829.02

**DETERMINATION OF THE ANTIMICROBIAL EFFICACY OF ONE TEST PRODUCT AND
ONE REFERENCE PRODUCT USING THE HEALTH CARE PERSONNEL HANDWASH PROCEDURE**

Prepared for:

INTERNATIONAL LABORATORY TECHNOLOGY CORPORATION (SPONSOR)
3389 Sheridan Street, Suite 149
Hollywood, Florida 33021

Prepared by:

BIO SCIENCE LABORATORIES, INC. (COMPANY)
P.O. Box 190
Bozeman, Montana 59771
(406) 587-5735

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EXECUTIVE SUMMARY

This study evaluated the antimicrobial efficacy of one (1) test product (Pure Rx - Antimicrobial Handwash with 1397 ppm [parts per million] Benzalkonium Chloride) and one (1) reference product (Hibiclens®). Thirty (30) subjects utilized each product (a total of sixty, [60] subjects). The subjects' hands were inoculated with *Serratia marcescens* (ATCC #14756), a red-pigmented bacterial species used as a marker microorganism. The microbial populations on the hands were then determined using the glove juice procedure; this provided the baseline measurements. Subjects were again inoculated with the microorganism, and then applied their randomly assigned product to their hands for thirty (30) seconds. The hands were again sampled using the glove juice procedure to determine the contaminant microbial populations remaining on the hands after the product application. This inoculation/product application procedure was performed ten (10) times, with microbial samples taken after inoculation/wash cycles one (1), three (3), seven (7), and ten (10). The evaluation procedure was based on *ASTM E 1174-97*, Standard Test Method for Evaluation of Healthcare Personnel Handwash Formulations.

Both products demonstrated statistically significant \log_{10} reductions in bacterial populations from baseline populations. The Pure Rx (Antimicrobial Handwash with 1397 ppm [parts per million] Benzalkonium Chloride) demonstrated reductions of 3.19 \log_{10} at Wash 1 and 3.08 \log_{10} at Wash 10. The reference product (Hibiclens®) demonstrated reductions of 2.48 \log_{10} at Wash 1 and 4.56 \log_{10} at Wash 10.

March 7, 2000

FINAL REPORT #990829.02

1.0 **TITLE:** **DETERMINATION OF THE ANTIMICROBIAL EFFICACY OF ONE TEST PRODUCT AND ONE REFERENCE PRODUCT USING THE HEALTH CARE PERSONNEL HANDWASH PROCEDURE**

2.0 **SPONSOR:** **INTERNATIONAL LABORATORY TECHNOLOGY CORPORATION**
3389 Sheridan Street, Suite 149
Hollywood, Florida 33021

3.0 **COMPANY:** **BIOSCIENCE LABORATORIES, INC.**
P.O. Box 190
Bozeman, Montana 59771

4.0 **STUDY DIRECTORS:**

Carol Riccardi - Principal Study Director
Christopher Beausoleil - Associate Study Director
Daryl S. Paulson, Ph.D. - Project Director/Associate Study Director

5.0 **PURPOSE:**

This study evaluated the antimicrobial effectiveness of one (1) test product and one (1) reference product using the healthcare personnel handwash procedure.

6.0 **SCOPE:**

The antimicrobial effectiveness of one (1) test product and one (1) reference product was determined utilizing thirty (30) human subjects per formulation (for a total of sixty [60] subjects) over the course of ten (10) consecutive hand contaminations/product applications, with microbial samples taken at baseline and after product applications one (1), three (3), seven (7), and ten (10). *Serratia marcescens* (ATCC #14756) was used as the marker organism.

7.0 **TEST MATERIAL:**

Samples of the test product required in this evaluation were supplied by Sponsor. Company supplied the reference product. Records of lot numbers utilized were maintained by both Sponsor and Company. The products evaluated were:

Test Product 1: Pure Rx - Antimicrobial Handwash with 1397 ppm (parts per million) Benzalkonium Chloride
International Laboratory Technology Corporation
Lot Number: X 396
Manufacture Date: 07/29/99
Expiration Date: 07/29/01

Reference Product: Hibiclens® (4% Chlorhexidine Gluconate)
ZENECA Pharmaceuticals
Lot Number: 3204B
Expiration Date: 02/01

8.0 EQUIPMENT:

- 8.1 Steam Autoclaves: BSLI 91113 and BSLI 91127
- 8.2 Laminar Biological Flowhood (certified): BSLI 91119
- 8.3 Scrub Sink: BSLI 960101
- 8.4 Scrub Sink Thermometer: BSLI TI-971007
- 8.5 Continuously Adjustable Pipette, 20 μ L - 200 μ L Capacity: BSLI 971203
- 8.6 Continuously Adjustable Pipette, 100 μ L - 1000 μ L Capacity: BSLI 961002
- 8.7 Portable Pipettors: BSLI 961104, BSLI 971205, and BSLI 980902
- 8.8 Autoplate 4000 Spiral Plater: BSLI 980409
- 8.9 CASBA 4 Spiral Plater Counter: BSLI 980410
- 8.10 Walk-in Environmental Chamber, 25° \pm 2°C: BSLI 930812
- 8.11 Walk-in Environmental Chamber Thermometers: BSLI TI-960101, BSLI TI-960102, BSLI TI-960103, and BSLI TI-960105
- 8.12 Incubator, 55° - 60°C: BSLI 91059 (BIs Only)
- 8.13 Incubator Thermometer: BSLI TI-2064
- 8.14 Vortex Mixers: BSLI 931201 and BSLI 980103
- 8.15 Calibrated Minute/Second Timers: BSLI 941002, BSLI 960113, BSLI 960114, BSLI 961003, BSLI 961005, BSLI 961006, BSLI 961007, BSLI 961008, BSLI 961010, BSLI 980102, BSLI 980402, BSLI 980403, BSLI 980404, BSLI 980405, and BSLI 980406
- 8.16 Orion pH Meter Model 720: BSLI 931104
- 8.17 Mettler BB240 Balance: BSLI 930409
- 8.18 A & D Balance Model EK-2000G: BSLI 960801
- 8.19 Troemner Weights: BSLI 930408
- 8.20 Ohaus Weights: BSLI 961011
- 8.21 Hewlett-Packard HP-15C Hand Calculator
- 8.22 Texas Instruments TI-35X Hand Calculator
- 8.23 MiniTab® Statistical Software (PC Version, Release 8.2 and 10extra)

9.0 SUPPLIES:

- 9.1 Sterile 5.0 mL Capacity Pipettes: Becton-Dickinson Lot Numbers 918412, 920447, and 930407
- 9.2 Sterile Dilution Tubes and Bottles: DG L2 91127, 9/1/99, DG L2 91127, 9/14/99, DG L1 91127, 9/3/99, and DG L1 91127, 9/15/99
- 9.3 Sterile Polystyrene Petri Dishes: Lot Number R9J36006
- 9.4 Sterile Powder-Free Surgical Gloves: Ansell Perry Lot Numbers 755968, 785337, and 711276703
- 9.5 Non-Sterile Gloves: Ultra Care Lot Numbers R8A04039 and R8B18118
- 9.6 Nitrile Gloves: High Five Lot Number DY98036
- 9.7 Sterile 1.0 mL and 0.1 mL Capacity Pipette Tips: Lot Numbers 705854 and 707140
- 9.8 Sterile 5 cc Syringes: Becton-Dickinson Lot Number 9A855
- 9.9 Sterile Surgical Scrub Brushes: Baxter Lot Number Y2D070 and Allegiance Lot Number Y8J0142
- 9.10 70% Ethanol: BSLI Lot Numbers 70%EtOH991117C, 70%EtOH991207D, and 70%EtOH991215E
- 9.11 Bland Soap (Baby San®): Huntington Laboratories Lot Number L082071, Expires 08/00
- 9.12 Antibacterial Soap (Hibiclens®): Lot Number 4685A, Expires 10/00
- 9.13 Polysporin: Lot Number 9C1839

10.0 TEST SOLUTIONS AND MEDIA:

Sampling Solution

- 10.1 Sterile Stripping Fluid (SSF): SSF991111D, SSF991112D, SSF991201B, SSF991201C, SSF991201D, SSF991207A, and SSF991207B

Neutralizing/Diluting Fluid

- 10.2 Butterfield's Phosphate Buffer Solution with Product Neutralizers (BBP++): BBP++991007C, BBP++991126D, BBP++991208A, and BBP++991215D
- 10.3 Butterfield's Phosphate Buffer solution (BBP) for Neutralization Assay: BBP990930A and BBP991112E

Media

- 10.4 Tryptic Soy Agar with product neutralizers (TSA+): TSA+991130B, TSA+991201A, TSA+991203A, TSA+991203B, TSA+991203C, TSA+991213A, and TSA+991213B
- 10.5 Tryptic Soy Agar (TSA) for Inoculum Preparation: TSA991117A
- 10.6 Tryptic Soy Broth (TSB) for Neutralization Assay and Inoculum Preparation: TSB991111E, TSB991201E, and TSB991207C

11.0 TEST METHODS:

Institutional Review Board

- 11.1 Informed Consent Forms and any other supportive material relevant to the safety of the subjects were supplied by principal investigators to the Gallatin Institutional Review Board (GIRB) for their review and approval. The primary purpose of the GIRB is the protection of the rights and welfare of the subjects involved (reference CFR 21, Parts 50 and 56). This study began only after GIRB approval was obtained.

Subjects

- 11.2 The study employed sixty (60) subjects using one (1) handwash product or a reference product (thirty [30] subjects per product) over the course of eleven (11) consecutive microbial contamination procedures, followed by ten (10) product application procedures.

- 11.3 Ninety-three (93) overtly healthy subjects over the age of eighteen (18), but under the age of seventy (70) were admitted into the study. Sixty (60) subjects completed the study. Of the sixty (60) subjects who completed the study, thirty-one (31) were female, twenty-nine (29) were male, forty-seven (47) were Caucasian, eleven (11) were Asian-American, one (1) was African-American, and one (1) was Mexican-American. The median age of the subjects who completed the study was twenty-six (26) years, with eighteen (18) being the youngest and sixty-one (61) the oldest tested. All subjects' hands were free from clinically evident dermatosis, injuries to the hands or forearms, open wounds, hangnails, and/or any other disorders which could compromise the subject and the study. All subjects signed Informed Consent Forms and the Study Description (Addendum I, Appendix I) prior to participating in the study.

Concurrent Treatment

- 11.4 No subject was admitted into the study who was using any topical or systemic antimicrobials, steroids, or any other medications known to affect the normal microbial flora of the skin. Only subjects meeting the inclusion criteria (Addendum I, Sections 11.4 - 11.8) and none of the exclusion criteria (Addendum I, Sections 11.9 - 11.17) were admitted into the study.

Pre-Test Period

- 11.5 The seven (7) days prior to the test portion of the study constituted the pre-test period. During that time, subjects were instructed to avoid using medicated soaps, lotions, deodorants and shampoos, as well as skin contact with solvents, detergents, acids and bases, or any other products known to effect the normal microbial populations of the skin (Addendum I, Appendix II). Subjects were supplied a personal hygiene kit containing non-medicated soap, shampoo, deodorant, lotion, and rubber gloves worn when contact with antimicrobials, solvents, detergents, acids, or bases could not be avoided. Subjects were instructed to use the contents of this kit exclusively during their participation in the study and also to avoid using UV tanning beds and swimming or bathing in biocide-treated pools or hot tubs.
- 11.6 A study description, personal hygiene kit, and the Informed Consent statement were provided to each subject prior to their beginning the study. Trained laboratory personnel explained the study to each participant and were available to answer any questions which arose.

Inoculum Preparation

- 11.7 *Serratia marcescens* (ATCC #14756) was used to challenge the efficacy of the test and reference products.
- 11.8 Using aseptic technique, a 10 mL tube of Tryptic Soy Broth was inoculated with a loopful of *Serratia marcescens* (ATCC #14756) stock culture. The inoculated tube of Tryptic Soy Broth was incubated at $25^{\circ} \pm 2^{\circ}\text{C}$ for 24 ± 2 hours. After incubation, 1.0 mL of the 10.0 mL Broth culture was aseptically transferred to a 2-liter flask containing 1 liter of Tryptic Soy Broth. The flask was incubated for 20 ± 2 hours at $25^{\circ} \pm 2^{\circ}\text{C}$. Prior to testing, the cultures were Gram-stained. The cultures used were pure. The cultures were assayed of the number of organisms/mL at the beginning and end of the use-period. Prior to any withdrawal of culture, whether for hand contamination or for numbers assay, the suspension was gently swirled. Each suspension was not used for more than eight (8) hours. Eight (8) inoculum flasks were used during the course of the testing. The results of the initial and final population assays are listed in the table at the top of the next page.

Flask #	Initial Population	Final Population
1	1.44 x 10 ⁹	1.76 x 10 ⁹
2	8.65 x 10 ⁸	1.45 x 10 ⁹
3	1.11 x 10 ⁹	1.20 x 10 ⁹
4	9.01 x 10 ⁸	Assay Not Performed
5	4.81 x 10 ⁸	9.90 x 10 ⁸
6	1.26 x 10 ⁹	1.08 x 10 ⁹
7	7.55 x 10 ⁸	1.57 x 10 ⁹
8	1.63 x 10 ⁹	1.54 x 10 ⁹

Neutralization

- 11.9 Prior to initiation of this study, *Serratia marcescens* (ATCC #14756) was used to confirm the adequacy of the antimicrobial product neutralizer in accordance with *Standard Practices for Evaluation Inactivators of Antimicrobial Agents Used in Disinfectant, Sanitizer, Antiseptic, or Preserved Products* (ASTM E 1054-91).

Test Period

- 11.10 Each subject was utilized for two (2) to three (3) hours on a single day of the test period. Subjects clipped their fingernails to a free edge of ≤ 1 mm, if they had not already done so. All jewelry was removed from the hands and arms prior to washing.
- 11.11 A practice wash was performed using a bland soap to remove dirt and oil from the hands and to familiarize the subjects with the reference product wash procedure. The temperature of the water used for this, and all subsequent wash cycles was controlled at $40^{\circ} \pm 2^{\circ}\text{C}$.
- 11.12 On the designated test day and test phase, a 5.0 mL aliquot of a suspension containing approximately 1.0×10^8 CFU/mL of *Serratia marcescens* (ATCC# 14756) was transferred into each subject's cupped hands in three (3) aliquots of approximately 1.5 mL, 1.5 mL, and 2 mL. The inoculum was then distributed evenly over both hands, and not reaching above the wrists, via gentle continuous massage for forty-five (45) seconds. After a timed two (2) minute air-dry, the Glove Juice Sampling Procedure was performed (Section 11.15). This first contamination cycle provided the baseline recovery levels. It was followed with a thirty (30) second handwash using a non-medicated, bland soap.
- 11.13 The microbial inoculum was again evenly distributed over both hands, and not reaching above the wrists, via gentle continuous massage for forty-five (45) seconds. After a timed two (2) minute air-dry, the subjects applied their assigned product according to the following use directions. This was followed by the Glove Juice Sampling Procedure (Section 11.15).

Product-Use Instructions - Reference Product

1. Five (5) mL of Reference Product was dispensed into the subject's cupped hands.
2. Subjects rubbed hands together and lathered for thirty (30) seconds.
3. Subjects rinsed for thirty (30) seconds.
4. For washes followed by a sample, the hands were gloved wet. For washes not followed by a sample, subjects lightly dried hands with a disposable paper towel.

Product-Use Instructions - Test Product

1. Three (3) mL of Test Product was dispensed into the subjects' cupped hands.
 2. Subjects rubbed the handwash into the hands thoroughly, making sure to get under the fingernails and into the interdigital spaces.
 3. Two (2) mL of Test Product was dispensed into the subjects' cupped hands and again rubbed thoroughly into the hands for thirty (30) seconds.
 4. The handwash remained on the hands for five (5) minutes.
 5. The subject's hands were rinsed for thirty (30) seconds.
 6. For washes followed by a sample, the hands were gloved wet. For washes not followed by a sample, subjects lightly dried their hands with a disposable paper towel.
- 11.14 Each subject completed this contamination/product application a total of ten (10) consecutive times, with a minimum of five (5), and a maximum of fifteen (15) minutes between microbe/product applications. The hands were sampled for residual *Serratia marcescens* (ATCC #14756) after contamination/product application cycles one (1), three (3), seven (7), and ten (10). All samples were taken using the Glove Juice Sampling Procedure (Section 11.15).

Glove Juice Sampling Procedure

- 11.15 Following the prescribed product application procedure (Section 11.13), powder-free, loose-fitting sterile latex gloves were donned. At the designated sampling time, seventy-five (75) mL of Sterile Stripping Fluid without product neutralizers were instilled into each glove. The wrists were secured and attendants massaged the hand through the gloves in a uniform manner for sixty (60) seconds. A 5.0 mL aliquot of the glove juice (dilution 10^0) was removed and serially diluted in Butterfield's Phosphate Buffer solution with product neutralizers.

Plating

- 11.16 Triplicate spiral plates were prepared from appropriate dilutions using Tryptic Soy Agar with product neutralizers. The plates were incubated at $25^\circ \pm 2^\circ\text{C}$ for approximately forty-eight (48) hours. *Serratia marcescens* (ATCC #14756) produced red colonies, and only those colonies were counted.

Data Collection

- 11.17 The plates were counted and the data recorded using the computerized CASBA™ plate-counting system. If 10⁰ plates gave an average count of zero (0), the average plate count was expressed as 1.00. This is because in log₁₀ scale, the log₁₀ of 0 is undefined, but the log₁₀ of 1.00 is 0. The estimate number of viable microorganisms recovered was obtained from the formula, 75 x Dilution Factor x Mean Plate Count for the three (3) plates.

Subject Safety

- 11.18 Subjects were not allowed to leave the laboratory for any reason once the testing began. Additionally, subjects were required to wear protective garments and not touch their clothing, faces, or any other body parts with their hands during the test period. On completion of testing, subjects were required to perform a one (1) minute rinse with 70% ethanol, an air-dry, and a water-rinse followed by a supervised four (4) minute surgical scrub using a 4% Chlorhexidine Gluconate solution. A topical antibiotic ointment was applied to the hands following the decontamination procedure.
- 11.19 An antibiotic sensitivity profile for the *Serratia marcescens* (ATCC #14756) used in this study is retained on file at BSLI.

12.0 METHODS OF ANALYSIS:

- 12.1 The plate count data collected from this study were evaluated using MiniTab® statistical computer software.
- 12.2 The estimated log₁₀ number of viable microorganisms recovered from each hand was designated the "R-value." It is the adjusted average log₁₀ colony count measurement for each subject at each sampling time. Each R-value was determined using the following formula:

$$R = \log_{10} [75 \times C_i \times 10^{-D} \times 2]$$

Where:

75	=	the amount (mL) of stripping solution instilled into each glove
C _i	=	the arithmetic average colony count of the three (3) plate counts for each subject at a particular dilution level
D	=	the dilution factor
2	=	the neutralization dilution

NOTE: A log₁₀ transformation was performed on these data to convert them to a linear scale. A linear scale, more appropriately a log₁₀ linear scale, is a requirement of the statistical models used.

Statistical Analysis

12.3 A pre-post experimental design was utilized to evaluate and compare the antimicrobial effectiveness of the test product.

Pre-Product Application	Post-Product Application
R(1) O _{BL}	A(1) ₁ O ₁ A(1) ₃ O ₃ A(1) ₇ O ₇ A(1) ₁₀ O ₁₀
R(2) O _{BL}	A(2) ₁ O ₁ A(2) ₃ O ₃ A(2) ₇ O ₇ A(2) ₁₀ O ₁₀

Where:

R(I) = Subjects randomly assigned one (1) of two (2) products

I = 1, if test product
2, if reference product

A(I)_j = Independent variables - Test Products

j = 1, if product application #1
3, if product application #3
7, if product application #7
10, if product application #10

O_k = Dependant variables - Microbial Counts

k = BL, if baseline
1, if product application #1
3, if product application #3
7, if product application #7
10, if product application #10

12.4 Prior to performing a statistical analysis, Exploratory Data Analysis was performed on the data. Stem-Leaf Ordering, Letter Value Displays, and Box Plots were generated which assured that the data collected approximated the normal distribution. A series of Student's *t* tests were conducted using the 0.05 level of significance for Type I (α) error. Any outlier values were noted.

13.0 RESULTS:

13.1 The Student's *t* test ($\alpha = 0.05$) was used to assure that baseline values for the left and right hands for each product were statistically equivalent before combining the data. The left hand baseline values and right hand baseline values were found to be equivalent (*p* value ≤ 0.69). A statistical summary of the baseline values is presented in Table I.

Table I: Summary of Baseline Values for Left and Right Hands

Baseline	Sample Size	Mean	Standard Deviation
Left Hand	60	8.83	0.24
Right Hand	60	8.85	0.22

13.2 All wash values were significantly different from Baseline ($p < 0.05$). Tables II and III list the results of the analyses performed for each product.

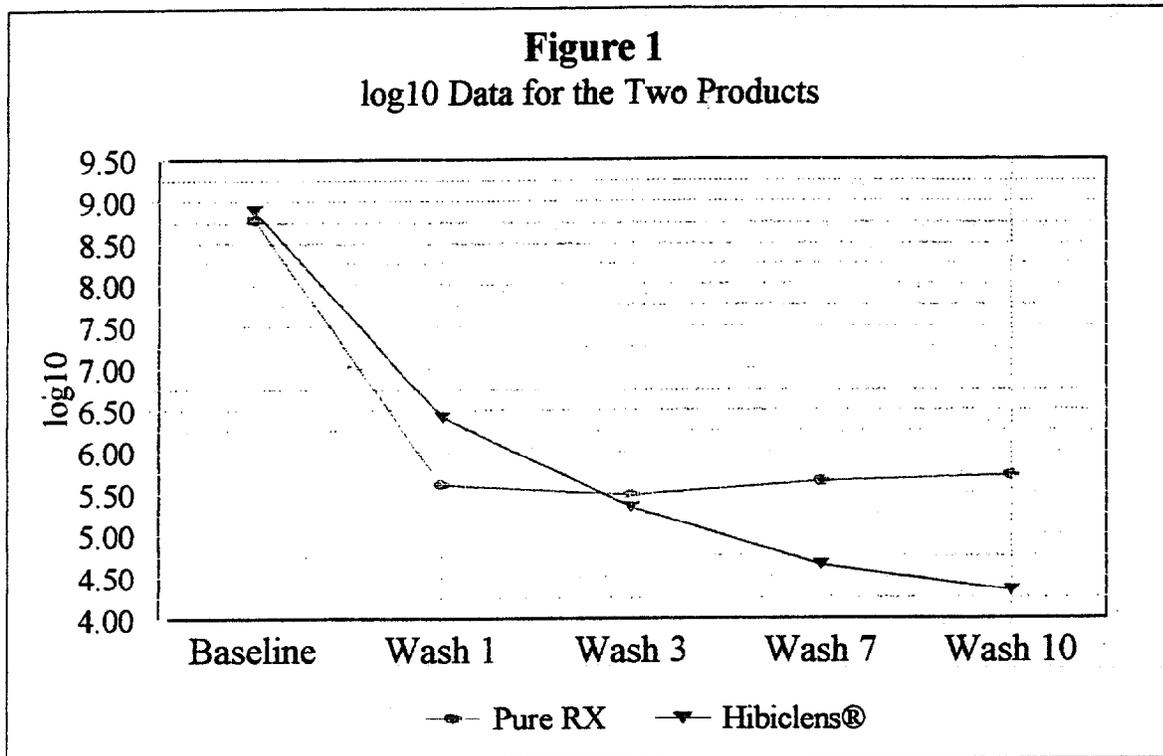
**Table II: Statistical Summary of Sample Data for Test Product
Pure Rx - Antimicrobial Handwash with 1397 ppm (parts per million) Benzalkonium Chloride**

Sample	Sample Size	Mean of \log_{10} Values	Standard Deviation	95% Confidence Intervals	Reduction from Baseline (\log_{10})	Percent Reduction
Baseline	60	8.79	0.22	8.73 to 8.85	N/A	N/A
Wash 1	60	5.60	0.65	5.43 to 5.77	3.19	99.94%
Wash 3	60	5.48	0.59	5.33 to 5.63	3.31	99.95%
Wash 7	60	5.64	0.58	5.49 to 5.79	3.15	99.93%
Wash 10	60	5.71	0.73	5.52 to 5.90	3.08	99.92%

**Table III: Statistical Summary of Sample Data for Reference Product
Hibiclens®**

Sample	Sample Size	Mean of \log_{10} Values	Standard Deviation	95% Confidence Intervals	Reduction from Baseline (\log_{10})	Percent Reduction
Baseline	60	8.89	0.22	8.83 to 8.95	N/A	N/A
Wash 1	60	6.41	0.62	6.25 to 6.57	2.48	99.67%
Wash 3	60	5.33	0.39	5.23 to 5.43	3.56	99.97%
Wash 7	60	4.64	0.37	4.54 to 4.74	4.25	99.99%
Wash 10	60	4.33	0.47	4.20 to 4.45	4.56	> 99.99%

13.3 The \log_{10} data for the products evaluated are presented graphically in Figure 1.



14.0 CONCLUSION:

Both products demonstrated statistically significant \log_{10} reductions in bacterial populations from baseline populations. The Pure Rx (Antimicrobial Handwash with 1397 ppm [parts per million] Benzalkonium Chloride) demonstrated reductions of 3.19 \log_{10} at Wash 1 and 3.08 \log_{10} at Wash 10. The reference product (Hibiclens®) demonstrated reductions of 2.48 \log_{10} at Wash 1 and 4.56 \log_{10} at Wash 10.

15.0 ADVERSE EVENTS:

Subject 34 experienced an Adverse Event and was advised to treat the area with Neosporin/Polysporin Ointment. The Adverse Event was not related to a product and resolved over time with treatment. Details of the Adverse Event are included in Addendum VIII.

16.0 ACCEPTANCE:

BIOSCIENCE LABORATORIES, INC.
P.O. Box 190
Bozeman, Montana 59771

Project Director/
Associate Study
Director:

Daryl S Paul
Daryl S. Paulson, Ph.D.

3-10-00
Date

Executive Director
of Operations/
Principal
Study Director:

Carol Riccardi
Carol Riccardi

3/10/00
Date

Manager of
Clinical
Laboratory/
Associate
Study Director:

Christopher Beausoleil
Christopher Beausoleil

3/10/00
Date

QUALITY ASSURANCE STATEMENT:

This study was inspected by the Quality Assurance Unit, and reports were submitted to the Study Director and Management in accordance with Standard Operating Procedures, as follows:

<u>Phase</u>	<u>Date</u>
Neutralization Assay	09/07/99
Product Testing	09/09/99
Data Audit	10/13/99
Final Report Review	10/13/99

Reports to Study Director
and Management

09/07/99 & 09/09/99

This study was conducted in compliance with Good Laboratory Practices standards, as described by the FDA (21 CFR Part 58), with the following exception: test article preparations were not analyzed to confirm concentration, stability, or homogeneity.

Director of
Quality
Assurance:

John A Mitchell
John A. Mitchell, Ph.D.

3/10/00
Date

INDEX OF ADDENDA

- I **GIRB-Approved Protocol #990829**
- II **CASBA™4 Plate Count Data and Calculations and CASBA™4 Plate Counter Data Sheets (Form No. 98-L-012)**
- III **Qualification Criteria for the Health Care Personnel Handwash Studies (Form No. 96-CT-019)**
- IV **Sampling Data Sheets for Health Care Personnel Handwash Studies (Form No. 96-CT-016) and Irritation Evaluations (Form No. 91-CT-007)**
- V **Statistical Analysis**
- VI **Neutralization Evaluation**
 - A. **Neutralization Assay Data Sheets (Form No. 91-L-013)**
 - B. **Project Notes (Form No. 95-G-001)**
 - C. **Statistics**
- VII **Study Notes and General Records**
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 - C. **Equipment Tracking Forms (Form No. 98-L-007)**
 - D. **Incubator Log Form (Form No. 96-L-008)**
 - E. **Water Temperature Monitoring Sheets (Form No. 96-CT-017)**
 - F. **Inoculum Preparation Tracking Forms (Form No. 96-L-016)**
 - G. **Autoplate 4000 Data Sheets (Form No. 98-L-011)**
- VIII **Adverse Event Form (Form No. 96-QA-009)**
- IX **Media/Diluent Tracking Forms (Form No. 97-L-007) and Media Production and Growth Testing Data Sheets (Form No. 91-L-003)**
- X **Log of Samples (Form No. 92-L-023), Sample Tracking Forms (Form No. 93-L-029), Sponsor Sample Submission Form (Form No. 94-G-007), and MSDS**
- XI **Qualification Criteria for the Healthcare Personnel Handwash Studies for subjects who did not show up for testing or were dismissed (Form No. 96-CT-019)**
- XII **Assays of Product for Active Ingredient**

FINAL REPORT AMENDMENT FORM

FINAL REPORT TITLE: Determination of the Antimicrobial Efficacy of One Test Product and One Reference Product Using the Health Care Personnel Handwash Procedure

STUDY NUMBER: 990829.01 REQUESTED BY: J. McDonnell DATE: 03/07/00

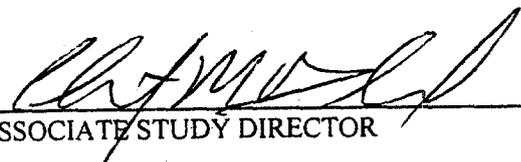
SPONSOR: International Laboratory Technology Corporation

REASON(S) FOR AMENDMENT(S): Sponsor requested that all descriptions of Pure Rx as Antimicrobial Handwash with 0.1% Benzalkonium Chloride be changed to Antimicrobial Handwash with parts per million of Benzalkonium Chloride; these amendments apply, as well, to all addenda to the Final Report. The parts per million is obtained from the Kappa Laboratories reports which are added as Addendum XII.

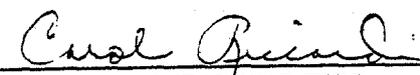
APPROVALS:


PRESIDENT AND CEO/ASSOCIATE STUDY DIRECTOR

3 / 10 / 00
DATE


ASSOCIATE STUDY DIRECTOR

3 / 10 / 00
DATE


PRINCIPAL STUDY DIRECTOR

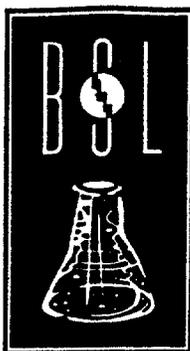
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QUALITY ASSURANCE

3 / 10 / 00
DATE


SPONSOR

3 / 13 / 00
DATE



BIO SCIENCE
LABORATORIES • INC

March 7, 2000

FINAL REPORT #990830.02

**PERSISTENT ANTIMICROBIAL EFFICACY EVALUATION OF ONE TEST
PRODUCT FORMULATION USING THE AGAR PATCH TECHNIQUE**

Prepared for:

INTERNATIONAL LABORATORY TECHNOLOGY CORPORATION (SPONSOR)
3389 Sheridan Street, Suite 149
Hollywood, Florida 33021

Prepared by:

BIO SCIENCE LABORATORIES, INC. (COMPANY)
P.O. Box 190
Bozeman, Montana 59771-0190
(406) 587-5735

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EXECUTIVE SUMMARY

This test method determined the persistent antimicrobial efficacy of one (1) test formulation by measuring the inhibition of two different marker microorganisms on agar patch plates following contact with untreated forearm skin for the control group or following contact with forearm skin treated with test product at three (3) post-application time intervals: ten (10) minutes, two (2) hours, and four (4) hours. Seventy-two (72) subjects completed this study (eighteen [18] forearms per microorganism at each time interval and eighteen [18] forearms per microorganism per control). The study consisted of a seven (7) day washout period followed by a one (1) day test (product-use) period. On the test day, the agar patch contact plates were inoculated with either *Escherichia coli* (ATCC #11229) or *Staphylococcus aureus* (ATCC# 6538). Inoculated agar patch contact plates were placed on each of three (3) forearm sites treated with the test product or left untreated for the control. Plates remained exposed to the sites for thirty (30) minutes. Each subject was randomly assigned to one (1) of the three (3) time intervals or to the control group. The two (2) bacterial species were randomly assigned to the left or the right forearm.

For *Escherichia coli* (ATCC #11229), a mean \log_{10} CFU value of 1.92 was recovered from the untreated control arms, and the Pure Rx (Antimicrobial Handwash with 1397 ppm [parts per million] Benzalkonium Chloride) demonstrated significant persistent \log_{10} inhibitory effects of 0.33 at 10-minutes, 0.39 at 2-hours, and 0.24 at 4-hours post-product application. For *Staphylococcus aureus* (ATCC #6538) total inhibition was observed at all time intervals, a mean \log_{10} CFU value of 1.75 was recovered from the untreated control arms, and the Pure Rx (Antimicrobial Handwash with 1397 ppm [parts per million] Benzalkonium Chloride) demonstrated significant persistent \log_{10} inhibitory effects of 1.75 at 10-minutes, 2-hours, and 4-hours post-product application.

March 7, 2000

FINAL REPORT #990830.02

1.0 **TITLE:** PERSISTENT ANTIMICROBIAL EFFICACY EVALUATION OF ONE TEST PRODUCT FORMULATION USING THE AGAR PATCH TECHNIQUE

2.0 **SPONSOR:** INTERNATIONAL LABORATORY TECHNOLOGY CORPORATION
3389 Sheridan Street, Suite 149
Hollywood, Florida 33021

3.0 **COMPANY:** BIOSCIENCE LABORATORIES, INC.
P.O. Box 190
Bozeman, Montana 59771

4.0 **STUDY DIRECTORS:**

Christopher Beausoleil - Principal Study Director
Daryl S. Paulson, Ph.D. - Project Director/Associate Study Director
Carol Riccardi - Associate Study Director

5.0 **PURPOSE:**

This study utilized the agar patch technique to evaluate the persistent antimicrobial effectiveness of one (1) test formulation, as measured by the inhibition of marker microorganisms. The persistent antimicrobial efficacy was measured at ten (10) minutes, two (2) hours, and four (4) hours after application of the test product. This test method was based on ASTM Method E 1982-97, "Standard Test Method for Evaluation of Antimicrobial Formulation by the Agar Patch Technique."

6.0 **SCOPE:**

This test method determined the persistent antimicrobial efficacy of one (1) test formulation by measuring the inhibition of two different marker microorganisms on agar patch plates following contact with untreated forearm skin for the control group or following contact with forearm skin at three (3) post-product-application time intervals: ten (10) minutes, two (2) hours, and four (4) hours. Seventy-two (72) subjects completed this study (eighteen [18] forearms per microorganism at each time interval and eighteen [18] forearms per microorganism for the control). The study consisted of a seven (7) day washout period followed by a one (1) day test (product-use) period. On the test day, the agar patch contact plates were inoculated with either *Escherichia coli* (ATCC #11229) or *Staphylococcus aureus* (ATCC# 6538). Inoculated agar patch contact plates were placed on each of three (3) forearm sites treated with the test product or left untreated for the control. Plates remained exposed to the sites for thirty (30) minutes. Each subject was assigned randomly to one (1) of the three (3) time intervals or to the control group. The two (2) bacterial species were assigned randomly to the left or the right forearm. Responsibility for the identity, strength, purity, composition, and stability of the test products remained with Sponsor.

7.0 TEST MATERIAL:

Samples of the test product formulation required in this evaluation were supplied by Sponsor. Records of lot numbers utilized were maintained by both Sponsor and Company. The product evaluated was:

Pure Rx - Antimicrobial Handwash with 1397 ppm (parts per million) Benzalkonium Chloride
International Laboratory Technology Corporation

Lot Number: X 396

Manufacture Date: 07/29/99

Expiration Date: 07/29/01

8.0 EQUIPMENT:

- 8.1 Steam Autoclaves: BSLI 91113 and BSLI 91127
- 8.2 Laminar Biological Flowhood (certified): BSLI 91119
- 8.3 Continuously Adjustable Pipetter, 100 μ L - 1000 μ L Capacity: BSLI 961002
- 8.4 Eppendorf Pipetter: BSLI 971204
- 8.5 Incubator, 30° \pm 2°C: BSLI 930905
- 8.6 Incubator Thermometer: BSLI TI-971003
- 8.7 Incubator, 55° - 60°C: BSLI 91059 (BIs Only)
- 8.8 Incubator Thermometer: BSLI TI-2064
- 8.9 Vortex Mixer: BSLI 931201
- 8.10 Calibrated Minute/Second Timers: BSLI 941002, BSLI 961008, BSLI 961010, BSLI 980101, BSLI 980405, and BSLI 980406
- 8.11 Orion pH Meter Model 720: BSLI 931104
- 8.12 Mettler BB240 Balance: BSLI 930409
- 8.13 A & D Balance Model EK-2000G: BSLI 960801
- 8.14 Troemner Weights: BSLI 930408
- 8.15 Ohaus Weights: BSLI 961011
- 8.16 Hewlett-Packard HP-15C Hand Calculator
- 8.17 Texas Instruments TI-35X Hand Calculator
- 8.18 MiniTab[®] Statistical Software (PC Version, Release 8.2 and 10extra)

9.0 SUPPLIES:

- 9.1 Sterile 5.0 mL Capacity Serological Pipettes: Becton-Dickinson Lot Numbers 920447 and 930407
- 9.2 Sterile 5 cc Syringes: Becton-Dickinson Lot Number 9A855
- 9.3 Sterile Polystyrene Petri Dishes (35 mm x 10 mm and 150 mm x 15 mm): Lot Numbers 00661101 and E0103982
- 9.4 Sterile Powder-Free Surgical Gloves: Pro Guard Lot Number 29661 11376
- 9.5 Surgical Tape: Micropore Lot Numbers 2004-07AA and 2004-07BE
- 9.6 Sterile Surgical Scrub Brushes: Baxter Lot Number Y8J0142
- 9.7 Sterile 1.0 mL and 0.1 Capacity Pipette Tips: Lot Numbers 705854 and 707140
- 9.8 Glass Hockey Sticks
- 9.9 70% Ethanol: BSLI Lot Number 70%EtOH991215E
- 9.10 Propane Gas Bottles
- 9.11 0.5 mL Eppendorf Combitips: Eppendorf Catalog Number 22 26 610-1
- 9.12 Antimicrobial Soap (Hibiclens[®]): Lot Number 4685A, Expires 10/00

10.0 TEST SOLUTIONS AND MEDIA:

Diluting Fluid

10.1 Phosphate Buffered Saline solution (PBS): PBS991208D

Media

10.2 Tryptic Soy Agar (TSA): TSA991126A and TSA991215C

10.3 Tryptic Soy Broth (TSB) for Inoculum Preparation: TSB991111E

11.0 TEST METHODS:

Institutional Review Board

11.1 Informed Consent Forms and any other supportive material relevant to the safety of the subjects were supplied by principal investigators to the Gallatin Institutional Review Board (GIRB) for review and approval. The primary purpose of the GIRB is the protection of the rights and welfare of the subjects involved (reference CFR 21, Parts 50 and 56). This study began only after GIRB approval had been obtained.

Subjects

11.2 This study involved seventy-two (72) subjects using one (1) test formulation over the course of a thirty (30) minute agar patch exposure. Each subject was assigned randomly to one (1) of the three (3) time intervals or to an untreated control group. The inoculated agar patch plates were placed on untreated forearms immediately or on treated forearms ten (10) minutes, two (2) hours, or four (4) hours after application of the test product.

11.3 Seventy-eight (78) overtly healthy subjects over the age of eighteen (18), but under the age of seventy (70) were admitted into the study. Seventy-two (72) subjects completed the study. Of the seventy-two (72) subjects who completed the study, forty-three (43) were female, twenty-nine (29) were male, sixty-one (61) were Caucasian, five (5) were Asian-American, one (1) was Mexican-American, one (1) was Native-American, and two (2) were African-American. The median age of the seventy-two (72) subjects who completed the study was twenty-nine (29) years, with eighteen (18) being the youngest and sixty-eight (68) the oldest tested. All subjects' forearms were free from clinically evident dermatosis, open wounds, and/or any other disorders which could compromise the subject and the study. All subjects signed Informed Consent Forms and the Study Description (Addendum I, Appendix I) prior to participating in the study.

Concurrent Treatment

11.4 No subject was admitted into the study who was currently using any topical or systemic antimicrobials, steroids, or any other medications known to affect the normal microbial flora of the skin.

Pre-Test Period

- 11.5 The seven (7) days prior to the test portion of the study constituted the pre-test period. During that time, subjects were instructed to avoid the use of medicated soaps, lotions, deodorants and shampoos, as well as skin contact with solvents, detergents, acids and bases, or any other products known to effect the normal microbial populations of the skin (Addendum I, Appendix II). Subjects were supplied a personal hygiene kit containing non-medicated soap, shampoo, deodorant, lotion, and rubber gloves worn when contact with antimicrobials, solvents, detergents, acids, or bases could not be avoided. Subjects were instructed to use the contents of this kit exclusively during their participation in the study and also to avoid using UV tanning beds and swimming or bathing in biocide-treated pools or hot tubs.
- 11.6 A study description and the Informed Consent statement were provided to each subject prior to their beginning the study. Trained laboratory personnel explained the study to each participant and were available to answer any questions which arose.

Inoculum Preparation

- 11.7 Approximately forty-eight (48) hours prior to initiating the study, an inoculating loop was used to inoculate one (1) sterile tube of Tryptic Soy Broth from stock cultures containing either *Escherichia coli* (ATCC #11229) or *Staphylococcus aureus* (ATCC #6538). The microorganism cultures were incubated at $30^{\circ} \pm 2^{\circ}\text{C}$ for approximately twenty-four (24) hours.
- 11.8 Approximately twenty-four (24) hours prior to initiating the study, the broth cultures prepared as described in Section 11.7 were inoculated onto the surface of Tryptic Soy Agar plates and incubated at $30^{\circ} \pm 2^{\circ}\text{C}$ for approximately twenty-four (24) hours.

Challenge Suspensions

- 11.9 Immediately prior to initiating the test procedure, an inoculating loop was used to prepare a suspension in Phosphate Buffered Saline solution from the cultures of solid media prepared as described in Section 11.8. Suspension concentrations were adjusted to approximately 1.0×10^8 CFU/mL, by comparison to a McFarland Standard.
- 11.10 Ten-fold serial dilutions in Phosphate Buffered Saline solution were prepared to achieve final inocula of $1.0 - 3.0 \times 10^4$ CFU/mL for use on the agar patch plates.

Test Period

- 11.11 Subjects were utilized for up to five (5) hours on a single day of the test period. All jewelry was removed from the forearms. The volar aspect of each forearm was rinsed with 70% Ethanol and allowed to air-dry for ten (10) minutes.
- 11.12 Each subject was assigned randomly to one (1) of the three (3) time intervals, or to an untreated control (no product) group. The time intervals were ten (10) minutes, two (2) hours, and four (4) hours post-product application.
- 11.13 The agar patch plates were inoculated with $10 \mu\text{L}$ of the suspension containing approximately $1.0 - 3.0 \times 10^4$ CFU/mL of either *Escherichia coli* (ATCC #11229) or *Staphylococcus aureus* (ATCC# 6538), and the inocula were spread with a sterile glass hockey stick. Three (3) agar patch plates were inoculated with each of the marker microorganisms for use as inoculum control plates.

- 11.14 Three (3) sites on the volar aspect of the subject's forearms were left untreated or were treated with the test formulation, as described below. Three (3) agar patch plates were applied to each forearm for an exposure period of thirty (30) minutes immediately for control forearms or after each of the three (3) randomly assigned, post-product application time intervals for test forearms.

Product-Use Instructions

1. 2.0 mL aliquots of handwash were dispensed into a technician's polyethylene-gloved hands.
2. The product was applied to the volar aspect of the subjects' forearms by rubbing into the skin.
3. The forearms were allowed to air-dry for five (5) minutes.
4. The test product was reapplied two (2) additional times.
5. The technicians waited for the assigned time interval to elapse before applying agar patch plates to the sites on each forearm.

Incubation

- 11.15 After thirty (30) minutes of exposure, the plates were removed carefully and incubated at $30^{\circ} \pm 2^{\circ}\text{C}$ for twenty-four (24) to forty-eight (48) hours. Three (3) control plates (inoculated with microorganism, but not exposed to product) were also incubated.

Subject Safety

- 11.16 Subjects were not allowed to leave the laboratory for any reason once the testing began. Additionally, subjects were required to wear protective garments and not touch their clothing, faces or any other body parts with their forearms during the test period. On completion of testing, subjects were required to perform a one (1) minute rinse with 70% ethanol, an air-dry, and a water-rinse, followed by a supervised four (4) minute surgical scrub of the forearms with a 4% Chlorhexidine Gluconate solution.
- 11.17 Antibiotic sensitivity profiles for the strains of *Escherichia coli* (ATCC #11229) and *Staphylococcus aureus* (ATCC #6538) used in this study were retained on file at BSLI.

Data Collection

- 11.18 The Colony-Forming Units (CFU) of each plate were counted, and the average Colony-Forming Units (CFU) of the three (3) contact plates were determined and translated to Log_{10} scale.
- 11.19 The Percent Difference was calculated using the geometric mean (antilog of the mean CFU/plate).

12.0 CALCULATIONS:

- 12.1 The Log_{10} and the CFU of the average of the triplicate plate counts for the control (untreated) plates and the agar patch plates after exposure to the product were calculated as follows:

$$\text{CFU/plate} = (C_i) \quad \text{Log}_{10} \text{ Average} = \text{Log}_{10} (C_i)$$

Where:

$$C_i = \text{Average CFU of the Three (3) Plate Counts}$$

- 12.2 The Log_{10} Difference was calculated for each microorganism as follows:

$$\text{Log}_{10} \text{ Difference} = \text{IP} - P_{\text{EX}}$$

Where:

$$\text{IP} = \text{Log}_{10} \text{ of the Control Plates after Exposure to the Untreated Sites}$$

$$P_{\text{EX}} = \text{Log}_{10} \text{ of the Average Population after Exposure to the Product}$$

- 12.3 The Percent Difference was calculated for each microorganism as follows:

$$\text{Percent Difference} = \frac{(\text{Antilog IP}) - (\text{Antilog } P_{\text{EX}})}{(\text{Antilog IP})} \times 100$$

Where:

$$\text{IP} = \text{Log}_{10} \text{ of the Control Plates after Exposure to the Untreated Sites}$$

$$P_{\text{EX}} = \text{Log}_{10} \text{ of the Average Population after Exposure to the Product}$$

Data Analysis

- 12.4 An Exploratory Data Analysis was performed on the data. Stem-Leaf Ordering, Letter Value Displays, and Box Plots were generated and these assured the data collected approximated the normal distribution. A series of Student's *t* tests were conducted using the 0.05 level of significance for Type I (α) error comparing the Log_{10} values from each organism at each time interval to the Control (no product). Any outlier values were noted.

13.0 RESULTS:

- 13.1 The average *Escherichia coli* (ATCC #11229) population on inoculum control plates prior to testing was 275.67 CFU/plate on the 09/21/99 test date and 243.00 CFU/plate on the 09/22/99 test date. The average *Staphylococcus aureus* (ATCC #6538) population on inoculum control plates prior to testing was 309.00 CFU/plate on the 09/21/99 test date and 307.33 CFU/plate on the 09/22/99 test date.
- 13.2 Tables I through IV present the average colony counts and Log_{10} averages for each subject, post-exposure, on the agar patch plates at each time interval (10-minute, 2-hour, and 4-hour) and for the control (immediate) sample for *Escherichia coli* (ATCC #11229). Tables V through VIII present the average colony counts and Log_{10} averages for each subject, post-exposure, on the agar patch plates at each time interval (10-minute, 2-hour, and 4-hour) and for the control (immediate) sample for *Staphylococcus aureus* (ATCC #6538).

Table I: Average Colony Counts and Log₁₀ Averages of *Escherichia coli* (ATCC #11229) for Test Product (Pure Rx - Antimicrobial Handwash with 1397 ppm [parts per million] Benzalkonium Chloride) at the 10-Minute Sample

Subject Number	Arm	Test Product - 10-Minute Sample	
		Average Colony Count	Log ₁₀ Average
8	Left	30.67	1.49
9	Left	61.00	1.79
14	Left	11.33	1.05
15	Left	82.00	1.91
16	Left	58.67	1.77
25	Left	90.33	1.96
28	Left	63.67	1.80
30	Left	93.67	1.97
36	Left	34.00	1.53
41	Left	69.00	1.84
47	Left	23.00	1.36
54	Left	50.33	1.70
64	Left	48.00	1.68
65	Left	25.00	1.40
68	Left	36.33	1.56
74	Left	14.00	1.15
75	Left	15.33	1.19
78	Left	35.00	1.54

Table II: Average Colony Counts and Log₁₀ Averages of *Escherichia coli* (ATCC #11229) for Test Product (Pure Rx - Antimicrobial Handwash with 1397 ppm [parts per million] Benzalkonium Chloride) at the 2-Hour Sample

Subject Number	Arm	Test Product - 2-Hour Sample	
		Average Colony Count	Log ₁₀ Average
3	Right	30.00	1.48
4	Right	26.00	1.41
6	Right	91.00	1.96
7	Right	72.33	1.86
12	Right	47.00	1.67
19	Right	37.00	1.57
21	Right	28.33	1.45
23	Right	2.33	0.37
40	Right	57.00	1.76
45	Right	13.67	1.14
46	Right	79.33	1.90
48	Right	58.33	1.77
49	Right	46.67	1.67
50	Right	47.67	1.68
52	Right	63.00	1.80
55	Right	57.00	1.76
69	Right	25.67	1.41
73	Right	6.67	0.82

Table III: Average Colony Counts and Log₁₀ Averages of *Escherichia coli* (ATCC #11229) for Test Product (Pure Rx - Antimicrobial Handwash with 1397 ppm [parts per million] Benzalkonium Chloride) at the 4-Hour Sample

Subject Number	Arm	Test Product - 4-Hour Sample	
		Average Colony Count	Log ₁₀ Average
2	Left	80.00	1.90
20	Left	21.33	1.33
22	Left	61.33	1.79
26	Left	47.33	1.68
27	Left	26.00	1.41
29	Left	47.33	1.68
32	Left	40.67	1.61
37	Left	35.33	1.55
38	Left	60.33	1.78
39	Left	47.33	1.68
42	Left	52.67	1.72
43	Left	53.33	1.73
53	Left	29.00	1.46
56	Left	66.33	1.82
58	Left	55.67	1.82
59	Left	58.67	1.77
61	Left	64.33	1.81
72	Left	58.67	1.77

Table IV: Average Colony Counts and Log₁₀ Averages of *Escherichia coli* (ATCC #11229) for Control (No Product) at the Immediate Sample

Subject Number	Arm	Control (No Product) - Immediate Sample	
		Average Colony Count	Log ₁₀ Average
1	Right	91.33	1.96
5	Right	61.67	1.79
10	Right	100.33	2.00
13	Right	101.33	2.01
24	Right	106.00	2.03
31	Right	100.33	2.00
33	Right	91.33	1.96
35	Right	52.67	1.72
51	Right	85.33	1.93
57	Right	77.00	1.89
63	Right	81.33	1.91
66	Right	81.00	1.91
67	Right	94.33	1.97
70	Right	96.67	1.99
71	Right	78.00	1.89
76	Right	68.67	1.84
77	Right	83.33	1.92
79	Right	74.33	1.87

Table V: Average Colony Counts and Log₁₀ Averages of *Staphylococcus aureus* (ATCC #6538) for Test Product (Pure Rx - Antimicrobial Handwash with 1397 ppm [parts per million] Benzalkonium Chloride) at the 10-Minute Sample

Subject Number	Arm	Test Product - 10-Minute Sample	
		Average Colony Count	Log ₁₀ Average
8	Right	0.00	0.00
9	Right	0.00	0.00
14	Right	0.00	0.00
15	Right	0.00	0.00
16	Right	0.00	0.00
25	Right	0.00	0.00
28	Right	0.00	0.00
30	Right	0.00	0.00
36	Right	0.00	0.00
41	Right	0.00	0.00
47	Right	0.00	0.00
54	Right	0.00	0.00
64	Right	0.00	0.00
65	Right	0.00	0.00
68	Right	0.00	0.00
74	Right	0.00	0.00
75	Right	0.00	0.00
78	Right	0.00	0.00

Table VI: Average Colony Counts and Log₁₀ Averages of *Staphylococcus aureus* (ATCC #6538) for Test Product (Pure Rx - Antimicrobial Handwash with 1397 ppm [parts per million] Benzalkonium Chloride) at the 2-Hour Sample

Subject Number	Arm	Test Product - 2-Hour Sample	
		Average Colony Count	Log ₁₀ Average
3	Left	0.00	0.00
4	Left	0.00	0.00
6	Left	0.00	0.00
7	Left	0.33	0.00
12	Left	0.00	0.00
19	Left	0.00	0.00
21	Left	0.00	0.00
23	Left	0.00	0.00
40	Left	0.00	0.00
45	Left	0.00	0.00
46	Left	0.00	0.00
48	Left	0.00	0.00
49	Left	0.00	0.00
50	Left	0.00	0.00
52	Left	0.00	0.00
55	Left	0.00	0.00
69	Left	0.00	0.00
73	Left	0.00	0.00

Table VII: Average Colony Counts and Log₁₀ Averages of *Staphylococcus aureus* (ATCC #6538) for Test Product (Pure Rx - Antimicrobial Handwash with 1397 ppm [parts per million] Benzalkonium Chloride) at the 4-Hour Sample

Subject Number	Arm	Test Product - 4-Hour Sample	
		Average Colony Count	Log ₁₀ Average
2	Right	0.00	0.00
20	Right	0.00	0.00
22	Right	0.33	0.00
26	Right	0.33	0.00
27	Right	0.00	0.00
29	Right	0.33	0.00
32	Right	0.67	0.00
37	Right	0.00	0.00
38	Right	0.67	0.00
39	Right	0.00	0.00
42	Right	0.00	0.00
43	Right	0.00	0.00
53	Right	0.00	0.00
56	Right	0.33	0.00
58	Right	0.00	0.00
59	Right	0.00	0.00
61	Right	0.00	0.00
72	Right	0.00	0.00

Table VIII: Average Colony Counts and Log₁₀ Averages of *Staphylococcus aureus* (ATCC #6538) for Control (No Product) at the Immediate Sample

Subject Number	Arm	Control (No Product) - Immediate Sample	
		Average Colony Count	Log ₁₀ Average
1	Left	19.00	1.28
5	Left	62.00	1.79
10	Left	98.67	1.99
13	Left	59.00	1.77
24	Left	84.33	1.93
31	Left	82.33	1.92
33	Left	30.00	1.48
35	Left	8.67	0.94
51	Left	77.67	1.89
57	Left	66.33	1.82
63	Left	57.67	1.76
66	Left	69.67	1.84
67	Left	80.00	1.90
70	Left	80.00	1.90
71	Left	71.00	1.85
76	Left	52.00	1.72
77	Left	51.33	1.71
79	Left	90.00	1.95

- 13.3 Table IX presents a statistical summary comparing the Test Product at each time interval to the Control (No Product) for *Escherichia coli* (ATCC #11229). Table X presents a statistical summary comparing the Test Product at each time interval to the Control (No Product) for *Staphylococcus aureus* (ATCC #6538). Figure 1 graphically presents the mean Log₁₀ values at each time interval and control for each microorganism.

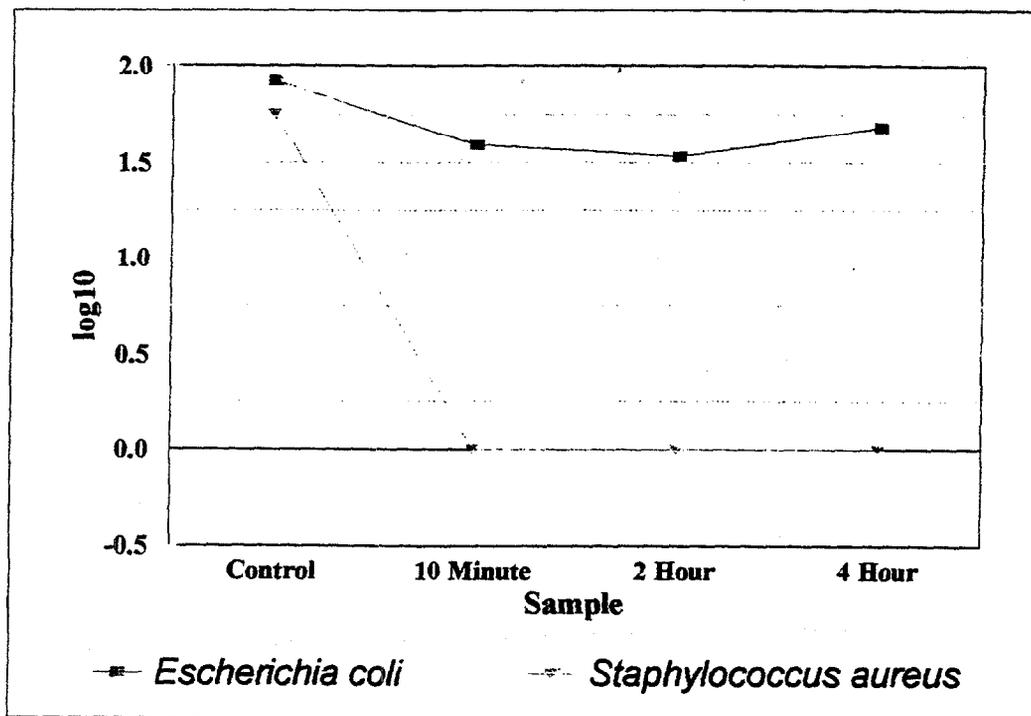
Table IX: Average Colony Counts and Log₁₀ Averages of *Escherichia coli* (ATCC #11229) for the Test Product at each Time Interval versus the Control (No Product)

Product	Sample	Sample Size	Mean of Log ₁₀ Values	Standard Deviation	95% Confidence Intervals	Log ₁₀ Inhibition	Percent Inhibition
Control (No Product)	Immediate	18	1.92	0.08	1.88 to 1.96	N/A	N/A
Test Product Pure Rx	10-Minute	18	1.59	0.28	1.45 to 1.73	0.33	53.23%
	2-Hour	18	1.53	0.40	1.33 to 1.73	0.39	59.26%
	4-Hour	18	1.68	0.16	1.61 to 1.76	0.24	42.46%

Table X: Average Colony Counts and Log₁₀ Averages of *Staphylococcus aureus* (ATCC #6538) for the Test Product at each Time Interval versus the Control (No Product)

Product	Sample	Sample Size	Mean of Log ₁₀ Values	Standard Deviation	95% Confidence Intervals	Log ₁₀ Inhibition	Percent Inhibition
Control (No Product)	Immediate	18	1.75	0.27	1.61 to 1.88	N/A	N/A
Test Product Pure Rx	10-Minute	18	0.00	0.00	0.00 to 0.00	1.75	98.22%
	2-Hour	18	0.00	0.00	0.00 to 0.00	1.75	98.22%
	4-Hour	18	0.00	0.00	0.00 to 0.00	1.75	98.22%

Figure 1: Graphical Presentation of the Log₁₀ Averages of *Escherichia coli* (ATCC #11229) and *Staphylococcus aureus* (ATCC #6538) at each Time Interval after Exposure to Pure Rx



14.0

CONCLUSION:

For *Escherichia coli* (ATCC #11229), a mean Log₁₀ CFU value of 1.92 was recovered from the untreated control arms, and the Pure Rx (Antimicrobial Handwash with 1397 ppm [parts per million] Benzalkonium Chloride) demonstrated significant persistent Log₁₀ inhibitory effects of 0.33 at 10-minutes, 0.39 at 2-hours, and 0.24 at 4-hours post-product application. For *Staphylococcus aureus* (ATCC #6538) total inhibition was observed at all time intervals, a mean Log₁₀ CFU value of 1.75 was recovered from the untreated control arms, and the Pure Rx (Antimicrobial Handwash with 1397 ppm [parts per million] Benzalkonium Chloride) demonstrated significant persistent Log₁₀ inhibitory effects of 1.75 at 10-minutes, 2-hours, and 4-hours post-product application.

15.0 ACCEPTANCE:

BIOSCIENCE LABORATORIES, INC.

P.O. Box 190
Bozeman, Montana 59771

Project Director/
Associate Study
Director:

Daryl S Paul
Daryl S. Paulson, Ph.D.

3-10-00
Date

Principal Study
Director:

Chris Beansoleil
Christopher Beansoleil

3/10/00
Date

Associate Study
Director:

Carol Riccardi
Carol Riccardi

3/10/00
Date

QUALITY ASSURANCE STATEMENT:

This study was inspected by the Quality Assurance Unit, and reports were submitted to the Study Director and Management in accordance with Standard Operating Procedures, as follows:

<u>Phase</u>	<u>Date</u>
Product Testing	09/21/99
Data Audit	10/13/99
Final Report Review	10/13/99

Reports to Study Director
and Management 09/21/99

This study was conducted in compliance with Good Laboratory Practices standards, as described by the FDA (21 CFR Part 58), with the following exception: test article preparations were not analyzed to confirm concentration, stability, or homogeneity.

Director of
Quality
Assurance:

John A. Mitchell
John A. Mitchell, Ph.D.

3/10/00
Date

INDEX OF ADDENDA

- I GIRB Approved Protocol #990830 and Protocol Amendment Form (Form No. 94-G-006)
- II Data Recording Sheets for Protocol #990830
- III Sample Data Sheets for Protocol #990830
- IV Statistical Analysis
- V Study Notes and General Records
 - A. Project Notes (Form No. 95-G-001)
 - B. Randomizations
 - C. Equipment Tracking Forms (Form No. 98-L-007)
 - D. Incubator Log Form (Form No. 96-L-008)
 - E. Inoculum Preparation Tracking Forms (Form No. 96-L-016)
- VI Media/Diluent Tracking Form (Form No. 97-L-007) and Media Production and Growth Testing Data Sheets (Form No. 91-L-003)
- VII Log of Samples (Form No. 92-L-023), Sample Tracking Forms (Form No. 93-L-029), Sponsor Sample Submission Form (Form No. 94-G-007), and MSDS
- VIII Sample Data Sheets for Protocol #990830 for subjects who did not show up for testing, were dropped, or were dismissed
- IX Assays of Product for Active Ingredient

FINAL REPORT AMENDMENT FORM

FINAL REPORT TITLE: Persistent Antimicrobial Efficacy Evaluation of One Test Product Formulation
Using the Agar Patch Technique

STUDY NUMBER: 990830.01 REQUESTED BY: J. McDonnell DATE: 03/07/00

SPONSOR: International Laboratory Technology Corporation

REASON(S) FOR AMENDMENT(S): Sponsor requested that all descriptions of Pure Rx as Antimicrobial
Handwash with 0.1% Benzalkonium Chloride be changed to Antimicrobial Handwash with parts per million of
Benzalkonium Chloride; these amendments apply, as well, to all addenda to the Final Report. The parts per million
is obtained from the Kappa Laboratories reports which are added as Addendum IX.

APPROVALS:

David S. Paul
PRESIDENT AND CEO/ASSOCIATE STUDY DIRECTOR

3 / 10 / 00
DATE

Carol Quaid
ASSOCIATE STUDY DIRECTOR

3 / 10 / 00
DATE

Cliff W. Wolf
PRINCIPAL STUDY DIRECTOR

3 / 10 / 00
DATE

John Mitchell
QUALITY ASSURANCE

3 / 10 / 00
DATE

David E. Hill
SPONSOR

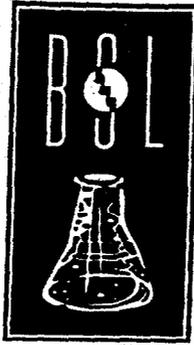
3 / 13 / 00
DATE

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Form No. 98-G-003
Rev. 2 05/99



BIO SCIENCE
LABORATORIES • INC

March 7, 2000

FINAL REPORT #980907.03

**EVALUATION OF THE ANTIMICROBIAL EFFICACY OF ONE HANDWASH PRODUCT
FORMULATION USING THE CYLINDER SAMPLING TECHNIQUE**

Prepared for:

INTERNATIONAL LABORATORY TECHNOLOGY CORPORATION (SPONSOR)
3389 Sheridan Street #149
Hollywood, Florida 33021

Prepared by:

BIO SCIENCE LABORATORIES, INC. (COMPANY)
P.O. Box 190
Bozeman, Montana 59771-0190
(406) 587-5735

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EXECUTIVE SUMMARY

This study evaluated the antimicrobial efficacy of one (1) product formulation utilizing the forearms of fifteen (15) subjects. One (1) site on each forearm was inoculated with *Staphylococcus aureus* (ATCC# 6538). Samples were taken using the Cylinder Sampling Technique. This provided the baseline samples. The forearms were washed with a bland soap, dried, and the test handwash formulation was applied to each forearm. The handwash was massaged into the skin. The forearm was then reinoculated with *Staphylococcus aureus* at the randomly assigned time. A light mist of sterile deionized water was applied two (2) minutes after inoculation. After a five (5) minute total exposure time, the forearms were sampled using the Cylinder Sampling Technique. The antimicrobial efficacy of the product was measured at ten (10) minutes, two (2) hours, and four (4) hours after product application as a function of reduction of the marker organism from baseline levels.

Pure Rx (Antibacterial Handwash with 1206 ppm [parts per million] Benzalkonium Chloride) demonstrated a significant persistent antimicrobial effect at 10 minutes, two hours and 4 hours post-product application. The \log_{10} reductions of 0.72 at ten minutes, 0.21 at 2 hours, and 0.05 at 4 hours post-product application were all below that of the baseline sample.

March 7, 2000

FINAL REPORT #980907.03

1.0 **TITLE:** EVALUATION OF THE ANTIMICROBIAL EFFICACY OF ONE HANDWASH PRODUCT FORMULATION USING THE CYLINDER SAMPLING TECHNIQUE

2.0 **SPONSOR:** INTERNATIONAL LABORATORY TECHNOLOGY CORPORATION
3389 Sheridan Street #149
Hollywood, Florida 33021

3.0 **COMPANY:** BIOSCIENCE LABORATORIES, INC.
P.O. Box 190
Bozeman, Montana 59771

4.0 **STUDY DIRECTORS:**

Carol Riccardi - Principal Study Director
Daryl S. Paulson, Ph.D. - Associate Study Director
Christopher Beausoleil - Associate Study Director

5.0 **PURPOSE:**

This study evaluated the antimicrobial efficacy of one (1) product formulation, as measured by the reduction of a marker organism following use. The antimicrobial efficacy was measured at ten (10) minutes, two (2) hours, and four (4) hours after product application. The study consisted of a seven (7) day washout period followed by a one (1) day treatment (product-use) period. Enrolled subjects were instructed to refrain from using antibacterial/antimicrobial soaps and medicated lotions, creams, antiperspirants, and dandruff shampoos until the study was completed. Subjects were provided a personal hygiene kit containing products to be used which would not compromise testing. One site on each forearm was inoculated with *Staphylococcus aureus* (ATCC# 6538). Samples were taken using the Cylinder Sampling Technique. This provided the baseline samples. The forearms were washed with a bland soap and dried. The test handwash formulation was applied to each forearm and massaged into the skin. The forearms were then reinoculated with *Staphylococcus aureus* at the randomly assigned time. At two (2) minutes post-inoculation, the test sites were misted lightly with sterile deionized water. After a five (5) minute total exposure time, the forearms were sampled using the Cylinder Sampling Technique.

6.0 **SCOPE:**

This test method determined the antimicrobial efficacy of an antimicrobial handwash formulation by measuring the reduction of a marker organism following contact with skin treated with the antimicrobial handwash formulation. Fifteen (15) subjects were utilized in this study. The antimicrobial efficacy was measured at ten (10) minutes, two (2) hours, and four (4) hours after product application.

7.0 TEST MATERIAL:

Samples of the test product formulation required in this evaluation were supplied by Sponsor. Records of lot numbers utilized were maintained by both Sponsor and Company. The product evaluated was:

Test Product

Pure Rx (Antibacterial Handwash with 1206 ppm [parts per million] Benzalkonium chloride)

Lot Number: X 301

Manufacture Date: 10/14/98

Expiration Date: 10/14/99

8.0 EQUIPMENT:

- 8.1 Steam Autoclaves: BSLI 91113 and BSLI 91127
- 8.2 Laminar Biological Flowhood (certified): BSLI 91119
- 8.3 Scrub Sink: BSLI 960101
- 8.4 Continuously Adjustable Pipette, 20 μ L - 200 μ L Capacity: BSLI 950106
- 8.5 Continuously Adjustable Pipette, 100 μ L - 1000 μ L Capacity: BSLI 961002
- 8.6 Portable Pipetters: BSLI 971205, BSLI 980602, BSLI 980901, and BSLI 980902
- 8.7 Eppendorf Repeater Plus: BSLI 980407
- 8.8 Autoplate 4000 Spiral Plater: BSLI 980409
- 8.9 CASBA4[®] Spiral Plater Counter: BSLI 980410
- 8.10 Incubator, 30 $^{\circ}$ \pm 2 $^{\circ}$ C: BSLI 930905
- 8.11 Incubator Thermometer: BSLI TI-960608
- 8.12 Incubator, 35 $^{\circ}$ \pm 2 $^{\circ}$ C: BSLI 91101
- 8.13 Incubator Thermometers: BSLI TI-960302 and BSLI TI-960109
- 8.14 Incubator, 55 $^{\circ}$ - 60 $^{\circ}$ C: BSLI 91059 (BIs Only)
- 8.15 Incubator Thermometer: BSLI TI-2064
- 8.16 Vortex Mixers: BSLI 931201 and BSLI 980103
- 8.17 Calibrated Minute/Second Timers: BSLI 961005, BSLI 961006, BSLI 961007, BSLI 961010, BSLI 960114, BSLI 980101, BSLI 980102, BSLI 980402, and BSLI 980405
- 8.18 Orion pH Meter Model 720: BSLI 931104
- 8.19 Denver Instruments Balance A200DS: BSLI 931105
- 8.20 Mettler BB240 Balance: BSLI 930409
- 8.21 A & D Balance Model EK-2000G: BSLI 960801
- 8.22 Troemner Weights: BSLI 930408
- 8.23 Ohaus Weights: BSLI 961011
- 8.24 Hewlett-Packard HP-15C Hand Calculator
- 8.25 Texas Instruments TI-35X Hand Calculator
- 8.26 MiniTab[®] Statistical Software (PC Version, Release 8.2 and 10xtra)

9.0 SUPPLIES:

- 9.1 Sterile Stainless Steel Cylinders (3.46 cm² inner area)
- 9.2 Sterile Rubber Policeman
- 9.3 Sterile 5.0 mL Capacity Serological Pipettes, Sterilin Lot No.: 2597 and 2698
- 9.4 Sterile Polystyrene Petri Dishes (35 mm x 10 mm and 100 mm x 20 mm)
- 9.5 Sterile Powder-Free Surgical Gloves
- 9.6 Sterile 1.0 mL Capacity Pipette Tips
- 9.7 Sterile 0.1 mL Capacity Pipette Tips
- 9.8 Surgical Scrub Brushes, Baxter Lot No.: Y2D070
- 9.9 Sterile 5 cc Syringes, Becton-Dickinson Lot No.: 8H990
- 9.10 Glass Hockey Sticks
- 9.11 70% Ethanol, BSLI Lot No.: 70% EtOH 990127C
- 9.12 Propane Gas Bottles

10.0 TEST SOLUTIONS AND MEDIA:

Neutralizing Fluid

- 10.1 Butterfield's Phosphate Buffer Solution (with Product Neutralizers) (BBP++): BBP++980121B

Diluting Fluid

- 10.2 Butterfield's Phosphate Buffer Solution (BBP): BBP990120C and BBP990212E

Media

- 10.3 Tryptic Soy Agar with product neutralizers (TSA+): TSA+990123A and TSA+990213B
- 10.4 Tryptic Soy Agar (TSA): TSA990206A
- 10.5 Tryptic Soy Broth (TSB) for Inoculum Preparation: TSB990113A and TSB990126C
- 10.6 Sterile Deionized Water (SDW): SDW990119C

11.0 TEST METHODS:

Subjects

- 11.1 Twenty(20) overtly healthy subjects at least eighteen (18) years of age, but under the age of seventy (70) were admitted into the study. Fifteen (15) subjects completed the study. Of the subjects that completed testing, five (5) were male, fifteen (15) were female, and all twenty (20) were Caucasian. The median age of the subjects who completed the study was twenty-four (24) years, with nineteen (19) being the youngest and sixty-one (61) the oldest tested. All subjects' forearms were free from clinically evident dermatoses, open wounds, and/or any other disorders which could have compromised the subject and the study. All subjects signed Informed Consent Forms and the Study Description (Addendum I, Appendix I) prior to participating in the study.
- 11.2 This study involved fifteen (15) subjects using one (1) test product evaluated over the course of a five (5) minute bacterial exposure. Each subject was randomly assigned to two (2) of the three (3) time intervals for sampling. Aliquots of a *Staphylococcus aureus* (ATCC# 6538) suspension were applied to the test sites at ten (10) minutes, two (2) hours, and four (4) hours post-product application, and sampling was performed five (5) minutes later. All samples were taken using the Cylinder Sampling Technique (Sections 11.16 to 11.19).

Concurrent Treatment

- 11.3 No subject was admitted into the study who was known to be currently using any topical or systemic antimicrobials, steroids, or any other medications known to affect the normal microbial flora of the skin.

Institutional Review Board

- 11.4 Informed Consent Forms (Addendum I, Appendix I), and any other supportive material relevant to the safety of the subjects, were supplied by principal investigators for review and approval by the Gallatin Institutional Review Board (GIRB). The primary purpose of the GIRB is the protection of the rights and welfare of the subjects involved (reference CFR 21, Parts 50 and 56). This study began only after GIRB approval had been obtained.

Pre-Test Period

- 11.5 The seven (7) days prior to the test portion of the study constituted the pre-test period. During that time, subjects were instructed to avoid the use of medicated soaps, lotions, deodorants and shampoos, as well as skin contact with solvents, detergents, acids and bases, or any other products known to effect the normal microbial populations of the skin (Addendum I, Appendix II). Subjects were supplied a personal hygiene kit containing nonmedicated soap, shampoo, deodorant, lotion, and rubber gloves to be worn when contact with antimicrobials, solvents, detergents, acids, or bases could not be avoided. Subjects were instructed to use the contents of this kit exclusively during their participation in the study and also to avoid using UV tanning beds and swimming or bathing in biocide-treated pools or hot tubs.
- 11.6 A study description, personal hygiene kit and the Informed Consent statement was provided to each subject prior to their beginning the study. Trained laboratory personnel explained the study to each participant and were available to answer any questions which arose.

Inoculum Preparation

- 11.7 Approximately forty-eight (48) hours prior to initiating the study, an inoculating loop was used to inoculate one (1) tube of Tryptic Soy Broth with *Staphylococcus aureus* (ATCC# 6538) from stock cultures containing this microorganism. The microorganism culture was incubated at $30 \pm 2^\circ\text{C}$ for approximately twenty-four (24) hours.
- 11.8 Approximately twenty-four (24) hours prior to initiating the study, the broth culture prepared as described in Section 11.7 was inoculated onto the surface of Tryptic Soy Agar and incubated at $30 \pm 2^\circ\text{C}$ for approximately twenty-four (24) hours.

Challenge Suspension

- 11.9 Immediately prior to initiating the test procedure, an inoculating loop was used to prepare a suspension in Butterfield's Phosphate Buffer solution from the cultures on solid media prepared as described in Section 11.8. Suspension concentrations were adjusted to approximately 1.0×10^8 CFU/mL, by comparison with a McFarland Standard.

Test Period

- 11.10 Each subject was employed for approximately five (5) hours on a single day of the test period. All jewelry was removed from the forearms prior to product application.
- 11.11 Each subject was randomly assigned to two (2) of the three (3) product sampling times, one (1) per forearm.

Baseline

- 11.12 One (1) site on the volar aspect of each forearm was inoculated with 25 μ L of approximately 2.19×10^8 CFU/mL of *Staphylococcus aureus* (ATCC# 6538) which exposed approximately 5.48×10^6 CFU to each site, and the inoculum was spread on the sites with sterile glass hockey sticks. Two (2) minutes after the inocula were spread on the sites, the sites were misted with sterile deionized water. Three (3) minutes after the sites were misted, they were sampled using the Cylinder Sampling Technique (Sections 11.16 to 11.19). This constituted the baseline sample.
- 11.13 The test sites were washed with a bland soap and pat-dried with paper toweling.

Post Treatment

- 11.14 Two (2) sites on the volar aspect of the subject's forearms were treated with the test product, as described in Section 11.15. Ten (10) minutes, two (2) hours or four (4) hours post-application, depending on random assignment, each site was inoculated with 25 μ L of the suspension containing approximately 2.19×10^8 CFU/mL of *Staphylococcus aureus* (ATCC# 6538) (approximately 5.48×10^6 CFU on each site), and the inocula were spread on the sites with sterile glass hockey sticks. Two (2) minutes after the inocula were spread on the sites, the sites were misted with sterile deionized water. Three (3) minutes after the sites were misted, they were sampled using the Cylinder Sampling Technique (Sections 11.16 to 11.19).

Product Application

- 11.15 1.0 mL of handwash was applied to the test sites, lightly rubbed in, and allowed to dry.

Cylinder Sampling Technique

- 11.16 At the designated times, a sterile cylinder with inside area of 3.46 cm² was held firmly onto the test site to be sampled. 1.0 mL of Butterfield's Phosphate Buffer Solution with appropriate product neutralizers (BBP++) was instilled into the cylinder, and the skin area inside the cylinder was massaged in a circumferential manner for one (1) minute using a sterile rubber policeman.
- 11.17 The 1.0 mL of BBP++ was removed with a pipette and placed into a sterile test tube. A second 1.0 mL aliquot of BBP++ was instilled into the cylinder, and the skin area again massaged for one (1) minute using a sterile rubber policeman.
- 11.18 The second 1.0 mL aliquot was then pipetted out and pooled in the test tube with the first aliquot.
- 11.19 1.0 mL aliquots of the microorganism suspension (10^0 dilution) were removed and serially diluted in Butterfield's Phosphate Buffer Solution with product neutralizers. Duplicate spiral plates were prepared from appropriate dilutions using Tryptic Soy Agar with product neutralizers. The plates were incubated for approximately forty-eight (48) hours at $30^\circ \pm 2C$.

Subject Safety

- 11.20 Subjects were not allowed to leave the laboratory for any reason once the testing began. Additionally, subjects were required to wear protective garments and not touch their clothing, faces or any other body parts with their forearms during the test period. On completion of testing, subjects were required to perform a one (1) minute rinse with 70% ethanol, an air-dry, and a water-rinse, followed by a supervised four (4) minute surgical scrub of the forearms with a 4% Chlorhexidine Gluconate solution.

Data Collection

- 11.21 The Colony-Forming Units (CFU) of each plate were counted, and the average Colony-Forming Units (CFU) of the two plates was determined and translated to Log₁₀ scale.

12.0 CALCULATIONS:

- 12.1 In order to convert the volumetric measurement collected during sampling into the number of colony-forming units per square centimeter (cm²), the following formula was employed:

$$R = \left[\frac{F \left(\frac{\sum c_i}{n} \right) 10^{-D}}{A} \right]$$

WHERE:

- R = the average colony-forming unit count in log₁₀ scale per cm² of sampling surface
F = total number of mL of stripping fluid added to the sampling cylinder; in this study, F = 2.0 mL.
 $\frac{\sum c_i}{n}$ = average of the duplicate colony counts for each sample collected
D = dilution factor of the plate counts
A = inside area of the cylinder in cm²; in this study, A = 3.46 cm².

NOTE: The reason that a log₁₀ transformation was performed on the collected data was to obtain a linear scale. A linear scale, more appropriately a log₁₀ linear scale, is a basic requirement of the statistical models used in this study.

Data Analysis

- 12.2 An Exploratory Data Analysis was performed on the data. Stem-Leaf Ordering, Letter Value Displays, and Box Plots were generated which assured that the data collected approximated the normal distribution. A series of Student's *t* tests were conducted using the 0.05 level of significance for Type I (α) error. Any outlier values were noted.
- 12.3 The log₁₀ reductions were calculated as the difference between the baseline populations per cm² and the post-product exposure populations per cm².

13.0 RESULTS:

13.1 Table I presents the statistical summary of the log₁₀ values.

TABLE I
Statistical Analysis

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Intervals	Log ₁₀ Reduction	Percent Reduction
Baseline	30	5.77	0.12	5.73 to 5.83	N/A	N/A
10 Minute	20	5.05	0.78	4.68 to 5.42	0.72	80.95%
2 Hour	20	5.56	0.47	5.34 to 5.78	0.21	38.34%
4 Hour	20	5.72	0.25	5.60 to 5.83	0.05	10.87%

13.2 The ten-minute sample was significantly different from the baseline sample ($p \leq 0.0007$).

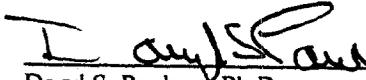
14.0 CONCLUSION:

Pure Rx (Antimicrobial Handwash with 1206 ppm [parts per million] Benzalkonium Chloride) demonstrated a significant persistent antimicrobial effect at 10 minutes, two hours and 4 hours post-product application. The log₁₀ reductions of 0.72 at ten minutes, 0.21 at 2 hours, and 0.05 at 4 hours post-product application were all below that of the baseline sample.

15.0 ACCEPTANCE:

BIOSCIENCE LABORATORIES, INC.
P.O. Box 190
Bozeman, Montana 59771

President & CEO/
Study
Director:



Daryl S. Paulson, Ph.D.

3-10-00
Date

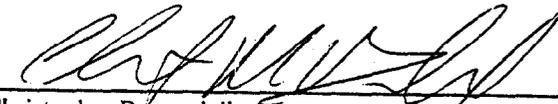
Director of
Laboratories/
Principal
Study Director:



Carol Riccardi

3/10/00
Date

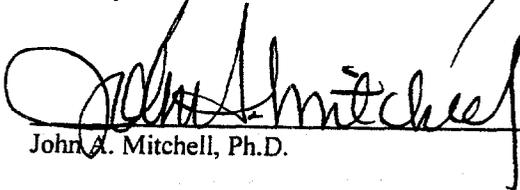
Manager of
Clinical
Laboratories/
Associate Study
Director:



Christopher Beausoleil

5/10/00
Date

Director of
Quality
Assurance:



John A. Mitchell, Ph.D.

3/10/00
Date

INDEX OF ADDENDA

- I Protocol 980907.01
- II CASBA™4 Plate Counter Data Sheets (Form No. 98-L-012) and CASBA®4 Plate Count Data and Calculations
- III Qualification Criteria for the Healthcare Personnel Handwash Studies (Form No. 96-CT-019)
- IV Sample Data Sheets for Protocol 980907
- V Statistical Analysis
- VI Neutralization Evaluation
 - A. Project Notes (Form No. 95-G-001)
 - B. Neutralization Assay Data Sheets (Form No. 91-L-013)
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 - A. Project Notes (Form No. 95-G-001)
 - B. Randomization
 - C. Equipment Tracking Forms (Form No. 98-L-007)
 - D. Incubator Log Forms (Form No. 96-L-008)
 - E. Inoculum Preparation Tracking Forms (Form No. 96-L-016)
 - F. Autoplate 4000 Data Sheet (Form No. 98-L-011)
- VIII Media/Diluent Tracking Form and Media Production and Growth Testing Data Sheets (Form No. 97-L-007 and Form No. 91-L-003)
- IX Log of Samples, Sample Tracking Form, and Sponsor Sample Submission Form (Form No. 92-L-023, Form No. 93-L-029, and Form No. 94-G-007)
- X Qualification Criteria for the Healthcare Personnel Handwash Studies for subjects who did not show up for testing or were dismissed (Form No. 96-CT-019)
- XI Assays of Product for Active Ingredient

FINAL REPORT AMENDMENT FORM

FINAL REPORT TITLE: Evaluation of the Antimicrobial Efficacy of One Lotion Product Formulation
Using the Cylinder Sampling Technique

STUDY NUMBER: 980907.02 REQUESTED BY: J. McDonnell DATE: 03/07/00

SPONSOR: International Laboratory Technology Corporation

REASON(S) FOR AMENDMENT(S): Sponsor requested that all descriptions of Pure Rx as Antimicrobial
Handwash with 0.1% Benzalkonium Chloride be changed to Antimicrobial Handwash with parts per million of
Benzalkonium Chloride; these amendments apply, as well, to all addenda to the Final Report. The parts per million
is obtained from the Kappa Laboratories reports which are added as Addendum XI

APPROVALS:

Daryl Spaul
PRESIDENT AND CEO/ASSOCIATE STUDY DIRECTOR

3 / 10 / 00
DATE

Cheryl M. Kelly
ASSOCIATE STUDY DIRECTOR

3 / 10 / 00
DATE

Carol Guandi
PRINCIPAL STUDY DIRECTOR

3 / 10 / 00
DATE

John Mitchell
QUALITY ASSURANCE

3 / 10 / 00
DATE

David E. Miller
SPONSOR

3 / 13 / 00
DATE

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Form No. 98-G-003
Rev. 2 05/99