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APPENDIX B

Efficacy Evaluation of Triclosan Handwashing Products for Use in the Health Care Environment

**Conducted at Hill Top Biolabs
Miamiville, Ohio**

September 2000

HILL TOP RESEARCH, INC.

REPORT FOR

**EFFICACY EVALUATION OF
HEALTH CARE PERSONNEL HANDWASH PRODUCTS**

HTR STUDY NO. 00-105877-11

January 10, 2001

FOR



BY
HILL TOP RESEARCH, INC.
Main and Mill Sts.
Miamiville, OH 45147

BOOK I

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IMPORTANT NOTICE

1.0 SUMMARY

- The purpose of this study was to determine the ability of antimicrobial hand washing agents to give reduction of transient microbial flora (contaminants) when used in a hand washing procedure with a marker organism, *Serratia marcescens* ATCC 14756.

Seventy-five subjects completed the study.

- Three test articles identified by the sponsor as 3434-9 (HTR Code A), 3434-10 (HTR Code B) and Hibiclens® (HTR Code C) were evaluated in this study.
- The test article evaluated in this study, identified by the sponsor as 3434-9 (HTR Code A), achieved a 3.73 log₁₀ reduction of the marker organism *Serratia marcescens* ATCC 14756 following a single 30-second handwashing procedure. After 11 repetitive washes a 3.97 log₁₀ reduction of the marker organisms was achieved. The second test article evaluated, identified by the sponsor as 3434-10 (HTR Code B), achieved a 3.64 log₁₀ reduction of the marker organism following a single 30-second handwashing procedure and a 3.79 log₁₀ reduction of the marker organism after 11 repetitive washes. The third test article evaluated, identified as Hibiclens® (HTR Code C), achieved a 2.51 log₁₀ reduction of the marker organism following a single 15-second handwashing procedure and a 3.53 log₁₀ reduction of the marker organism after 11 repetitive washes.

2.0 STUDY MONITOR



3.0 INVESTIGATIVE PERSONNEL

Investigator:	Gayle K. Mulberry, M.S.
Sub-Investigators:	Kathleen A. Baxter, B.S. Ann R. Brady, A.S.
Medical Consultant:	E. Linn Jones, M.D., D.A.B.D.
Biostatistician:	James P. Bowman, M.S.
Manager Biostatistics:	Barbara M. Fath

4.0 CLINICAL RESEARCH STANDARDS

The clinical investigation, including the informed consent, was reviewed by an Institutional Review Board in accordance with Title 21 of the Code of Federal Regulations, Parts 50 and 56. Approval by the Board was obtained on September 22, 2000, prior to initiation of the investigation (see Appendix I).

This study was conducted according to applicable Good Clinical Practices and the Standard Operating Procedures of Hill Top Research, Inc.

5.0 PROTOCOL

The Study Protocol was followed (see Appendix II) except for the following deviations:

- Subject No. 45 put their hands in the water prior to receiving the test product HTR Code B at wash 5.
- Subject No. 71, at baseline the inner bag leaked into the outer bag during the massage. The sample was taken from the outer bag.

In the opinion of the Investigator, these deviations did not compromise the integrity of the study.

HTR Study No.: 00-105877-11

5.0 PROTOCOL (CONT.)

The media, dilution fluid and other items used in the study but not defined in the protocol are shown in Appendix III, "Miscellaneous Procedural Information."

6.0 SUBJECTS

One hundred thirty-four (134) subjects were enrolled in the pre-test conditioning phase. Seventy-five (75) subjects, twenty-one (21) males and fifty-four (54) females who met the study criteria were enrolled in the test phase and completed the study.

Fifty-nine (59) subjects were excluded or withdrew from the study. The subject's screening number and reason each subject was excluded or withdrew are shown in Appendix IV.

7.0 STUDY SCHEDULE

Screening/Conditioning Dates:	September 25, 2000
Date Initiated:	October 2, 2000
Date Completed:	November 3, 2000

8.0 TEST ARTICLES

The following test articles were received by Hill Top Research on September 13, 2000.

<u>HTR Code</u>	<u>Sponsor Code</u>	<u>Description</u>	<u>No. of Units</u>
A	3434-9	Green plastic bottle with white plastic pump nozzle unit with liquid inside	10
B	3434-10	Green plastic bottle with white plastic pump nozzle unit with liquid inside	10
C	Hibiclens®, Lot 3107C, Exp: 11/01	Blue-green plastic bottle with white plastic cap with liquid inside	2

Randomization of the assignment of test articles for subject treatment is shown in Appendix V.

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8.0 TEST ARTICLES (CONT.)

Test articles will be returned to sponsor within one week of issuance of final report.

9.0 ADVERSE EVENTS

There were sixteen adverse events reported during the course of the study. (See Appendix VI).

10.0 TEST FOR ADEQUACY OF NEUTRALIZER

A report on testing performed to demonstrate the effectiveness of the antimicrobial neutralizer used in this study is shown in Appendix VII.

11.0 METHOD OF STATISTICAL ANALYSIS

The data were statistically analyzed using analysis of variance methods. The statistical methods are described below.

Bacterial counts recovered from the hands were transformed into \log_{10} counts. The data used in the statistical analysis were the averages of each subject's right and left-hand \log_{10} counts. Analysis of variance techniques were used to:

- Compare the baseline counts of subjects assigned different test articles.
- Evaluate the effectiveness of each treatment as a function of the number of treatments (within treatment analysis using \log_{10} reductions).

Percent reductions of bacterial counts from baseline were also determined.

The test articles used in this study are as follows:

HTR Code A (Lot Code 3434-9)
HTR Code B (Lot Code 3434-10)
HTR Code C (Hibiclens®)

Hypothesis testing was performed at the $\alpha = 0.05$ level.

12.0 RESULTS OF STATISTICAL ANALYSIS

12.1 Baseline Bacterial Log Count Comparison

The source data for the baseline analysis were the average log₁₀ values for the right and left hands of each subject. Potential differences among the treatment groups at baseline were examined using a one-factor analysis of variance procedure.

Mean Log₁₀ Baseline Counts

HTR Code A	HTR Code B	HTR Code C	ANOVA p-value
9.2728	9.2249	9.2141	0.0894 ¹

¹ No significant difference among groups at baseline

12.2 Within-Treatment Analysis

The data (log₁₀ reductions) were evaluated by analysis of variance techniques to determine the existence, if any, of significant differences between test washes for each test article. The log₁₀ average differences from baseline and the p-values from the ANOVA are shown below.

HTR Code	Mean Log ₁₀ Reductions		p-value
	WASH I	WASH II	
HTR Code A (n=30)	3.7302	3.9724	0.0020 ¹
HTR Code B (n=30)	3.6372	3.7912	0.1535
HTR Code C (n=15)	2.5143	3.5326	<0.0001 ¹

¹ Significantly better antimicrobial activity after eleven test washes.

12.3 Percent Reduction of Bacterial Counts

The log reduction and percent reductions of bacterial counts and associated confidence limits are presented below.

HTR Code	Log ₁₀ Reduction	95% Confidence Limits		Percent Reduction	95% Confidence Limits	
		Lower	Upper		Lower	Upper
WASH I						
HTR Code A	3.7302	3.5261	3.9343	99.98%	99.97%	99.99%
HTR Code B	3.6372	3.4608	3.8136	99.98%	99.97%	99.98%
HTR Code C	2.5143	2.3254	2.7032	99.69%	99.53%	99.80%
WASH II						
HTR Code A	3.9724	3.7643	4.1806	99.99%	99.98%	99.99%
HTR Code B	3.7912	3.5489	4.0335	99.98%	99.97%	99.99%
HTR Code C	3.5326	3.3389	3.7263	99.97%	99.95%	99.98%

The Statistical Tables of Results are shown in Appendix VIII.

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13.0 SUBJECT DATA COLLECTION FORMS

The Data Collection Forms for each subject selected for the study are shown in Appendix IX.

Appendix IX-A - Subjects Completing the Study

Appendix IX-B - Subjects Excluded/Withdrawn

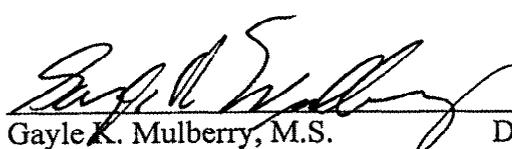
14.0 CONCLUSION

Three test articles, 3434-9 (HTR Code A), 3434-10 (HTR Code B) and Hibiclens® (HTR Code C) were evaluated in this Health Care Personnel Handwash study. Seventy-five (75) subjects completed the study, thirty (30) using HTR Code A, thirty (30) using HTR Code B and fifteen (15) using HTR Code C.

The test article evaluated in this study, identified by the sponsor as 3434-9 (HTR Code A), achieved a 3.73 log₁₀ reduction of the marker organism *Serratia marcescens* ATCC 14756 following a single 30-second handwashing procedure. After 11 repetitive washes a 3.97 log₁₀ reduction of the marker organisms was achieved. The second test article evaluated, identified by the sponsor as 3434-10 (HTR Code B), achieved a 3.64 log₁₀ reduction of the marker organism following a single 30-second handwashing procedure and a 3.79 log₁₀ reduction of the marker organism after 11 repetitive washes. The third test article evaluated, identified as Hibiclens® (HTR Code C), achieved a 2.51 log₁₀ reduction of the marker organism following a single 15-second handwashing procedure and a 3.53 log₁₀ reduction of the marker organism after 11 repetitive washes.

15.0 SIGNATURE

HILL TOP RESEARCH, INC.


Gayle K. Mulberry, M.S.
Investigator

1-10-01
Date

HTR Study No.: 00-105877-11

APPENDIX I

Total number of pages = 13

**IRB Approval Letter, Approved Consent Forms,
Subject Instructions and IRB Membership Directory**

INSTITUTIONAL REVIEW BOARD

OF

HILL TOP RESEARCH, INC.

Nancy J. Pelc, M.D., Chairman

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PAGE NO.	I-1

September 22, 2000

Gayle K. Mulberry, M.S.
Hill Top Research, Inc.
Main and Mill Streets
Miami, OH 45147

Ref: 00-105877-11
Title: PROTOCOL FOR EFFICACY EVALUATION OF HEALTH CARE
PERSONNEL HANDWASH PRODUCTS
Protocol Date: September 19, 2000
Sponsor: [REDACTED]

Dear Mr. Mulberry:

The Institutional Review Board of Hill Top Research, Inc. has reviewed and approved the above referenced study by the expedited review procedure. Documents included in this review were: protocol, consent forms (2), subject instructions (2) and safety information. Approval of this study has been granted for one year from the date of this letter.

Please remember that the FDA requires you to receive approval from the IRB for any amendments or changes in the protocol or consent form and for any new advertisements. Serious and unexpected adverse experiences and unanticipated problems involving risk to subjects must be reported promptly to the IRB. If the study is expected to last beyond the one-year approval, you must request re-approval for continuation at least 30 days in advance of the expiration date.

The Institutional Review Board of Hill Top Research, Inc. is a duly constituted institutional review board under CFR, Title 21, Parts 50 and 56.

Sincerely,

Nancy J. Pelc, M.D.

9-22-00

Nancy J. Pelc, M.D.
Chairman

Date

NJP/rdp

Institution: Hill Top Research, Inc.
Investigator: Gayle K. Mulberry, M.S.
Study Title: "Efficacy Evaluation of Health Care Personnel Handwash Products"

HTR Study No. 00-105877-11
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CONSENT FORM

INTRODUCTION: You are being asked to take part in a research study. Before you give your consent to be a subject, it is important that you take enough time to read and understand what your participation would involve. In preparing this consent form, it has been necessary to use some technical language. Please ask questions if there is anything you do not understand.

You will be given a signed copy of this consent form and any other necessary written information prior to the start of the study.

PURPOSE: The purpose of this research study is to measure the ability of three liquid soap products to reduce the number of bacteria on the hands after repetitive use. Approximately one hundred thirty (130) people between and including the ages of 18 – 65 will be screened as potential subjects in this study. Seventy-five (75) subjects are expected to complete the three-visit study.

TEST ARTICLES: Two of the test articles are experimental antibacterial liquid soap products. The other test article is a marketed antibacterial liquid soap product. One product will be randomly assigned to each participating subject.

STUDY PROCEDURES: Prior to enrollment in the test, you will be asked to complete a brief medical history questionnaire. It is possible that you may not be able to participate based on your answers to these questions. If you qualify, you will be given a kit containing non-antibacterial bar soap, shampoo, Ban® antiperspirant/deodorant, and rubber and poly gloves to be used at least one week prior to the start of the actual study. You will be given written instructions on how to use the kit.

After at least one week, you will be required to return to the lab. You will be asked to complete another brief medical history questionnaire. It is possible that you may not be able to participate based on your answers to these questions or the condition of the skin on your hands and wrists. You will wash your hands with a non-medicated soap. Then, your hands will be contaminated with a watery liquid containing a non-harmful bacteria (*Serratia marcescens*). This liquid containing the bacteria will be spread over the surfaces of the hands, and the hands will be allowed to air dry. Following air drying, the hands will be sampled. Sampling is accomplished by having you place your hands into large plastic bags to which will be added a mild soap-like solution. A laboratory technician will massage each bagged hand for one minute. The hands will be removed from the bags and the solution from each bag will be tested to determine the number of test bacteria added to the hands. Following the baseline sampling, your hands will be rinsed with tap water and

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washed with a non-medicated soap and dried. You will then begin the treatment part of the study. Prior to each treatment, your hands will be contaminated with bacteria as described above. Your hands and wrists will then be treated (washed) with the test material, following specific instructions. Your hands will be contaminated and treated 11 times. Your hands will be sampled (to determine the number of bacteria removed or killed by treatment) after the 1st and 11th washes. After the 1st and 11th sampling wash, the hands are washed with a non-medicated soap. Following the last sampling, your hands will be treated with alcohol, rinsed with water followed by a wash with Hibiclens®, an antimicrobial soap, prior to leaving the lab.

After completing the treatment visit and until your follow-up visit, you will need to check the skin on your hands each day for any pimples, bumps or rashes. Within four to eight days after you have completed treatment, you will be required to return to the lab for a follow-up visit. Your hands will be checked for infection by a Dermatologist trained in observing infection.

FEMALES OF CHILDBEARING POTENTIAL: You may not participate in this study if you are pregnant or nursing. As part of giving your consent you must agree to have a urine pregnancy test at the start of the study.

RISKS: The risks associated with this test are primarily related to contamination with the test bacteria. For healthy persons, the possibility of a skin infection exists; however, this possibility is remote because, (1) test bacteria are applied only to intact skin, and (2) the skin is cleansed with antibacterial products following contact with the test bacteria.

You may also develop a reaction on your hands from the test materials. A reaction could be redness, swelling, itching, cracking, peeling, or in rare cases, blistering.

No risks to you as a study participant, other than those described above, are anticipated during the study. Reactions are usually due to irritation, although an allergic reaction might occur. If you become allergic, it is possible that future exposures to the same ingredient may cause a skin reaction. If this occurs, you will be provided with information to minimize the chance for future exposures.

You may experience risks or side effects that are not known at this time. You will be informed in a timely manner if new information becomes available that may influence your willingness to continue in this study.

BENEFITS: You will not benefit from the applications of test article but the study results may allow a new or improved product to be marketed.

ALTERNATIVE PROCEDURES/TREATMENTS: Because you are not being treated for a medical condition, alternative treatments do not apply to this study.

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CONFIDENTIALITY: Information concerning you that is obtained in connection with this study will be kept confidential by Hill Top Research, except that the sponsoring company whose product is being tested will receive a copy of the study records. The records will be coded to protect your identity. In addition, the Institutional Review Board (IRB) and government regulatory agencies, including the U.S. Food and Drug Administration (FDA), may inspect the records of the study. Information obtained in the study may be used for medical or scientific publication, but your identity will remain confidential.

MEDICAL TREATMENT: If in the course of this study you experience illness, discomfort or injury that appears to be a result of the study, Hill Top Research will provide you with medical care at no cost to you. Providing such medical care is not an admission of legal responsibility. If such illness, discomfort or injury does occur, ask any staff member to arrange a meeting for you with the appropriate personnel.

In certain cases of illness or injury resulting from this study, workers' compensation coverage may be available. In accordance with Ohio law, Hill Top Research has secured workers' compensation coverage for participants in its studies and tests, and has paid and will pay appropriate premiums into the State Insurance Fund on behalf of such participants.

WHO TO CONTACT: If you have any questions about this study or in case of an emergency, contact Glenna, Study Coordinator, at 831-3114 ext. 2920 during business hours (M-F, 8:00 A.M. - 5:00 P.M.) or Ann Brady, Study Manager, at 831-3354 after hours. In addition, if you have any questions as to your rights as a research subject, contact the Institutional Review Board of Hill Top Research, Nancy J. Pelc, M.D., Chairman, at 1-513-831-3114.

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VOLUNTARY PARTICIPATION/WITHDRAWAL: Your participation in this research study is strictly voluntary. You may refuse to participate or may discontinue participation at any time during the study without penalty or loss of benefits to which you are otherwise entitled.

If you agree to participate in this study, you are also agreeing to provide Hill Top Research with accurate information and to follow study instructions as given to you. If you fail to comply with study procedures, your participation may be terminated.

Your participation in the study may be discontinued at any time without your consent by the Investigator, the IRB, the FDA, or the sponsoring company.

COMPENSATION: You will be paid \$80.00 for the completion of this study. You will be compensated according to the following schedule:

If you complete	Visit 1	You will receive	\$0*
If you do not qualify	Visit 2	you will receive	\$10.00
If you qualify but are eliminated as an extra subject	Visit 2	you will receive	\$20.00
If you complete	Visit 2	you will receive	\$50.00
If you complete	Visit 3	you will receive	\$80.00

*No payment-kit products given.

Payments will be made at the end of the study.

There are no anticipated expenses to you for participating in this study. All test related materials will be provided at no cost to you. (Soap, shampoo, roll-on antiperspirant/deodorant and gloves)

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Institution: Hill Top Research, Inc.
Investigator: Gayle K. Mulberry, M.S.

HTR Study No. 00-105877-11

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Study Title: "Efficacy Evaluation of Health Care Personnel Handwash Products"
Neutralizer Validation Study

CONSENT FORM-2

INTRODUCTION: You are being asked to take part in a research study. Before you give your consent to be a subject, it is important that you take enough time to read and understand what your participation would involve. In preparing this consent form, it has been necessary to use some technical language. Please ask questions if there is anything you do not understand.

You will be given a signed copy of this consent form and any other necessary written information prior to the start of the study.

PURPOSE: The purpose of this research study is to assure that the materials used in the main study, for growing and counting bacteria recovered from the hands of subjects, will allow the growth of the bacteria. Approximately three (3) people between and including the ages of 18 - 65 will be screened as potential subjects in this study. Three (3) subjects are expected to complete the one visit study.

TEST ARTICLES: Two of the test articles are experimental antibacterial liquid soap products. The other test article is a marketed antibacterial liquid soap product. One product will be randomly assigned to each participating subject.

STUDY PROCEDURES: As a participant, your hands and wrists will be washed eleven times following specific directions. Your hands will be sampled after the first and eleventh wash. Sampling is accomplished by having you place your hands into large plastic bags to which will be added a mild soap-like solution. A laboratory technician will massage each bagged hand for one minute. Your hands will be removed from the bags and the solution from each bag will be taken to the laboratory. The solution collected after massaging will then be tested to determine if it can be neutralized to allow growth of bacteria, which the laboratory will add to it. Following the sampling, you will rinse your hands and forearms in tap water.

FEMALES OF CHILDBEARING POTENTIAL: You may not participate in this study if you are pregnant or nursing. As part of giving your consent you must agree to have a urine pregnancy test at the start of the study.

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RISKS: Your hands may show a "reaction." A "reaction" could be redness, swelling, itching, cracking or peeling, or in rare cases, small blisters. It is unlikely, but possible, that a rash could develop. No risk to study participants, other than those described above as "reactions" are anticipated during the study. Reactions are usually due to irritation, although an allergic reaction might also occur. If you become allergic, it is possible that future exposures to the same ingredient may cause a skin reaction. If this occurs, you will be provided with information to minimize the chance for future exposures.

BENEFITS: You will not benefit from the applications of test article but the test results may allow a new or improved product to be marketed.

ALTERNATIVE PROCEDURES/TREATMENTS: Because you are not being treated for a medical condition, alternative treatments do not apply to this study.

CONFIDENTIALITY: Information concerning you that is obtained in connection with this study will be kept confidential by Hill Top Research, except that the sponsoring company whose product is being tested will receive a copy of the study data. The data will be coded to protect your identity. In addition, the U.S. Food and Drug Administration (FDA), the Institutional Review Board (IRB), and foreign regulatory agencies may inspect the records of the study. Information obtained in the study may be used for medical or scientific publication, but your identity will remain confidential.

MEDICAL TREATMENT: If in the course of this study you experience illness, discomfort or injury that appears to be a result of the study, Hill Top Research will provide you with medical care at no cost to you. Providing such medical care is not an admission of legal responsibility. If such illness, discomfort or injury does occur, ask any staff member to arrange a meeting for you with the appropriate personnel.

In certain cases of illness or injury resulting from this study, workers' compensation coverage may be available. In accordance with Ohio law, Hill Top Research has secured workers' compensation coverage for participants in its studies and tests, and has paid and will pay appropriate premiums into the State Insurance Fund on behalf of such participants.

WHO TO CONTACT: If you have any questions about this study or in case of an emergency, contact Glenna, Study Coordinator, at 831-3114 during business hours (M-F, 8:00 A.M. - 5:00 P.M.) or Ann Brady, Study Manager, at 831-3354 after hours. In addition, if you have any questions as to your rights as a research subject, contact the Institutional Review Board of Hill Top Research, Nancy J. Pelc, M.D., Chairman, at 1- 513-831-3114.

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VOLUNTARY PARTICIPATION/WITHDRAWAL: Your participation in this research study is strictly voluntary. You may refuse to participate or may discontinue participation at any time during the study without penalty or loss of benefits to which you are entitled.

If you agree to participate in this study, you are also agreeing to provide Hill Top Research with accurate information and to follow study instructions as given to you. If you fail to comply with study procedures, your participation may be terminated.

Your participation in the study may be discontinued at any time without your consent by the Investigator, the IRB, the FDA, or the sponsoring company.

COMPENSATION: You will be paid \$10.00 for the completion of this study.

Payment will be made at the end of the study.

There are no anticipated expenses to you for participating in this study. All test related materials will be provided at no cost to you.

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Approved**

EXHIBIT B**EVALUATION OF HEALTH CARE PERSONNEL HANDWASH
SUBJECT INSTRUCTIONS**

Today you will be given a kit of products (bar soap, shampoo, and deodorant/antiperspirant) to use exclusively during this study. Please set aside all products you normally use in these categories and use only the products in the kit. In addition, please refrain from using perfumes, deodorants or antiperspirants (other than the ones furnished), powders and anti-dandruff hair shampoos, and do not swim in a chlorinated pool or hot tub during the study.

Beginning today, no body lotions, medicated creams or ointments should be applied to any area of your skin. Also, do not take any antibiotics. These medications may affect the bacteria of the skin. If antibiotics are necessary due to illness, please report this to Hill Top Research at the phone number below.

Please use the rubber gloves provided with the product kit for all household chores involving detergents, acid, alkalis, and solvents until the completion of the study.

SUBJECT SCHEDULE**TEST DAY**

Time of Visit: _____

1. Plan to arrive at the laboratory about 10 minutes before your scheduled time. You are expected to be prompt.
2. Please wear clothing that will allow easy access to your hands.
3. You will be required to remove all jewelry, watches, and bracelets before washing.
4. You will undergo a supervised wash regimen at the laboratory.
5. Approximate time at the laboratory - hours.
6. Additional instructions will be provided for the Follow Up Visit.

FOLLOW UP VISIT

Time of Visit: _____

1. A Dermatologist will check your hands for infection
2. Approximate time at the lab - 1/2 hour.

If you have any questions regarding this study, please contact Glenna, Study Coordinator, at 831-3114 ext. 2920 between 8:00 a.m. - 5:00 p.m. or Ann Brady, Study Manager, after hours and on weekends at 831-3354.

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EXHIBIT C

SUBJECT'S INSTRUCTIONS FOLLOWING STUDY COMPLETION

You have just completed participation in a clinical study, "Efficacy Evaluation of Health Care Personnel Handwash Products". During this study, your hands were in contact with a liquid containing bacteria (*Serratia marcescens*). Although we do not expect you to have any adverse experience as a result of participation in this study, there is a remote possibility that an infection may develop on your hands.

To determine whether you have developed an infection from the test bacteria, we would like you to examine your hands and wrists daily. If you notice the appearance of any pimples, blisters or raised bumps surrounded by redness and/or swelling, please contact Glenna, Study Coordinator at (513) 831-3114 during normal business hours (8:00 am- 5 pm) or Ann Brady at (513) 831-3354 after hours.

You are required to return to the test site for a follow-up visit. Your follow-up is scheduled for:

Date

Time

Thank you for your cooperation.

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Hill Top Research**

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**INSTITUTIONAL REVIEW BOARD
OF
HILL TOP RESEARCH, INC.**

Nancy J. Pelc, M.D., Chairman

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MEMBERSHIP DIRECTORY

Core Members

Nancy J. Pelc, M.D. (Chairman)
Dermatologist

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Consultant, Pathology and Toxicology

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Richard D. Hubbard
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(Nonscientific member)

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Dermatologist

Judith A. Summerlin, B.S.
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Hill Top Research, Inc.
(Nonscientific member)

Saul S. Bloomfield, M.D.
Consultant, Clinical Pharmacology

Alternate Members

Richard K. Bath, M.D.
Medical Director
Hill Top Research, Inc./Kenwood
(Alternate for Dr. Pelc, Dr. Adams or Dr. Bloomfield)

Shirley L. Lowe, B.A.
IRB Administrator
Hill Top Research, Inc.
(Nonscientific alternate member)

Edwin V. Buehler, Ph.D.
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(Alternate for Dr. Gibson)

Phyllis Wene
Bookkeeper
(Nonscientific alternate member)

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Carol Eory, R.N.
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8/99

HTR Study No.: 00-105877-11

APPENDIX II

Total number of pages = 35

Protocol

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HILL TOP RESEARCH, INC.

**PROTOCOL FOR
EFFICACY EVALUATION OF
HEALTH CARE PERSONNEL HANDWASH PRODUCTS**

FOR:



HTR STUDY NO.: 00-105877-11

HTR Study No.:00-105877-11

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EXHIBITS

- Exhibit A: Sample Consent Form
- Exhibit B: Subject Instructions - Handwash Study
- Exhibit C: Subject Instructions Following Study Completion

DATA COLLECTION FORMS

- 1 Demographics/Dermatological/Medical History Form
- 2 Inclusion/Exclusion Form
- 3 Intercurrent Illness/Concomitant Medication Form
- 4 Health Care Personnel Handwash Bacterial Counts
- 5 Adverse Event Report
- 6 Follow up Visit

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1.0 INTRODUCTION

The FDA issued a tentative final monograph (Federal Register, Vol. 59, pp. 31402 to 31452, June 17, 1994) prescribing the use of a health care personnel handwash method to demonstrate the antimicrobial efficacy of cleansing products containing antimicrobial ingredients for frequent use.

The required procedure is a modification of ASTM E-1174-87 (The Annual Book of ASTM Standards, Vol. 11.04, pp. 209-212, 1987). This protocol is aligned with a revised version of the ASTM Method currently under consideration within ASTM Technical Committee E-35.15.

The procedure is designed to simulate routine hand washing conducted for the purpose of reducing the level of hand contamination of health care personnel under conditions of frequent use. For this procedure a broth culture of *Serratia marcescens*, ATCC 14756, is used as an artificial contaminant bacteria on the hands. Activity is measured by comparing the number of marker bacteria removed from artificially contaminated hands after a single use of the hand washing formulation to the baseline number, the number recovered from contaminated unwashed hands. A similar comparison is made following the 11th wash of a multiple (11) wash procedure. Prior to each of the washes, the hands are artificially contaminated with the *S. marcescens*.

The method described in this protocol eliminates a shortcoming common to the Proposed Monograph version of the method and the current ASTM version of the method, E1174-94. Both of these methods fail to provide procedures to assure adequate rapid neutralization of the antimicrobial in the handwash formulation. A neutralizer is only included in the hand sampling fluid used to sample the last wash and is omitted from the hand sampling fluid used to sample washes preceding the final wash. This failure to include neutralizers in the hand sampling fluid may provide data that falsely exaggerates the effectiveness of the antimicrobial handwash formulation. This issue is resolved in this protocol by requiring immediate neutralization in the hand sampling fluid at all sampling points.

2.0 OBJECTIVE

The purpose of this study is to determine the ability of antimicrobial hand-washing agents to give reduction of transient microbial flora (contaminants) when used in a hand washing procedure with a marker organism.

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3.0 STUDY SPONSOR AND MONITOR



REPRESENTATIVE: 

4.0 INVESTIGATIVE ORGANIZATION AND PERSONNEL

Hill Top Research, Inc.
Main and Mill Streets
Miami, Ohio 45147
Telephone No.: (513) 831-3114
Fax No.: (513) 831-1217

Investigator: Gayle K. Mulberry, M.S.
Technical Director
Microbiological Services

Sub-Investigators: Kathleen A. Baxter, B.S.
Ann R. Brady, A.S.

Medical Consultant: E. Linn Jones, M.D., D.A.B.D.

5.0 CLINICAL RESEARCH STANDARDS

The clinical investigation, including the informed consent, will be reviewed by an Institutional Review Board in accordance with Title 21 of the Code of Federal Regulations, Parts 50 and 56. Written approval by the Board must be obtained prior to the initiation of the study.

The study will be conducted in compliance with the Good Clinical Practice Regulations, the Standard Operating Procedures of Hill Top Research, Inc., the Sponsor's protocol and protocol amendment(s).

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6.0 EXPERIMENTAL DESIGN

This will be a three sample (test article) study utilizing a direct paired comparison test design of baseline bacterial populations vs. post treatment bacterial populations. The study will consist of a one-week pretest conditioning period and one day of treatment. Seventy-five (75) subjects are expected to start and complete the study, thirty (30) using HTR Code A, thirty (30) using HTR Code B and fifteen (15) using HTR Code C.

7.0 STUDY MATERIAL

7.1 Test Article

<u>HTR Code</u>	<u>Code and Description</u>	
A	<u>Test Formulation:</u>	Foaming handwash
	<u>Lot Code:</u>	3434-9
	<u>Description:</u>	thin colorless liquid
B	<u>Test Formulation:</u>	Foaming handwash
	<u>Lot Code:</u>	3434-10
	<u>Description:</u>	thin colorless liquid
C	<u>Control Formulation:</u>	Hibiclens
	<u>Lot Code:</u>	3107C exp. 11/01
	<u>Description:</u>	clear red liquid

7.2 Equipment

7.2.1 Colony Counter - Quebec colony counter.

7.2.2 Incubator - Any incubator capable of maintaining a temperature of $25 \pm 2^\circ\text{C}$ may be used.

7.2.3 Sterilizer - Any suitable steam sterilizer capable of producing the conditions of sterilization.

7.2.4 Timer (stop-clock) - One that can be read for hours, minutes and seconds.

7.2.5 Plastic Bags to Sample Hands - Low bioburden - Glad Food Storage Bags, 29.2 cm x 31.8 cm. (Note: Bioburden is determined according to Hill Top Microbiology Department SOP No. 11-TOPC-20-0016A.)

7.2.6 Bacteriological Pipettes, Sterile - 10.0 mL, 5.0 mL, 2.0 mL and 1.0 mL capacity.

7.2.7 Water Dilution Bottles - Any container that can be sterilized, having a 150 to 200 mL capacity and a tight closure may be used.

7.2.8 Test Tubes and Closures - Any of suitable size.

7.2.9 Handwashing Sink - A sink of sufficient size to permit subjects to wash without touching hands to sink surface or other subjects.

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7.0 STUDY MATERIAL (CONT.)

7.2 Equipment (Cont.)

- 7.2.10 Water faucets - located above the sink at a height, which permits the hands to be held higher than the elbow during the washing procedure.
- 7.2.11 Tap Water Temperature Regulator and Temperature Monitor - To monitor and regulate water temperature of $40 \pm 2^\circ\text{C}$.
- 7.2.12 Erlenmeyer Flask - 2 L capacity for culturing test organism.

7.3 Reagents and Materials

- 7.3.1 Kit Products for Washout Period: non-antimicrobial bar soap and shampoo, roll on antiperspirant/deodorant, rubber gloves, and disposable poly gloves.
 - 7.3.2 Baby San® liquid castile soap. Ecolab Inc.
 - 7.3.3 Stripping Fluid with Neutralizer - 0.075M phosphate buffer with 0.1% Triton X-100 (dissolve 0.41 g KH_2PO_4 , 10.3 g Na_2HPO_4 and 1.0 g Triton X-100 in 1-L distilled water containing an inactivator which rapidly quenches the antimicrobial activity of the test article(s). Final pH 7.8 ± 0.1 . Final volume 75 ± 1.0 mL).
 - 7.3.4 Dilution Fluid - Butterfield's phosphate buffered water (or other suitable diluent) containing an antimicrobial inactivator specific for the test formulation.
 - 7.3.5 Plating Medium - Trypticase Soy Agar
 - 7.3.6 Tryptic Soy Broth (BBL or Difco)
- 7.4 Test Microorganism
Serratia marcescens, ATCC 14756 is to be used as a marker organism.

8.0 STUDY POPULATION

An adequate number of potential subjects will be enrolled into the pre-test conditioning period in order to provide 75 subjects who fulfill the criteria described below and who complete the study. The subjects will be randomly assigned to three treatment groups, one for each test article. Subject eligibility will be based upon information provided in the Demographics/Dermatological/ Medical History Form (DCF 1) and the Inclusion/Exclusion Form (DCF 2); and completion of a written informed consent (Exhibit A).

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8.0 STUDY POPULATION (CONT.)

8.1 Subject Inclusion Criteria

Subjects will be eligible for enrollment if they:

- 8.1.1 Are a male or female, 18 through 65 years old;
- 8.1.2 Have signed a written informed consent (Exhibit A);
- 8.1.3 Are in good health, as evidenced by response to the Demographics/Dermatological/Medical History Form (DCF 1);
- 8.1.4 Have hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders;
- 8.1.5 Have fingernails that are clean and extend no longer than approximately one (1) mm past the nail bed;
- 8.1.6 Are willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and hand washing during the entire study;
- 8.1.7 Are willing to refrain from using anti-dandruff shampoo during the entire study;
- 8.1.8 Are willing to refrain from using medicated/antibacterial lotions and creams during the entire study, unless prescribed by a physician for an intercurrent illness;
- 8.1.9 Are willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness;
- 8.1.10 Are willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness; and
- 8.1.11 Are willing to comply with all study protocol requirements.

8.2 Subject Exclusion Criteria

Subjects will not be enrolled in the study if they:

- 8.2.1 Are currently participating in another clinical study at this or any other facility;
- 8.2.2 Have participated in any type of arm or hand wash study within the past seven (7) days;
- 8.2.3 Have cuts, scratches, or other skin disorders on their hands or wrists;
- 8.2.4 Have soap, detergent, and/or perfume allergies;
- 8.2.5 Have eczema or psoriasis on their hands or wrists;
- 8.2.6 Are currently pregnant;
- 8.2.7 Are currently lactating;
- 8.2.8 Have been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, or AIDS (or HIV positive); and/or
- 8.2.9 Have any other medical condition, which in the opinion of the Investigator(s) would preclude participation.
- 8.2.10 Have artificial nails or nail tips.

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8.0 STUDY POPULATION (CONT.)

8.3 Other Study Restrictions

- 8.3.1 Subjects should avoid using any other personal cleansing products except those provided by Hill Top Research, Inc.
- 8.3.2 Subjects should avoid hot tubs and swimming.
- 8.3.3 Subjects should avoid exposing their hands to harsh cleaning products, chlorine, or solvents.

9.0 SUBJECT WITHDRAWAL

After admission to the study, the subject may withdraw at any time for any reason. If possible, the reason for withdrawal will be recorded.

10.0 PROCEDURE

The study will be divided into three phases; subject enrollment period, a pre-test washout (conditioning) period of at least one week duration, and a one day test period.

10.1 Subject Qualification and Enrollment

Prospective subjects will visit the test facility to be screened for their eligibility to participate in the study. Eligibility will be based upon information provided in the Demographics/Dermatological/ Medical History Form (DCF 1) and the Inclusion/Exclusion Form (DCF 2); and completion of a written informed consent (Exhibit A). Qualified subjects will be given non-antibacterial containing soap, shampoo, roll-on-antiperspirant/deodorant, several pairs of disposable poly gloves, a pair of rubber gloves, a copy of the Subject's Study Instructions (Exhibit B). They will be instructed to use the soap, shampoo, antiperspirant/deodorant, poly gloves and rubber gloves and to follow the written instructions for the entire study period.

10.2 Washout Period

This period will last at least seven (7) days. Subjects will be expected to follow the study restrictions, use the non-antibacterial soap, shampoo, and antiperspirant/deodorant, rubber gloves and poly gloves.

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10.0 PROCEDURE (CONT.)

10.3 Test Day Schedule

On the day of the test period, subjects will return to the test facility. Their hands and wrists will be re-examined to ensure that they are still free of cuts, lesions, and other skin disorders. They will also be asked if they have had any illnesses or taken any medications (proprietary or prescribed) ordered by a physician since the last visit (DCF 3). Subjects who still meet the study criteria will be eligible to continue on the study. Subjects continuing on the study will be assigned a permanent subject number.

The following outlines the schedule of procedures for the test day:

- a. Subjects will wash with a mild soap for 15 seconds. (Section 10.3.1)
- b. Subjects' hands will be contaminated and baseline sampling performed. (Section 10.3.2)
- c. Subjects' hands treated with the test articles, each treatment preceded by hand contamination. (Section 10.3.3)
- d. Following treatments 1 and 11, subjects hands are sampled for post-treatment count and the *S. marcescens* in the sampling fluid enumerated. (Sections 10.3.5 and 10.3.6).
- e. Following each sampling of subject's hands the hands are washed with castile soap (7.3.2) and rinsed.
- f. After the hand sampling following treatment 11, the Subjects' hands will be rinsed with 70% Isopropyl Alcohol (Section 10.3.7) rinsed with water and washed with Hibiclens upon completing the castile soap wash.

10.3.1 Conditioning Wash

All subjects, prior to the baseline sampling perform a 15-second wash using a non-antimicrobial liquid soap, Baby San® (Section 7.3.2). This procedure, described below, removes oil and dirt and familiarizes the subjects with the treatment procedure.

- 10.3.1.1 Five mL of Baby San® Soap is dispensed into cupped hands and distributed over all surfaces of the hands taking care not to lose the substance.
- 10.3.1.2 After the material is spread, a small amount of tap water $40 \pm 2^\circ\text{C}$ is added, and the hands and lower third of the forearms are completely lathered for 15 seconds in a vigorous manner.
- 10.3.1.3 The hands and forearms are then rinsed under running tap water $40 \pm 2^\circ\text{C}$ for 30 seconds.
- 10.3.1.4 The hands are thoroughly dried with a disposable paper towel.

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10.0 PROCEDURE (CONT.)

10.3.2 Baseline Bacteria Count

After completing the conditioning wash, a total volume of 4.5 mL of *S. marcescens*, ATCC 14756 suspension (Section 10.4), (minimum of 10^8 organisms per mL) is added into the subjects' cupped hands in 1.5 mL increments. After each 1.5 mL aliquot is added, the suspension is rubbed thoroughly over the surface of both hands, not going above the wrist. Each application and spreading should last approximately twenty (20) seconds. Between each aliquot the hands will be held away from the body and allowed to air dry for approximately thirty (30) seconds. Following the third 1.5mL aliquot the hands are held motionless away from the body and allowed to air dry for 90 ± 5 seconds.

(NOTE: The hands may not be completely dry at this time.)

Plastic bags having documented low bioburden, (Section 7.2.5) are placed on the subject's right and left hands. A 75 mL aliquot of stripping solution (Section 7.3.3) is aseptically added into each bag and the bacterial sampling procedure is carried out as described under Section 10.3.5 (Bacterial Sampling Procedure). The hands and forearms are then washed thoroughly with castile soap (Section 7.3.2) and dried.

10.3.3 Multiple Treatment Procedure

Prior to each treatment, the subject's hands will be contaminated with 4.5 mL of the *S. marcescens* suspension-as described in Section 10.3.2

After completing the contamination step, the subjects perform a treatment with the assigned test article, under close supervision. The treatment procedure follows that described in the Section 10.3.4 (Method for Treating Hands). The lower third of the forearm is to be included in the wash procedure.

This procedure is repeated a total of 11 times with at least five minutes between each treatment. Within five (5) minutes of completing the 1st and 11th treatments, the hands are sampled as described in Section 10.3.5 (Bacterial Sampling Procedure).

10.3.4 Method for Treating Hands

10.3.4.1 Test Article HTR Code A and HTR Code B- Dispense two (2) pumps (3.2 mL) from the test article container into cupped palm of one hand and distribute over all surfaces of both hands. The material is worked vigorously over all surfaces of the hands and lower third of the forearm for thirty (30) seconds. (A small amount of water may be added to moisten the hands if necessary after approximately 15 seconds.) Particular attention is to be paid to the area between the fingers, beneath the nails and around the thumb. Rinse hands under running tap water for 30 seconds.

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10.0 PROCEDURE (CONT.)

10.3.4.2 Test Article HTR Code C - Immediately prior to treating the hands are to be wetted with small amount of water by passing hands rapidly under the tap. Dispense 5.0 ml from a syringe into cupped palm of one hand and distribute over all surfaces of both hands. The material is worked vigorously over all surfaces of the hands and lower third of the forearm for fifteen (15) seconds. Particular attention is to be paid to the area between the fingers, beneath the nails and around the thumb. Rinse hands under running tap water for 30 seconds.

NOTE: After treatments that are not followed by a sample collection, the subjects will thoroughly dry their hand and forearms with a disposable paper towel.

10.3.5 Bacterial Sampling Procedure

Plastic bags having low bioburden (Section 7.2.5) will be placed on the subject's right and left hands. A 75 mL aliquot of stripping fluid with neutralizer (Section 7.3.3) is aseptically added into each bag. The bag on each hand is secured and massaged for one minute in a uniform manner by a lab technician. An aliquot of the fluid is aseptically obtained directly from the bagged hands within one minute of completing the massaging and immediately placed into tubes containing sterile Dilution Fluid (Section 7.3.4).

Fluid samples for bacteria counts are to be labeled by an Investigator derived code so that the individuals who prepare the plates and count the colonies are unaware of the sources of the sampling solution.

After each bacterial sampling, subjects will wash their hands under running warm tap water $40 \pm 2^\circ\text{C}$ with 5 mL of castile soap (7.3.2) to help remove residual stripping fluid.

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10.0 PROCEDURE (CONT.)

10.3.6 Bacterial Counts of Sampling Solution

Aliquots of the stripping fluid or dilutions of the fluid are spread plated in duplicate on Trypticase Soy Agar plates (Section 7.3.5).

The dilutions of the baseline sample plated represent dilutions of 10^{-4} through 10^{-6} of milliliter aliquots of the stripping fluid. The aliquots or dilutions of the treatment sample fluid plated represent dilutions of 10^{-1} through 10^{-4} milliliter aliquots of the stripping fluid.

The prepared plates are to be incubated for 48 ± 4 hours at $25 \pm 2^{\circ}\text{C}$. Standard plate counting procedures are used to count only red pigmented colonies. The actual plate counts are recorded on the form entitled Handwash Bacterial Count Form (Data Collection Form 4).

10.3.7 Disinfection of Hands

After the final sampling is completed, subjects' hands and wrists will be treated for at least thirty (30) seconds with 70% Isopropyl Alcohol, rinsed with water, then washed for at least 60 seconds with 5 mL of Hibiclens.

To ensure that any delayed adverse events, such as primary skin infections, are reported to the Study Investigator, all test subjects will be given a copy of Subjects' Instructions Following Study Completion (Exhibit C) before leaving the clinical site after they have completed the study. This sheet will instruct the subjects to examine their hands daily until the final scheduled visit for the presence of pimples, blisters, or raised, red itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection. Subjects, who notice such lesions, will be instructed to call the clinical test site. The subjects will return to the clinical test site within eight (8) days after the study procedures have been completed to have their hands examined by the Medical Consultant. The Medical Consultant will complete Data Collection Form 6 for each subject on their follow-up visit.

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10.0 PROCEDURE (CONT.)

10.4 Marker Organism and Preparation

S. marcescens, ATCC 14756 will be used to challenge the efficacy of the test materials.

A stock culture of *S. marcescens*, ATCC 14756 is prepared by aseptically transferring one colony from an agar plate or slant to 10 mL of sterile Tryptic Soy Broth (TSB) (Section 7.3.6) which is then incubated at $25 \pm 2^\circ\text{C}$ for 24 ± 4 hours. A series of at least three but no more than 10 additional 24 hour broth transfers are made in 10 mL of TSB from this broth culture.

A 2-liter flask containing 1000 mL of TSB is inoculated with 1.0 mL of a 24-hour broth transfer. The flask is incubated for 24 ± 4 hours at $25 \pm 2^\circ\text{C}$. Prior to any withdrawal of culture, whether for hand contamination or for numbers assay, the suspension is stirred or shaken. A suspension is not used for more than eight hours.

The suspension is assayed for the number of organisms at the beginning and end of the use period.

11.0 DATA EVALUATION

The number of colony forming units (CFU) recovered per sample dilution will be tabulated. The total number of CFU per mL of sampling solution will be calculated as well as the number per hand.

The data will be evaluated using parametric statistical analyses as follows:

Bacterial counts recovered from the hands will be transformed into log counts. The log count of each subjects left and right hand will be averaged. The changes from baseline counts at each sampling interval will be obtained for each test article.

An analysis of variance will be performed on the data to:

Compare baseline counts of subjects assigned different test articles.

Evaluate the effectiveness of each treatments as a function of the number of treatments (within treatment analysis).

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12.0 ADVERSE EXPERIENCES

12.1 Definitions

An **Adverse Event/Experience/Experience** is any unexpected or undesirable experience occurring to a subject during a study, which may or may not be related to the test article. All adverse event/experiences will be recorded (Data Collection Form 5) and reported according to the Standard Operating Procedures of Hill Top Research, Inc.

A **Serious Adverse Drug Event/Experience** is any adverse drug experience occurring at any dose that results in any of the following outcomes:

- death;
- a life-threatening adverse drug experience;
- inpatient hospitalization or prolongation of existing hospitalization;
- a persistent or significant disability/incapacity;
- a congenital anomaly/birth defect

Important medical event/experiences that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

An **Unexpected Adverse Drug Event/Experience** is any adverse drug event/experience not listed in the current labeling for the test article or the current investigator's brochure

12.2 Follow-up

If an **Adverse Event/Experience** occurs, the subject under the direction of the Investigator (or designee), may be referred to Hill Top's consultant physician for treatment.

Serious or Unexpected Drug Event/Experience will be followed to resolution to the extent possible (e.g., medical attention by subject's primary care physician).

12.3 Notification

The sponsor will be notified of all adverse event/experiences. Any **Serious or Unexpected Adverse Drug Event/Experience** which occurs during the study must be reported promptly by the investigator to the sponsor and the reviewing IRB, where applicable, within 24-hours of the information being reported to Hill Top Research, Inc.

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13.0 INTERCURRENT ILLNESS REPORTING

If a subject reports that he/she has had an intercurrent illness during the wash-out period or during the one (1) day test period, the illness and any new medication taken will be documented on DCF 3. The subject may be discontinued from the study at the discretion of the Investigator(s).

14.0 CONCOMITANT MEDICATION

If the subject has taken any medication (proprietary or prescribed) ordered by a physician, information pertaining to that medication intake will be recorded appropriately on either DCF 3 or DCF 5.

15.0 DEVIATIONS FROM PROTOCOL

Any minor deviations from the protocol, not previously agreed to by the Sponsor and Investigator(s), that occur during the conduct of the study will be documented.

16.0 REPORT

The final report will summarize the method, data and conclusions relative to the test articles and the subjects. Source data will be retained by the testing facility on microfilm. The original source data will be maintained according to the investigator's standard operating procedure. A copy of the source documents may be obtained upon request of the Study Sponsor. Copies of transcribed data will be incorporated in the report.

17.0 NOTICE

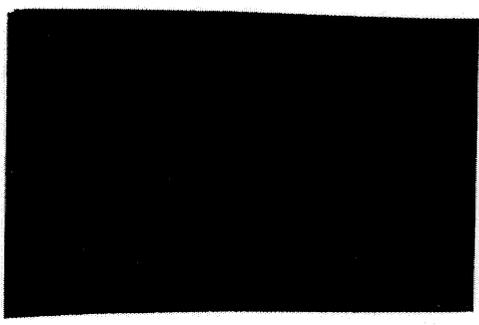
No amendments to the protocol will be permitted without approval from the Study Sponsor, Investigator and where applicable, the Institutional Review Board. Such changes will be documented in writing. Approval by the Board must be obtained prior to initiation of the amendment.

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18.0 PROTOCOL APPROVAL

HILL TOP RESEARCH, INC.

By: *Gayle K. Mulberry* 9-19-00
Gayle K. Mulberry (Date)
Investigator



-20 September 2000
(Date)

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EXHIBIT A
SAMPLE CONSENT FORM

Institution: Hill Top Research, Inc.
Investigator: Gayle K. Mulberry, M.S.
Study Title: "Efficacy Evaluation of Health Care Personnel Handwash Products"

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CONSENT FORM

INTRODUCTION: You are being asked to take part in a research study. Before you give your consent to be a subject, it is important that you take enough time to read and understand what your participation would involve. In preparing this consent form, it has been necessary to use some technical language. Please ask questions if there is anything you do not understand.

You will be given a signed copy of this consent form and any other necessary written information prior to the start of the study.

PURPOSE: The purpose of this research study is to measure the ability of two liquid soap products to reduce the number of bacteria on the hands after repetitive use. Approximately one hundred thirty (130) people between and including the ages of 18 – 65 will be screened as potential subjects in this study. Seventy-five (75) subjects are expected to complete the three-visit study.

TEST ARTICLES: Two of the test articles are experimental antibacterial liquid soap products. The other test material is a marketed antibacterial liquid soap product. One product will be randomly assigned to each participating subject.

STUDY PROCEDURES: Prior to enrollment in the test, you will be asked to complete a brief medical history questionnaire. It is possible that you may not be able to participate based on your answers to these questions. If you qualify, you will be given a kit containing non-antibacterial bar soap, shampoo, Ban® antiperspirant/deodorant, and rubber and poly gloves to be used at least one week prior to the start of the actual study. You will be given written instructions on how to use the kit.

After at least one week, you will be required to return to the lab. You will be asked to complete another brief medical history questionnaire. It is possible that you may not be able to participate based on your answers to these questions or the condition of the skin on your hands and wrists. You will wash your hands with a non-medicated soap. Then, your hands will be contaminated with a watery liquid containing a non-harmful bacteria (*Serratia marcescens*). This liquid containing the bacteria will be spread over the surfaces of the hands, and the hands will be allowed to air dry. Following air drying, the hands will be sampled. Sampling is accomplished by having you place your hands into large plastic bags to which will be added a mild soap-like solution. A laboratory technician will massage each bagged hand for one minute. The hands will be removed from the bags and the solution from each bag will be tested to determine the number of test bacteria added to the hands. Following the baseline sampling, your hands will be rinsed with tap water and

washed with a non-medicated soap and dried. You will then begin the treatment part of the study. Prior to each treatment, your hands will be contaminated with bacteria as described above. Your hands and wrists will then be treated (washed) with the test material, following specific instructions. Your hands will be contaminated and treated 11 times. Your hands will be sampled (to determine the number of bacteria removed or killed by treatment) after the 1st and 11th washes. After the 1st and 11th sampling wash, the hands are washed with a non-medicated soap. Following the last sampling, your hands will be treated with alcohol, rinsed with water followed by a wash with Hibiclens®, an antimicrobial soap, prior to leaving the lab.

After completing the treatment visit and until your follow-up visit, you will need to check the skin on your hands each day for any pimples, bumps or rashes. Within four to eight days after you have completed treatment, you will be required to return to the lab for a follow-up visit. Your hands will be checked for infection by a Dermatologist trained in observing infection.

FEMALES OF CHILDBEARING POTENTIAL: You may not participate in this study if you are pregnant or nursing. As part of giving your consent you must agree to have a urine pregnancy test at the start of the study.

RISKS: The risks associated with this test are primarily related to contamination with the test bacteria. For healthy persons, the possibility of a skin infection exists; however, this possibility is remote because, (1) test bacteria are applied only to intact skin, and (2) the skin is cleansed with antibacterial products following contact with the test bacteria.

You may also develop a reaction on your hands from the test materials. A reaction could be redness, swelling, itching, cracking, peeling, or in rare cases, blistering.

No risks to you as a study participant, other than those described above, are anticipated during the study. Reactions are usually due to irritation, although an allergic reaction might occur. If you become allergic, it is possible that future exposures to the same ingredient may cause a skin reaction. If this occurs, you will be provided with information to minimize the chance for future exposures.

You may experience risks or side effects that are not known at this time. You will be informed in a timely manner if new information becomes available that may influence your willingness to continue in this study.

BENEFITS: You will not benefit from the application of test product but the study results may allow a new or improved product to be marketed.

ALTERNATIVE PROCEDURES/TREATMENTS: Because you are not being treated for a medical condition, alternative treatments do not apply to this study.

CONFIDENTIALITY: Information concerning you that is obtained in connection with this study will be kept confidential by Hill Top Research, except that the sponsoring company whose product is being tested will receive a copy of the study records. The records will be coded to protect your identity. In addition, the Institutional Review Board (IRB) and government regulatory agencies, including the U.S. Food and Drug Administration (FDA), may inspect the records of the study. Information obtained in the study may be used for medical or scientific publication, but your identity will remain confidential.

MEDICAL TREATMENT: If in the course of this study you experience illness, discomfort or injury that appears to be a result of the study, Hill Top Research will provide you with medical care at no cost to you. Providing such medical care is not an admission of legal responsibility. If such illness, discomfort or injury does occur, ask any staff member to arrange a meeting for you with the appropriate personnel.

In certain cases of illness or injury resulting from this study, workers' compensation coverage may be available. In accordance with Ohio law, Hill Top Research has secured workers' compensation coverage for participants in its studies and tests, and has paid and will pay appropriate premiums into the State Insurance Fund on behalf of such participants.

WHO TO CONTACT: If you have any questions about this study or in case of an emergency, contact Glenna, Study Coordinator, at 831-3114 ext. 2920 during business hours (M-F, 8:00 A.M. - 5:00 P.M.) or Ann Brady, Study Manager, at 831-3354 after hours. In addition, if you have any questions as to your rights as a research subject, contact the Institutional Review Board of Hill Top Research, Nancy J. Pelc, M.D., Chairman, at 1-513-831-3114.

VOLUNTARY PARTICIPATION/WITHDRAWAL: Your participation in this research study is strictly voluntary. You may refuse to participate or may discontinue participation at any time during the study without penalty or loss of benefits to which you are otherwise entitled.

If you agree to participate in this study, you are also agreeing to provide Hill Top Research with accurate information and to follow study instructions as given to you. If you fail to comply with study procedures, your participation may be terminated.

Your participation in the study may be discontinued at any time without your consent by the Investigator, the IRB, the FDA, or the sponsoring company.

COMPENSATION: You will be paid \$80.00 for the completion of this study. You will be compensated according to the following schedule:

If you complete	Visit 1	You will receive	\$0*
If you do not qualify	Visit 2	you will receive	\$10.00
If you qualify but are eliminated as an extra subject	Visit 2	you will receive	\$20.00
If you complete	Visit 2	you will receive	\$50.00
If you complete	Visit 3	you will receive	\$80.00

*No payment-kit products given.

Payments will be made at the end of the study.

There are no anticipated expenses to you for participating in this study. All test related materials will be provided at no cost to you. (Soap, shampoo, roll-on antiperspirant/deodorant and gloves)

Institution: Hill Top Research, Inc.
Investigator: Gayle K. Mulberry, M.S.
Study Title: "Efficacy Evaluation of Health Care Personnel Handwash Products"
- Neutralizer Validation Study

HTR Study No. 00-105877-11
Page No. II-23

CONSENT FORM-2

INTRODUCTION: You are being asked to take part in a research study. Before you give your consent to be a subject, it is important that you take enough time to read and understand what your participation would involve. In preparing this consent form, it has been necessary to use some technical language. Please ask questions if there is anything you do not understand.

You will be given a signed copy of this consent form and any other necessary written information prior to the start of the study.

PURPOSE: The purpose of this research study is to assure that the materials used in the main study, for growing and counting bacteria recovered from the hands of subjects, will allow the growth of the bacteria. Approximately two (2) people between and including the ages of 18 - 65 will be screened as potential subjects in this study. Two (2) subjects are expected to complete the one visit study.

TEST ARTICLES: Two of the test articles are experimental antibacterial liquid soap products. The other test material is a marketed antibacterial liquid soap product. One product will be randomly assigned to each participating subject.

STUDY PROCEDURES: As a participant, your hands and wrists will be washed eleven times following specific directions. Your hands will be sampled after the first and eleventh wash. Sampling is accomplished by having you place your hands into large plastic bags to which will be added a mild soap-like solution. A laboratory technician will massage each bagged hand for one minute. Your hands will be removed from the bags and the solution from each bag will be taken to the laboratory. The solution collected after massaging will then be tested to determine if it can be neutralized to allow growth of bacteria, which the laboratory will add to it. Following the sampling, you will rinse your hands and forearms in tap water.

FEMALES OF CHILDBEARING POTENTIAL: You may not participate in this study if you are pregnant or nursing. As part of giving your consent you must agree to have a urine pregnancy test at the start of the study.

- **RISKS**: Your hands may show a "reaction." A "reaction" could be redness, swelling, itching, cracking or peeling, or in rare cases, small blisters. It is unlikely, but possible, that a rash could develop. No risk to study participants, other than those described above as "reactions" are anticipated during the study. Reactions are usually due to irritation, although an allergic reaction might also occur. If you become allergic, it is possible that future exposures to the same ingredient may cause a skin reaction. If this occurs, you will be provided with information to minimize the chance for future exposures.

BENEFITS: You will not benefit from the application of test product but the test results may allow a new or improved product to be marketed.

ALTERNATIVE PROCEDURES/TREATMENTS: Because you are not being treated for a medical condition, alternative treatments do not apply to this study.

CONFIDENTIALITY: Information concerning you that is obtained in connection with this study will be kept confidential by Hill Top Research, except that the sponsoring company whose product is being tested will receive a copy of the study data. The data will be coded to protect your identity. In addition, the U.S. Food and Drug Administration (FDA), the Institutional Review Board (IRB), and foreign regulatory agencies may inspect the records of the study. Information obtained in the study may be used for medical or scientific publication, but your identity will remain confidential.

MEDICAL TREATMENT: If in the course of this study you experience illness, discomfort or injury that appears to be a result of the study, Hill Top Research will provide you with medical care at no cost to you. Providing such medical care is not an admission of legal responsibility. If such illness, discomfort or injury does occur, ask any staff member to arrange a meeting for you with the appropriate personnel.

In certain cases of illness or injury resulting from this study, workers' compensation coverage may be available. In accordance with Ohio law, Hill Top Research has secured workers' compensation coverage for participants in its studies and tests, and has paid and will pay appropriate premiums into the State Insurance Fund on behalf of such participants.

WHO TO CONTACT: If you have any questions about this study or in case of an emergency, contact Glenna, Study Coordinator, at 831-3114 during business hours (M-F, 8:00 A.M. - 5:00 P.M.) or Ann Brady, Study Manager, at 831-3354 after hours. In addition, if you have any questions as to your rights as a research subject, contact the Institutional Review Board of Hill Top Research, Nancy J. Pelc, M.D., Chairman, at 1- 513-831-3114.

VOLUNTARY PARTICIPATION/WITHDRAWAL: Your participation in this research study is strictly voluntary. You may refuse to participate or may discontinue participation at any time during the study without penalty or loss of benefits to which you are entitled:

If you agree to participate in this study, you are also agreeing to provide Hill Top Research with accurate information and to follow study instructions as given to you. If you fail to comply with study procedures, your participation may be terminated.

Your participation in the study may be discontinued at any time without your consent by the Investigator, the IRB, the FDA, or the sponsoring company.

COMPENSATION: You will be paid \$10.00 for the completion of this study.

Payment will be made at the end of the study.

There are no anticipated expenses to you for participating in this study. All test related materials will be provided at no cost to you.

CONSENT TO PARTICIPATE

I know that my participation in this study is voluntary and that I have the right to refuse to participate. I know that I may withdraw from the study at any time without penalty or loss of benefits to which I am otherwise entitled. If I withdraw or am dismissed for failure to obey rules or follow directions, I understand I will only be paid for the portion of the test that I have completed. If, in the judgment of the Investigator, it is best to discontinue my participation in the study for other reasons, I will be paid either in full or for that portion of the test already completed.

If I am a female of childbearing potential, I am not currently pregnant or nursing an infant. I am using an adequate means of birth control and, if I become pregnant or believe I have become pregnant, I will notify the Investigator immediately.

CONSENT: I have read all of the above information and have been given an opportunity to ask questions about this study. Answers to such questions (if any) were satisfactory. I am eighteen years of age or older and freely and without reservation give my consent to serve as a subject in this study. By signing this form, I have not given up any of my legal rights as a research subject.

Subject's Name Printed: First

Middle Initial

Last

Subject's Signature

Date

Signature of Person Conducting Consent Discussion

Date

SUBJECT SCREEN NO. _____

SUBJECT NO. _____

EXHIBIT B**EVALUATION OF HEALTH CARE PERSONNEL HANDWASH
SUBJECT INSTRUCTIONS**

Today you will be given a kit of products (bar soap, shampoo, and deodorant/antiperspirant) to use exclusively during this study. Please set aside all products you normally use in these categories and use only the products in the kit. In addition, please refrain from using perfumes, deodorants or antiperspirants (other than the ones furnished), powders and anti-dandruff hair shampoos, and do not swim in a chlorinated pool or hot tub during the study.

Beginning today, no body lotions, medicated creams or ointments should be applied to any area of your skin. Also, do not take any antibiotics. These medications may affect the bacteria of the skin. If antibiotics are necessary due to illness, please report this to Hill Top Research at the phone number below.

Please use the rubber gloves provided with the product kit for all household chores involving detergents, acid, alkalis, and solvents until the completion of the study.

SUBJECT SCHEDULE**TEST DAY**

Time of Visit: _____

1. Plan to arrive at the laboratory about 10 minutes before your scheduled time. You are expected to be prompt.
2. Please wear clothing that will allow easy access to your hands.
3. You will be required to remove all jewelry, watches, and bracelets before washing.
4. You will undergo a supervised wash regimen at the laboratory.
5. Approximate time at the laboratory - hours.
6. Additional instructions will be provided for the Follow Up Visit.

FOLLOW UP VISIT

Time of Visit: _____

1. A Dermatologist will check your hands for infection
2. Approximate time at the lab -1/2 hour.

If you have any questions regarding this study, please contact Glenna, Study Coordinator, at 831-3114 ext. 2920 between 8:00 a.m. - 5:00 p.m. or Ann Brady, Study Manager, after hours and on weekends at 831-3354.

EXHIBIT C

SUBJECT'S INSTRUCTIONS FOLLOWING STUDY COMPLETION

You have just completed participation in a clinical study, "Efficacy Evaluation of Health Care Personnel Handwash Products". During this study, your hands were in contact with a liquid containing bacteria (*Serratia marcescens*). Although we do not expect you to have any adverse experience as a result of participation in this study, there is a remote possibility that an infection may develop on your hands.

To determine whether you have developed an infection from the test bacteria, we would like you to examine your hands and wrists daily. If you notice the appearance of any pimples, blisters or raised bumps surrounded by redness and/or swelling, please contact Glenna, Study Coordinator at (513) 831-3114 during normal business hours (8:00 am- 5 pm) or Ann Brady at (513) 831-3354 after hours.

You are required to return to the test site for a follow-up visit. Your follow-up is scheduled for:

Date

Time

Thank you for your cooperation.

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Subject Qualification	<u> </u> / <u> </u> / <u> </u> mm dd yy	<u> </u> / <u> </u> / <u> </u> F M L	Permanent #:	00-105877-11

Gender: <input type="checkbox"/> Male(1) <input type="checkbox"/> Female(2)	Age: _____ Years
---	------------------

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?			
2. Eczema ?			
3. Skin Cancer ?			
4. Skin Allergies ? Please specify:			
5. Hives ?			

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies.? Please specify.			
2. Hepatitis ?			
3. Heart and Vascular Disease?			
4. Liver Disease ?			
5. Kidney Disease ?			
6. Tuberculosis ?			
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []			
8. Cancer ?			
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?			
10. Organ transplant ?			
11. Any other condition not listed ? Please specify:			

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?			
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?			
3. Heart Medication ?			
4. Insulin ?			
5. Other ?			

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature:

Date: _____ / _____ / _____
mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 00-105877-11

Page No.: 11-30

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Subject Qualification	____/____/____ mm dd yy	____/____/____ F M L	Permanent #:	00-105877-11

INCLUSION CRITERIA

Check one		
YES	NO	Subject:
		1. Is 18 through 65 years ?
		2. Has signed informed consent ?
		3. Is healthy as evidenced by responses on DCF 1 ?
		4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
		5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
		6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
		7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
		8. Is willing to refrain from using medicated/antibacterial lotions and creams during the entire study, unless prescribed by a physician for an intercurrent illness ?
		9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
		10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
		11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			
YES	NO	N/A	Subject:
			1. Is currently participating in another clinical study at this or any other facility ?
			2. Has participated in any type of hand or arm wash study within the past 7 days ?
			3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
			4. Has artificial nails or nail tips?
			5. Has soap, detergent, and/or perfume allergies ?
			6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
			8. Is currently lactating ? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
			9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, or AIDS (or HIV positive) ?
			10. Has another medical condition which in the opinion of the Investigator would preclude participation ?

Based upon dermatologic evaluation and the information contained in Case Report Forms 1 and 2, the subject is:
 Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: _____ / _____

Investigator's Signature:	Date: ____/____/____ mm dd yy
----------------------------------	---

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Test Period	____/____/____ mm dd yy	____/____/____ F M L	Permanent #:	00-105877-11

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? Yes No
If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? Yes No
If no, please explain: _____

III. Has subject been ill since the last visit? Yes (Complete below) No

IV. Has subject used any oral or topical medication? Yes (Complete below) No

Based upon the above responses, the subject is: Qualified Not Qualified to continue on the study.

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? Not related Possibly related Definitely related Other (explain)

Action Taken: None Continued on study Withdrawn from the study Consulted physician
 Medication taken (Complete below) Hospitalized Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ : /	/ /	
		/ /	/ /	

Comments:

Interveiwer's Signature:

Date: ____/____/____
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS
CFU/mL of Sampling Solution

Date	Subject Initials	Subject Screen #	Study #
<u> </u> / <u> </u> / <u> </u> mm dd yy	<u> </u> / <u> </u> / <u> </u> F M L	Permanent #:	00-105877-11

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
CFU/mL _____ Counted by: _____ / _____			CFU/mL _____ Counted by: _____ / _____		

LEFT HAND				WASH 1		RIGHT HAND		
10 ^{-1*}	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ^{-1*}	10 ⁻²	10 ⁻³	10 ⁻⁴	
CFU/mL _____ Counted by: _____ / _____				CFU/mL _____ Counted by: _____ / _____				

LEFT HAND				WASH 11		RIGHT HAND		
10 ^{-1*}	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ^{-1*}	10 ⁻²	10 ⁻³	10 ⁻⁴	
CFU/mL _____ Counted by: _____ / _____				CFU/mL _____ Counted by: _____ / _____				

Calculations by: _____ / _____ Raw data reviewed by _____ / _____
 Calculations Verified by: _____ / _____

*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates in duplicate.
 TNTC – Too Numerous To Count

Investigator's Signature: _____	Date: _____ / _____ / _____ mm dd yy
---------------------------------	---

Data Collection Form 5A

Subject Initials _____ Subject # _____

Study No. 00-105877-11

Page No. II-33

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

¹Serious Adverse Event/Experience

FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	____/____/____ mm dd yy	____/____/____ F M L	Permanent #:	00-105877-11

Date Subject Entered the Study: ____/____/____ mm dd yy	Follow-Up Visit Date: ____/____/____ mm dd yy
---	---

Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?

YES NO If yes, complete below:

Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)

Comments:

Has the subject had any health related issues since the treatment procedure?

YES NO If yes, complete below

Comments:

Medical Consultant's Signature:	Recorded by:	Date ____/____/____ mm dd yy
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HTR Study No.: 00-105877-11

APPENDIX III

Total number of pages = 1

Miscellaneous Procedural Information

MISCELLANEOUS PROCEDURAL INFORMATION

1. **Stripping Solution with Neutralizer**

The stripping solution with neutralizer used for sampling contained 0.41 g KH_2PO_4 , 10.3 g Na_2HPO_4 , 1.0 g Triton X-100, 10.0 g Tween 80, and 3.0 g Lecithin in one liter purified water. The solution was dispensed into water dilution bottles, or other suitable containers, to yield a final volume of 75 ± 1.0 mL after autoclaving at 121°C . The final pH was 7.8 ± 0.1 .

2. **Dilution Fluid with Neutralizer**

The dilution fluid contained 1.25 mL AOAC Phosphate Buffer Stock*, 10.0 g Tween 80, and 3.0 g Lecithin in one liter purified water. The solution was dispensed into tubes to yield a final volume of 9 ± 0.1 mL after autoclaving at 121°C . The final pH was 7.2 ± 0.2 .

3. **Tryptic Soy Agar**

The plating medium contained 40.0 g Tryptic Soy Agar powder in one liter purified water. The media was autoclaved at 121°C . The pH was 7.3 ± 0.2 . After autoclaving and tempering, the media was aseptically dispensed into sterile Petri dishes, approximately 18 - 20 mL per plate.

*The AOAC Phosphate Buffer Stock contained 34.0 g KH_2PO_4 in one liter of purified water. The pH was adjusted to 7.2 prior to dispensing into water dilution bottles, to yield a final volume of approximately 100 mL after autoclaving at 121°C .

Note: Recipes which are given as liter volumes may be prepared in greater or lesser volumes.

HTR Study No.: 00-105877-11

APPENDIX IV

Total number of pages = 1

Subjects Excluded/Withdrawn from the Study

Subjects Excluded/Withdrawn from the Study

Subject Screening No.	Reason
102, 103, 107, 118, 119, 120, 121, 123, 128, 138, 146, 148, 153, 158, 160, 162, 163, 172, 186, 187, 191, 192, 200, 208, 216, 221, 222, 223	Subjects withdrew prior to test day – personal reasons
115, 145, 150, 151, 165, 171, 179, 181, 184, 194, 204, 211, 220	Subjects excluded – cut/scratch on hand or wrist
173, 180, 195, 205, 206, 212, 214, 219, 227, 229, 232	Subjects excluded – extra subject
125, 131, 132, 137, 168, 183, 202	Subjects excluded – late on test day

HTR Study No.: 00-105877-11

APPENDIX V

Total number of pages = 2

Randomization

STUDY RANDOMIZATION

PANELIST
NUMBER

SAMPLE

1	B
2	C
3	A
4	A
5	C
6	A
7	C
8	C
9	C
10	C
11	A
12	B
13	C
14	C
15	B
16	B
17	A
18	B
19	A
20	C
21	B
22	A
23	A
24	B
25	A
26	B
27	A
28	A
29	A
30	B
31	B
32	A
33	A
34	B
35	A
36	A
37	A
38	A
39	A
40	B
41	B
42	A
43	A
44	C
45	B
46	A
47	B
48	B
49	B
50	A

DLM
9/14/00

00-105877-11

STUDY RANDOMIZATION

PANELIST
NUMBER

SAMPLE

51
52
53
54
55
56
57
58
59
60
61
62
63
64
65
66
67
68
69
70
71
72
73
74
75

A
A
B
B
A
A
A
A
B
B
A
B
B
C
B
B
B
C
B
B
C
C
C
B
B

DL4
9/14/00

HTR Study No.: 00-105877-11

APPENDIX VII

Total number of pages = 4

Test for Adequacy of Neutralizer

HTR Study No.: 00-105877-11

TEST FOR ADEQUACY OF THE NEUTRALIZER

1.0 OBJECTIVE

To determine an appropriate antimicrobial neutralizer system for use in a Health Care Personnel Handwash study, HTR Study No. 00-105877-11.

2.0 TEST ARTICLES

The following test articles were received on September 13, 2000, for use in the study:

<u>HTR Code</u>	<u>Sponsor Code</u>	<u>Description</u>
A	3434-9	Green plastic bottle with white plastic pump nozzle unit with liquid inside
B	3434-10	Green plastic bottle with white plastic pump nozzle unit with liquid inside
C	Hibiclens®, Lot 3107C, Exp: 11/01	Blue-green plastic bottle with white plastic cap with liquid inside

3.0 PROCEDURE

Three subjects performed a conditioning wash according to the protocol directions using Baby San Soap. The subjects then treated their hands eleven times, each using either HTR Code A-1, B-1, or C-1 according to the protocol directions specific for the test product. At least five minutes elapsed between treatments.

The subject's hands were sampled after treatment 1 using stripping solution with neutralizer¹ according to protocol directions. The stripping solution from treatment 1 was discarded. The subjects then performed a conditioning wash according to the protocol directions and dried using a paper towel.

One hand from each subject was sampled according to protocol directions within five minutes of the 11th treatment using stripping solution with neutralizer. Aliquots from each subjects sampling solution were removed within one minute as follows and used to test the adequacy of the neutralizer. A ten (10.0) mL aliquot of the sampling solution with neutralizer was removed and placed in a sterile tube. An additional 1.0 mL aliquot of the sampling solution with neutralizer was added to a tube containing 9.0 mL of dilution fluid with neutralizer².

3.0 PROCEDURE (CONT.)

A 0.1 mL aliquot of diluted *Serratia marcescens* ATCC 14756 was added to each of the prepared tubes. The diluted culture was a 24 ± 4 hour Tryptic Soy Broth³ culture of *S. marcescens* ATCC 14756 serially diluted to 10^{-5} in 0.9% saline⁴.

After mixing, aliquots from each inoculated tube were surface plated immediately and again at 30 minutes by distributing 1.0 mL across three Tryptic Soy Agar⁵ plates in duplicate. The plates were incubated at $25 \pm 2^{\circ}\text{C}$ for 48 ± 4 hours. After incubation, the numbers of *S. marcescens* colony forming units were enumerated.

Number and toxicity control tubes were also prepared. The numbers control consisted of 10.0 mL 0.9% saline. Two different toxicity control tubes were prepared. One tube contained 10.0 mL stripping solution with neutralizer, and the second tube contained 1.0 mL stripping solution with neutralizer plus 9.0 mL dilution fluid with neutralizer. These control tubes were inoculated, plated, incubated, and enumerated in the same manner as the collected samples.

4.0 RESULTS

Results are shown in the Tables of Results.

5.0 CONCLUSIONS

The neutralizer system is considered effective if recovery is $\geq 75\%$ of the corresponding numbers control. In this study the neutralizer system adequately neutralized the antimicrobial ingredient(s) in the test products.

TABLES OF RESULTS
RECOVERY OF *S. MARCESCENS* ATCC 14756

ARTICLE	TIME	PLATE COUNTS* ¹						AVG. CFU/mL	% RECOVERY
Numbers Control 10.0 mL Saline	0 min.	81	94	87	97	101	83	2.7×10^2	NA* ²
	30 min.	91	89	77	95	93	66	2.6×10^2	NA
Toxicity Control Sample 1* ³	0 min.	87	95	91	99	80	95	2.7×10^2	100
	30 min.	101	71	88	86	83	96	2.6×10^2	100
Toxicity Control Sample 2* ⁴	0 min.	89	86	82	73	81	86	2.5×10^2	92
	30 min.	71	71	86	68	69	96	2.3×10^2	88
HTR Code A-1 Sample 1* ³	0 min.	79	94	82	85	93	104	2.7×10^2	100
	30 min.	113	93	89	80	96	88	2.8×10^2	108
HTR Code A-1 Sample 2* ⁴	0 min.	98	88	77	76	101	78	2.6×10^2	96
	30 min.	85	88	62	73	75	66	2.2×10^2	85
HTR Code B-1 Sample 1* ³	0 min.	86	74	94	82	81	86	2.5×10^2	92
	30 min.	91	104	92	72	85	69	2.6×10^2	100
HTR Code B-1 Sample 2* ⁴	0 min.	99	100	80	65	86	77	2.5×10^2	92
	30 min.	82	77	72	80	68	84	2.3×10^2	88
HTR Code C-1 Sample 1* ³	0 min.	97	78	98	90	121	97	2.9×10^2	107
	30 min.	100	86	81	74	85	102	2.6×10^2	100
HTR Code C-1 Sample 2* ⁴	0 min.	85	84	71	70	89	93	2.5×10^2	92
	30 min.	64	75	69	87	73	60	2.1×10^2	81

*¹1.0 mL spread across 3 plates in duplicate.

*²NA = Not Applicable

*³Sample 1 is control or test sample containing 10 mL Stripping with Neutralizer.

*⁴Sample 2 is control or test sample containing 1.0 mL Stripping with Neutralizer into 9 mL Dilution Fluid with Neutralizer.

$$0 \text{ Minute \% Recovery} = \frac{\text{Count at 0 min.}}{\text{Numbers Control Count at 0 min.}} \times 100$$

$$30 \text{ Minute \% Recovery} = \frac{\text{Count at 30 min.}}{\text{Numbers Control Count at 30 min.}} \times 100$$

REFERENCES

1. **Stripping Solution with Neutralizer**

The stripping solution with neutralizer used for sampling contained 0.41 g KH_2PO_4 , 10.3 g Na_2HPO_4 , 1.0 g Triton X-100, 10.0 g Tween 80, and 3.0 g Lecithin in one liter purified water. The solution was dispensed into water dilution bottles, or other suitable containers, to yield a final volume of 75 ± 1.0 mL after autoclaving at 121°C . The final pH was 7.8 ± 0.1 .

2. **Dilution Fluid with Neutralizer**

The dilution fluid contained 1.25 mL AOAC Phosphate Buffer Stock*, 10.0 g Tween 80, and 3.0 g Lecithin in one liter purified water. The solution was dispensed into tubes to yield a final volume of 9 ± 0.1 mL after autoclaving at 121°C . The final pH was 7.2 ± 0.2 .

3. **Tryptic Soy Broth**

The broth consisted of 30 g Tryptic Soy Broth powder in one liter purified water. The media was dispensed into tubes and sterilized by autoclaving at 121°C . The pH was 7.3 ± 0.2 .

4. **0.9% Saline**

The saline contained 9 g NaCl in one liter purified water. The material was dispensed into tubes to yield a final volume of 9 ± 0.1 mL after autoclaving at 121°C .

5. **Tryptic Soy Agar**

The plating medium contained 40.0 g Tryptic Soy Agar powder in one liter purified water. The media was autoclaved at 121°C . The pH was 7.3 ± 0.2 . After autoclaving and tempering, the media was aseptically dispensed into sterile Petri dishes, approximately 18 - 20 mL per plate.

*The AOAC Phosphate Buffer Stock contained 34.0 g KH_2PO_4 in one liter of purified water. The pH was adjusted to 7.2 prior to dispensing into water dilution bottles, to yield a final volume of approximately 100 mL after autoclaving at 121°C .

Note: Recipes which are given as liter volumes may be prepared in greater or lesser volumes.

APPENDIX VIII

Total number of pages = 24

Statistical Tables

Table 1	Summary of CFU counts and log conversions
Table 2a	Mean summary of \log_{10} averages
Table 2b	Mean summary of \log_{10} average reductions
Table 3	Means summary of \log_{10} reductions from baseline, percent microbial reductions, and confidence limits
Table 4	Analysis of variance for comparison of test article \log_{10} baseline counts
Table 5	Analysis of variance to evaluate the effectiveness of each treatment as a function of the number of treatments

HTR Study Number 00-105877-11
 Table 1. Summary of CFU counts and log conversions.

10:27 Monday, October 16, 2000

HTR Code=A: 3434-9 Foaming Handwash

Subject	Wash	Left			Right			Log10 Average	Log10 Reduction
		CFU/mL	CFU/Hand	Log10 CFU/Hand	CFU/mL	CFU/Hand	Log10 CFU/Hand		
3	Baseline	2.3E7	1.7E+09	9.2368	1.8E7	1.4E+09	9.1303	9.1836	.
	Wash 1	2.8E3	2.1E+05	5.3222	2.4E3	1.8E+05	5.2553	5.2887	3.8948
	Wash 11	9.4E3	7.1E+05	5.8482	1.2E3	9.0E+04	4.9542	5.4012	3.7823
4	Baseline	2.3E7	1.7E+09	9.2368	2.6E7	2.0E+09	9.2900	9.2634	.
	Wash 1	6.3E3	4.7E+05	5.6744	9.2E3	6.9E+05	5.8388	5.7566	3.5068
	Wash 11	2.5E3	1.9E+05	5.2730	3.5E3	2.6E+05	5.4191	5.3461	3.9173
6	Baseline	3.0E7	2.3E+09	9.3522	2.3E7	1.7E+09	9.2368	9.2945	.
	Wash 1	5.2E4	3.9E+06	6.5911	6.2E4	4.7E+06	6.6675	6.6293	2.6652
	Wash 11	1.7E4	1.3E+06	6.1055	2.3E4	1.7E+06	6.2368	6.1711	3.1233
11	Baseline	2.4E7	1.8E+09	9.2553	2.2E7	1.7E+09	9.2175	9.2364	.
	Wash 1	3.8E3	2.9E+05	5.4548	9.5E3	7.1E+05	5.8528	5.6538	3.5826
	Wash 11	2.6E3	2.0E+05	5.2900	4.5E3	3.4E+05	5.5283	5.4092	3.8272
17	Baseline	3.2E7	2.4E+09	9.3802	2.5E7	1.9E+09	9.2730	9.3266	.
	Wash 1	9.0E3	6.8E+05	5.8293	7.6E3	5.7E+05	5.7559	5.7926	3.5340
	Wash 11	9.6E2	7.2E+04	4.8573	2.7E3	2.0E+05	5.3064	5.0819	4.2447
19	Baseline	2.4E7	1.8E+09	9.2553	2.8E7	2.1E+09	9.3222	9.2887	.
	Wash 1	3.3E3	2.5E+05	5.3936	1.9E4	1.4E+06	6.1538	5.7737	3.5151
	Wash 11	4.7E3	3.5E+05	5.5472	1.5E4	1.1E+06	6.0512	5.7992	3.4896
22	Baseline	2.4E7	1.8E+09	9.2553	2.6E7	2.0E+09	9.2900	9.2727	.
	Wash 1	8.2E2	6.2E+04	4.7889	3.0E2	2.3E+04	4.3522	4.5705	4.7021
	Wash 11	9.5E1	7.1E+03	3.8528	4.2E2	3.2E+04	4.4983	4.1755	5.0971
23	Baseline	2.4E7	1.8E+09	9.2553	2.3E7	1.7E+09	9.2368	9.2460	.
	Wash 1	4.0E2	3.0E+04	4.4771	6.6E2	5.0E+04	4.6946	4.5859	4.6602
	Wash 11	1.6E2	1.2E+04	4.0792	1.4E3	1.1E+05	5.0212	4.5502	4.6958
25	Baseline	2.6E7	2.0E+09	9.2900	2.7E7	2.0E+09	9.3064	9.2982	.
	Wash 1	2.0E4	1.5E+06	6.1761	3.2E4	2.4E+06	6.3802	6.2782	3.0201
	Wash 11	6.4E3	4.8E+05	5.6812	5.0E5	3.8E+07	7.5740	6.6276	2.6706
27	Baseline	2.9E7	2.2E+09	9.3375	2.5E7	1.9E+09	9.2730	9.3052	.
	Wash 1	3.4E4	2.6E+06	6.4065	7.4E4	5.6E+06	6.7443	6.5754	2.7298
	Wash 11	3.3E4	2.5E+06	6.3936	2.4E4	1.8E+06	6.2553	6.3244	2.9808
28	Baseline	2.6E7	2.0E+09	9.2900	3.4E7	2.6E+09	9.4065	9.3483	.
	Wash 1	7.0E3	5.3E+05	5.7202	2.9E4	2.2E+06	6.3375	6.0288	3.3195
	Wash 11	1.5E3	1.1E+05	5.0512	6.3E3	4.7E+05	5.6744	5.3628	3.9855
29	Baseline	2.2E7	1.7E+09	9.2175	2.5E7	1.9E+09	9.2730	9.2452	.
	Wash 1	6.2E4	4.7E+06	6.6675	4.5E3	3.4E+05	5.5283	6.0979	3.1474
	Wash 11	1.2E3	9.0E+04	4.9542	1.5E3	1.1E+05	5.0512	5.0027	4.2425
32	Baseline	2.5E7	1.9E+09	9.2730	2.2E7	1.7E+09	9.2175	9.2452	.
	Wash 1	7.2E2	5.4E+04	4.7324	2.9E3	2.2E+05	5.3375	5.0349	4.2103
	Wash 11	1.1E3	8.3E+04	4.9165	1.6E3	1.2E+05	5.0792	4.9978	4.2474
33	Baseline	3.4E7	2.6E+09	9.4065	2.8E7	2.1E+09	9.3222	9.3644	.
	Wash 1	3.0E3	2.3E+05	5.3522	7.0E2	5.3E+04	4.7202	5.0362	4.3282

Where score has been recorded as <1.0E1, a score of 1.0E1 will be used in the analysis.

HTR Study Number 00-105877-11
 Table 1. Summary of CFU counts and log conversions.

10:27 Monday, October 16, 2000

HTR Code=A: 3434-9 Foaming Handwash

Subject	Wash	Left			Right			Log10 Average	Log10 Reduction
		CFU/mL	CFU/Hand	Log10 CFU/Hand	CFU/mL	CFU/Hand	Log10 CFU/Hand		
33	Wash 11	1.2E3	9.0E+04	4.9542	2.1E3	1.6E+05	5.1973	5.0758	4.2886
35	Baseline	2.8E7	2.1E+09	9.3222	4.2E7	3.2E+09	9.4983	9.4103	.
	Wash 1	4.2E3	3.2E+05	5.4983	1.9E4	1.4E+06	6.1538	5.8261	3.5842
	Wash 11	7.8E3	5.9E+05	5.7672	9.6E3	7.2E+05	5.8573	5.8122	3.5980
36	Baseline	2.6E7	2.0E+09	9.2900	2.6E7	2.0E+09	9.2900	9.2900	.
	Wash 1	3.1E3	2.3E+05	5.3664	3.1E4	2.3E+06	6.3664	5.8664	3.4236
	Wash 11	9.2E3	6.9E+05	5.8388	5.1E3	3.8E+05	5.5826	5.7107	3.5793
37	Baseline	3.4E7	2.6E+09	9.4065	3.0E7	2.3E+09	9.3522	9.3794	.
	Wash 1	2.6E4	2.0E+06	6.2900	1.9E4	1.4E+06	6.1538	6.2219	3.1574
	Wash 11	1.3E4	9.8E+05	5.9890	1.3E4	9.8E+05	5.9890	5.9890	3.3904
38	Baseline	1.4E7	1.1E+09	9.0212	1.2E7	9.0E+08	8.9542	8.9877	.
	Wash 1	4.2E2	3.2E+04	4.4983	3.2E2	2.4E+04	4.3802	4.4393	4.5485
	Wash 11	8.0E2	6.0E+04	4.7782	4.8E2	3.6E+04	4.5563	4.6672	4.3205
39	Baseline	2.2E7	1.7E+09	9.2175	2.4E7	1.8E+09	9.2553	9.2364	.
	Wash 1	2.3E3	1.7E+05	5.2368	7.0E2	5.3E+04	4.7202	4.9785	4.2579
	Wash 11	2.7E2	2.0E+04	4.3064	3.4E2	2.6E+04	4.4065	4.3565	4.8799
42	Baseline	3.0E7	2.3E+09	9.3522	2.7E7	2.0E+09	9.3064	9.3293	.
	Wash 1	2.3E3	1.7E+05	5.2368	1.0E3	7.5E+04	4.8751	5.0559	4.2734
	Wash 11	2.6E3	2.0E+05	5.2900	8.2E2	6.2E+04	4.7889	5.0395	4.2898
43	Baseline	3.2E7	2.4E+09	9.3802	2.6E7	2.0E+09	9.2900	9.3351	.
	Wash 1	5.8E3	4.4E+05	5.6385	5.3E3	4.0E+05	5.5993	5.6189	3.7162
	Wash 11	2.4E3	1.8E+05	5.2553	3.6E3	2.7E+05	5.4314	5.3433	3.9918
46	Baseline	2.2E7	1.7E+09	9.2175	2.2E7	1.7E+09	9.2175	9.2175	.
	Wash 1	7.0E3	5.3E+05	5.7202	9.4E3	7.1E+05	5.8482	5.7842	3.4333
	Wash 11	2.6E4	2.0E+06	6.2900	3.3E3	2.5E+05	5.3936	5.8418	3.3757
50	Baseline	2.0E7	1.5E+09	9.1761	2.4E7	1.8E+09	9.2553	9.2157	.
	Wash 1	2.4E3	1.8E+05	5.2553	3.2E3	2.4E+05	5.3802	5.3177	3.8979
	Wash 11	5.6E3	4.2E+05	5.6232	4.5E3	3.4E+05	5.5283	5.5758	3.6399
51	Baseline	3.0E7	2.3E+09	9.3522	2.6E7	2.0E+09	9.2900	9.3211	.
	Wash 1	9.6E2	7.2E+04	4.8573	1.6E3	1.2E+05	5.0792	4.9683	4.3529
	Wash 11	2.5E3	1.9E+05	5.2730	6.7E3	5.0E+05	5.7011	5.4871	3.8340
52	Baseline	2.6E7	2.0E+09	9.2900	5.4E7	4.1E+09	9.6075	9.4487	.
	Wash 1	4.7E3	3.5E+05	5.5472	7.3E3	5.5E+05	5.7384	5.6428	3.8060
	Wash 11	3.3E3	2.5E+05	5.3936	3.8E3	2.9E+05	5.4548	5.4242	4.0245
55	Baseline	2.1E7	1.6E+09	9.1973	1.9E7	1.4E+09	9.1538	9.1755	.
	Wash 1	9.7E3	7.3E+05	5.8618	2.4E3	1.8E+05	5.2553	5.5586	3.6170
	Wash 11	1.0E3	7.5E+04	4.8751	5.4E2	4.1E+04	4.6075	4.7413	4.4343
56	Baseline	2.0E7	1.5E+09	9.1761	1.5E7	1.1E+09	9.0512	9.1136	.
	Wash 1	9.1E2	6.8E+04	4.8341	6.1E2	4.6E+04	4.6604	4.7472	4.3664
	Wash 11	9.6E2	7.2E+04	4.8573	3.4E2	2.6E+04	4.4065	4.6319	4.4817
57	Baseline	2.4E7	1.8E+09	9.2553	2.4E7	1.8E+09	9.2553	9.2553	.

Where score has been recorded as <1.0E1, a score of 1.0E1 will be used in the analysis.

Table 1. Summary of CFU counts and log conversions.

----- HTR Code=A: 3434-9 Foaming Handwash -----

Subject	Wash	Left			Right			Log10 Average	Log10 Reduction
		CFU/mL	CFU/Hand	Log10 CFU/Hand	CFU/mL	CFU/Hand	Log10 CFU/Hand		
57	Wash 1	2.4E3	1.8E+05	5.2553	5.0E3	3.8E+05	5.5740	5.4147	3.8406
	Wash 11	1.6E2	1.2E+04	4.0792	1.3E3	9.8E+04	4.9890	4.5341	4.7212
58	Baseline	2.8E7	2.1E+09	9.3222	2.7E7	2.0E+09	9.3064	9.3143	.
	Wash 1	1.3E4	9.8E+05	5.9890	2.5E4	1.9E+06	6.2730	6.1310	3.1833
61	Wash 11	9.4E2	7.1E+04	4.8482	9.6E3	7.2E+05	5.8573	5.3528	3.9616
	Baseline	2.4E7	1.8E+09	9.2553	2.2E7	1.7E+09	9.2175	9.2364	.
	Wash 1	3.4E3	2.6E+05	5.4065	8.5E3	6.4E+05	5.8045	5.6055	3.6309
	Wash 11	1.4E3	1.1E+05	5.0212	2.9E3	2.2E+05	5.3375	5.1793	4.0571

Where score has been recorded as <1.0E1, a score of 1.0E1 will be used in the analysis.

HTR Study Number 00-105877-11
 Table 1. Summary of CFU counts and log conversions.

10:27 Monday, October 16, 2000

HTR Code=B: 3434-10 Foaming Handwash

Subject	Wash	Left			Right			Log10 Average	Log10 Reduction
		CFU/mL	CFU/Hand	Log10 CFU/Hand	CFU/mL	CFU/Hand	Log10 CFU/Hand		
1	Baseline	1.4E7	1.1E+09	9.0212	2.2E7	1.7E+09	9.2175	9.1193	.
	Wash 1	1.5E4	1.1E+06	6.0512	1.6E4	1.2E+06	6.0792	6.0652	3.0542
	Wash 11	7.2E3	5.4E+05	5.7324	9.3E3	7.0E+05	5.8435	5.7880	3.3314
12	Baseline	2.1E7	1.6E+09	9.1973	2.1E7	1.6E+09	9.1973	9.1973	.
	Wash 1	1.8E3	1.4E+05	5.1303	6.2E3	4.7E+05	5.6675	5.3989	3.7984
	Wash 11	2.8E4	2.1E+06	6.3222	2.9E4	2.2E+06	6.3375	6.3298	2.8674
15	Baseline	2.3E7	1.7E+09	9.2368	2.0E7	1.5E+09	9.1761	9.2064	.
	Wash 1	5.2E3	3.9E+05	5.5911	4.8E3	3.6E+05	5.5563	5.5737	3.6328
	Wash 11	1.2E4	9.0E+05	5.9542	1.6E4	1.2E+06	6.0792	6.0167	3.1897
16	Baseline	8.6E6	6.5E+08	8.8096	1.1E7	8.3E+08	8.9165	8.8630	.
	Wash 1	1.5E2	1.1E+04	4.0512	5.3E2	4.0E+04	4.5993	4.3252	4.5378
	Wash 11	3.8E2	2.9E+04	4.4548	3.7E2	2.8E+04	4.4433	4.4491	4.4140
18	Baseline	3.5E7	2.6E+09	9.4191	3.0E7	2.3E+09	9.3522	9.3857	.
	Wash 1	5.4E2	4.1E+04	4.6075	2.0E3	1.5E+05	5.1761	4.8918	4.4939
	Wash 11	6.7E2	5.0E+04	4.7011	1.6E3	1.2E+05	5.0792	4.8902	4.4955
21	Baseline	2.6E7	2.0E+09	9.2900	2.5E7	1.9E+09	9.2730	9.2815	.
	Wash 1	2.7E2	2.0E+04	4.3064	4.8E2	3.6E+04	4.5563	4.4314	4.8502
	Wash 11	1.5E3	1.1E+05	5.0512	3.0E3	2.3E+05	5.3522	5.2017	4.0799
24	Baseline	2.0E7	1.5E+09	9.1761	2.7E7	2.0E+09	9.3064	9.2413	.
	Wash 1	1.0E4	7.5E+05	5.8751	6.5E3	4.9E+05	5.6880	5.7815	3.4597
	Wash 11	3.5E1	2.6E+03	3.4191	7.7E2	5.8E+04	4.7616	4.0903	5.1509
26	Baseline	3.0E7	2.3E+09	9.3522	2.3E7	1.7E+09	9.2368	9.2945	.
	Wash 1	2.0E3	1.5E+05	5.1761	2.7E3	2.0E+05	5.3064	5.2413	4.0532
	Wash 11	4.2E3	3.2E+05	5.4983	3.2E3	2.4E+05	5.3802	5.4393	3.8552
30	Baseline	1.6E7	1.2E+09	9.0792	1.8E7	1.4E+09	9.1303	9.1048	.
	Wash 1	9.7E2	7.3E+04	4.8618	4.6E3	3.5E+05	5.5378	5.1998	3.9049
	Wash 11	2.7E3	2.0E+05	5.3064	8.1E3	6.1E+05	5.7835	5.5450	3.5598
31	Baseline	2.9E7	2.2E+09	9.3375	2.6E7	2.0E+09	9.2900	9.3137	.
	Wash 1	2.1E3	1.6E+05	5.1973	5.9E3	4.4E+05	5.6459	5.4216	3.8922
	Wash 11	2.0E3	1.5E+05	5.1761	1.9E3	1.4E+05	5.1538	5.1650	4.1488
34	Baseline	3.0E7	2.3E+09	9.3522	2.6E7	2.0E+09	9.2900	9.3211	.
	Wash 1	9.2E3	6.9E+05	5.8388	8.4E3	6.3E+05	5.7993	5.8191	3.5020
	Wash 11	7.4E3	5.6E+05	5.7443	7.2E3	5.4E+05	5.7324	5.7383	3.5828
40	Baseline	1.7E7	1.3E+09	9.1055	2.0E7	1.5E+09	9.1761	9.1408	.
	Wash 1	2.5E3	1.9E+05	5.2730	2.0E4	1.5E+06	6.1761	5.7245	3.4163
	Wash 11	3.1E3	2.3E+05	5.3664	3.7E3	2.8E+05	5.4433	5.4048	3.7360
41	Baseline	2.3E7	1.7E+09	9.2368	6.8E7	5.1E+09	9.7076	9.4722	.
	Wash 1	6.3E3	4.7E+05	5.6744	1.4E4	1.1E+06	6.0212	5.8478	3.6244
	Wash 11	2.8E3	2.1E+05	5.3222	7.4E3	5.6E+05	5.7443	5.5333	3.9389
45	Baseline	2.4E7	1.8E+09	9.2553	3.6E7	2.7E+09	9.4314	9.3433	.
	Wash 1	2.1E4	1.6E+06	6.1973	5.6E4	4.2E+06	6.6232	6.4103	2.9331

Where score has been recorded as <1.0E1, a score of 1.0E1 will be used in the analysis.

HTR Study Number 00-105877-11
 Table 1. Summary of CFU counts and log conversions.

10:27 Monday, October 16, 2000

HTR Code=B: 3434-10 Foaming Handwash

Subject	Wash	Left			Right			Log10 Average	Log10 Reduction
		CFU/mL	CFU/Hand	Log10 CFU/Hand	CFU/mL	CFU/Hand	Log10 CFU/Hand		
45	Wash 11	2.3E4	1.7E+06	6.2368	1.0E5	7.5E+06	6.8751	6.5559	2.7874
47	Baseline	2.2E7	1.7E+09	9.2175	2.1E7	1.6E+09	9.1973	9.2074	.
	Wash 1	9.8E3	7.4E+05	5.8663	3.8E3	2.9E+05	5.4548	5.6606	3.5468
	Wash 11	6.8E3	5.1E+05	5.7076	1.6E3	1.2E+05	5.0792	5.3934	3.8140
48	Baseline	2.0E7	1.5E+09	9.1761	1.7E7	1.3E+09	9.1055	9.1408	.
	Wash 1	4.0E4	3.0E+06	6.4771	2.0E3	1.5E+05	5.1761	5.8266	3.3142
	Wash 11	2.7E4	2.0E+06	6.3064	2.2E3	1.7E+05	5.2175	5.7620	3.3788
49	Baseline	2.7E7	2.0E+09	9.3064	2.9E7	2.2E+09	9.3375	9.3219	.
	Wash 1	7.4E3	5.6E+05	5.7443	1.9E4	1.4E+06	6.1538	5.9491	3.3729
	Wash 11	5.2E4	3.9E+06	6.5911	4.6E4	3.5E+06	6.5378	6.5644	2.7575
53	Baseline	1.8E7	1.4E+09	9.1303	1.5E7	1.1E+09	9.0512	9.0907	.
	Wash 1	1.2E3	9.0E+04	4.9542	1.5E3	1.1E+05	5.0512	5.0027	4.0880
	Wash 11	1.3E3	9.8E+04	4.9890	9.2E2	6.9E+04	4.8388	4.9139	4.1768
54	Baseline	3.2E7	2.4E+09	9.3802	2.0E7	1.5E+09	9.1761	9.2782	.
	Wash 1	3.9E3	2.9E+05	5.4661	7.8E3	5.9E+05	5.7672	5.6166	3.6615
	Wash 11	1.2E3	9.0E+04	4.9542	2.4E3	1.8E+05	5.2553	5.1048	4.1734
59	Baseline	1.1E7	8.3E+08	8.9165	1.8E7	1.4E+09	9.1303	9.0234	.
	Wash 1	2.0E3	1.5E+05	5.1761	3.9E3	2.9E+05	5.4661	5.3211	3.7023
	Wash 11	1.0E3	7.5E+04	4.8751	1.7E3	1.3E+05	5.1055	4.9903	4.0331
60	Baseline	1.8E7	1.4E+09	9.1303	2.5E7	1.9E+09	9.2730	9.2017	.
	Wash 1	1.7E4	1.3E+06	6.1055	1.4E4	1.1E+06	6.0212	6.0633	3.1383
	Wash 11	1.6E4	1.2E+06	6.0792	2.0E4	1.5E+06	6.1761	6.1276	3.0740
62	Baseline	2.5E7	1.9E+09	9.2730	1.8E7	1.4E+09	9.1303	9.2017	.
	Wash 1	2.4E3	1.8E+05	5.2553	4.6E3	3.5E+05	5.5378	5.3965	3.8051
	Wash 11	2.2E3	1.7E+05	5.2175	1.8E3	1.4E+05	5.1303	5.1739	4.0278
63	Baseline	1.8E7	1.4E+09	9.1303	3.2E7	2.4E+09	9.3802	9.2553	.
	Wash 1	2.9E3	2.2E+05	5.3375	5.6E3	4.2E+05	5.6232	5.4804	3.7749
	Wash 11	1.4E4	1.1E+06	6.0212	9.2E3	6.9E+05	5.8388	5.9300	3.3253
65	Baseline	2.4E7	1.8E+09	9.2553	2.7E7	2.0E+09	9.3064	9.2808	.
	Wash 1	1.4E4	1.1E+06	6.0212	3.4E4	2.6E+06	6.4065	6.2139	3.0670
	Wash 11	1.1E4	8.3E+05	5.9165	2.4E4	1.8E+06	6.2553	6.0859	3.1950
66	Baseline	2.4E7	1.8E+09	9.2553	2.2E7	1.7E+09	9.2175	9.2364	.
	Wash 1	1.2E4	9.0E+05	5.9542	2.6E4	2.0E+06	6.2900	6.1221	3.1142
	Wash 11	9.1E3	6.8E+05	5.8341	1.1E4	8.3E+05	5.9165	5.8753	3.3611
67	Baseline	2.3E7	1.7E+09	9.2368	2.3E7	1.7E+09	9.2368	9.2368	.
	Wash 1	9.6E3	7.2E+05	5.8573	9.0E3	6.8E+05	5.8293	5.8433	3.3935
	Wash 11	2.8E3	2.1E+05	5.3222	9.5E3	7.1E+05	5.8528	5.5875	3.6493
69	Baseline	1.8E7	1.4E+09	9.1303	1.8E7	1.4E+09	9.1303	9.1303	.
	Wash 1	5.0E3	3.8E+05	5.5740	4.3E3	3.2E+05	5.5085	5.5413	3.5891
	Wash 11	1.8E2	1.4E+04	4.1303	6.4E2	4.8E+04	4.6812	4.4058	4.7245
70	Baseline	2.2E7	1.7E+09	9.2175	2.4E7	1.8E+09	9.2553	9.2364	.

Where score has been recorded as <1.0E1, a score of 1.0E1 will be used in the analysis.

HTR Study Number 00-105877-11
 Table 1. Summary of CFU counts and log conversions.

10:27 Monday, October 16, 2000

----- HTR Code=B: 3434-10 Foaming Handwash -----

Subject	Wash	Left			Right			Log10 Average	Log10 Reduction
		CFU/mL	CFU/Hand	Log10 CFU/Hand	CFU/mL	CFU/Hand	Log10 CFU/Hand		
70	Wash 1	2.2E3	1.7E+05	5.2175	3.6E3	2.7E+05	5.4314	5.3244	3.9120
	Wash 11	9.0E1	6.8E+03	3.8293	9.5E1	7.1E+03	3.8528	3.8410	5.3953
74	Baseline	3.2E7	2.4E+09	9.3802	3.0E7	2.3E+09	9.3522	9.3662	.
	Wash 1	1.7E3	1.3E+05	5.1055	2.1E4	1.6E+06	6.1973	5.6514	3.7148
75	Wash 11	1.5E3	1.1E+05	5.0512	3.1E3	2.3E+05	5.3664	5.2088	4.1574
	Baseline	2.4E7	1.8E+09	9.2553	2.4E7	1.8E+09	9.2553	9.2553	.
	Wash 1	4.2E4	3.2E+06	6.4983	4.0E4	3.0E+06	6.4771	6.4877	2.7676
	Wash 11	1.4E4	1.1E+06	6.0212	8.0E3	6.0E+05	5.7782	5.8997	3.3556

Where score has been recorded as <1.0E1, a score of 1.0E1 will be used in the analysis.

HTR Study Number 00-105877-11
 Table 1. Summary of CFU counts and log conversions.

10:27 Monday, October 16, 2000

HTR Code=C: 3107C Hibiclens

Subject	Wash	Left			Right			Log10 Average	Log10 Reduction
		CFU/mL	CFU/Hand	Log10 CFU/Hand	CFU/mL	CFU/Hand	Log10 CFU/Hand		
2	Baseline	1.9E7	1.4E+09	9.1538	1.7E7	1.3E+09	9.1055	9.1297	.
	Wash 1	2.0E4	1.5E+06	6.1761	1.4E4	1.1E+06	6.0212	6.0986	3.0310
	Wash 11	6.8E3	5.1E+05	5.7076	3.0E3	2.3E+05	5.3522	5.5299	3.5998
5	Baseline	1.9E7	1.4E+09	9.1538	2.4E7	1.8E+09	9.2553	9.2045	.
	Wash 1	7.2E4	5.4E+06	6.7324	8.2E4	6.2E+06	6.7889	6.7606	2.4439
	Wash 11	6.8E3	5.1E+05	5.7076	9.1E3	6.8E+05	5.8341	5.7708	3.4337
7	Baseline	2.2E7	1.7E+09	9.2175	2.7E7	2.0E+09	9.3064	9.2620	.
	Wash 1	3.8E4	2.9E+06	6.4548	6.6E4	5.0E+06	6.6946	6.5747	2.6872
	Wash 11	3.2E3	2.4E+05	5.3802	5.5E3	4.1E+05	5.6154	5.4978	3.7641
8	Baseline	2.6E7	2.0E+09	9.2900	2.6E7	2.0E+09	9.2900	9.2900	.
	Wash 1	9.5E4	7.1E+06	6.8528	4.4E4	3.3E+06	6.5185	6.6856	2.6044
	Wash 11	8.4E3	6.3E+05	5.7993	2.7E3	2.0E+05	5.3064	5.5529	3.7372
9	Baseline	2.0E7	1.5E+09	9.1761	3.4E7	2.6E+09	9.4065	9.2913	.
	Wash 1	5.0E4	3.8E+06	6.5740	1.7E5	1.3E+07	7.1055	6.8398	2.4515
	Wash 11	1.2E4	9.0E+05	5.9542	1.2E4	9.0E+05	5.9542	5.9542	3.3371
10	Baseline	2.1E7	1.6E+09	9.1973	2.4E7	1.8E+09	9.2553	9.2263	.
	Wash 1	1.8E5	1.4E+07	7.1303	2.3E5	1.7E+07	7.2368	7.1836	2.0427
	Wash 11	2.4E3	1.8E+05	5.2553	2.8E3	2.1E+05	5.3222	5.2887	3.9375
13	Baseline	2.1E7	1.6E+09	9.1973	2.6E7	2.0E+09	9.2900	9.2437	.
	Wash 1	1.6E4	1.2E+06	6.0792	3.6E4	2.7E+06	6.4314	6.2553	2.9884
	Wash 11	8.6E3	6.5E+05	5.8096	1.1E4	8.3E+05	5.9165	5.8630	3.3807
14	Baseline	3.0E7	2.3E+09	9.3522	2.6E7	2.0E+09	9.2900	9.3211	.
	Wash 1	3.4E4	2.6E+06	6.4065	2.4E4	1.8E+06	6.2553	6.3309	2.9902
	Wash 11	3.1E3	2.3E+05	5.3664	3.7E3	2.8E+05	5.4433	5.4048	3.9163
20	Baseline	1.8E7	1.4E+09	9.1303	2.0E7	1.5E+09	9.1761	9.1532	.
	Wash 1	6.4E4	4.8E+06	6.6812	1.1E5	8.3E+06	6.9165	6.7988	2.3544
	Wash 11	8.4E3	6.3E+05	5.7993	1.6E4	1.2E+06	6.0792	5.9393	3.2140
44	Baseline	1.9E7	1.4E+09	9.1538	2.8E7	2.1E+09	9.3222	9.2380	.
	Wash 1	1.6E5	1.2E+07	7.0792	1.5E5	1.1E+07	7.0512	7.0652	2.1729
	Wash 11	5.4E4	4.1E+06	6.6075	5.2E4	3.9E+06	6.5911	6.5993	2.6388
64	Baseline	2.4E7	1.8E+09	9.2553	2.3E7	1.7E+09	9.2368	9.2460	.
	Wash 1	6.6E4	5.0E+06	6.6946	1.3E5	9.8E+06	6.9890	6.8418	2.4042
	Wash 11	3.6E3	2.7E+05	5.4314	6.2E3	4.7E+05	5.6675	5.5494	3.6966
68	Baseline	2.6E7	2.0E+09	9.2900	2.0E7	1.5E+09	9.1761	9.2331	.
	Wash 1	3.4E5	2.6E+07	7.4065	3.4E5	2.6E+07	7.4065	7.4065	1.8265
	Wash 11	1.0E4	7.5E+05	5.8751	9.0E3	6.8E+05	5.8293	5.8522	3.3809
71	Baseline	1.4E7	1.1E+09	9.0212	1.9E7	1.4E+09	9.1538	9.0875	.
	Wash 1	2.6E4	2.0E+06	6.2900	6.0E4	4.5E+06	6.6532	6.4716	2.6159
	Wash 11	1.1E3	8.3E+04	4.9165	2.7E3	2.0E+05	5.3064	5.1114	3.9761
72	Baseline	1.4E7	1.1E+09	9.0212	1.9E7	1.4E+09	9.1538	9.0875	.
	Wash 1	4.5E4	3.4E+06	6.5283	5.3E4	4.0E+06	6.5993	6.5638	2.5237

Where score has been recorded as <1.0E1, a score of 1.0E1 will be used in the analysis.

Table 1. Summary of CFU counts and log conversions.

----- HTR Code=C: 3107C Hibiclens -----

Subject	Wash	Left			Right			Log10 Average	Log10 Reduction
		CFU/mL	CFU/Hand	Log10 CFU/Hand	CFU/mL	CFU/Hand	Log10 CFU/Hand		
72	Wash 11	4.0E3	3.0E+05	5.4771	2.8E3	2.1E+05	5.3222	5.3997	3.6878
73	Baseline	2.1E7	1.6E+09	9.1973	2.1E7	1.6E+09	9.1973	9.1973	.
	Wash 1	6.7E4	5.0E+06	6.7011	4.6E4	3.5E+06	6.5378	6.6195	2.5778
	Wash 11	1.6E4	1.2E+06	6.0792	7.3E3	5.5E+05	5.7384	5.9088	3.2885

Where score has been recorded as <1.0E1, a score of 1.0E1 will be used in the analysis.

HTR Study Number 00-105877-11
 Table 2a. Mean summary of log10 averages.

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		Log10 Average	Std. Dev.	N
HTR Code				
A: 3434-9 Foaming Handwash	Baseline	9.2728	0.0889	30
	Wash 1	5.5426	0.5819	30
	Wash 11	5.3004	0.5873	30
B: 3434-10 Foaming Handwash	Baseline	9.2249	0.1181	30
	Wash 1	5.5878	0.5031	30
	Wash 11	5.4337	0.6722	30
C: 3107C Hibiclens	Baseline	9.2141	0.0716	15
	Wash 1	6.6998	0.3493	15
	Wash 11	5.6815	0.3616	15

Table 3. Means summary of the log10 reductions from baseline, percent microbial reductions, and confidence limits.

		Confidence Interval			Confidence Interval		
		Average Log10 Difference	Log10 Lower Limit	Log10 Upper Limit	Percent Reduction	Percent Lower Limit	Percent Upper Limit
HTR Code							
A: 3434-9 Foaming Handwash	Wash 1	3.7302	3.5261	3.9343	99.98	99.97	99.99
	Wash 11	3.9724	3.7643	4.1806	99.99	99.98	99.99
B: 3434-10 Foaming Handwash	Wash 1	3.6372	3.4608	3.8136	99.98	99.97	99.98
	Wash 11	3.7912	3.5489	4.0335	99.98	99.97	99.99
C: 3107C Hibiclens	Wash 1	2.5143	2.3254	2.7032	99.69	99.53	99.80
	Wash 11	3.5326	3.3389	3.7263	99.97	99.95	99.98

Table 4. Analysis of variance comparison of test article log10 baseline counts (using the average of left and right hands).

The GLM Procedure

Class Level Information

Class	Levels	Values
HTRCode	3	HTR Code A HTR Code B HTR Code C
Number of observations		75

Table 4. Analysis of variance comparison of test article log10 baseline counts (using the average of left and right hands).

The GLM Procedure

Dependent Variable: lgavg

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	0.04893921	0.02446961	2.50	0.0894
Error	72	0.70551680	0.00979884		
Corrected Total	74	0.75445601			

R-Square Coeff Var Root MSE lgavg Mean
 0.064867 1.071088 0.098989 9.241921

Source	DF	Type I SS	Mean Square	F Value	Pr > F
HTRCode	2	0.04893921	0.02446961	2.50	0.0894

Source	DF	Type III SS	Mean Square	F Value	Pr > F
HTRCode	2	0.04893921	0.02446961	2.50	0.0894

Table 4. Analysis of variance comparison of test article log10 baseline counts (using the average of left and right hands).

The GLM Procedure

Level of HTRCode	N	-----lgavg----- Mean	Std Dev
HTR Code A	30	9.27282766	0.08886415
HTR Code B	30	9.22493706	0.11814674
HTR Code C	15	9.21407745	0.07156794

Table 4. Analysis of variance comparison of test article log10 baseline counts (using the average of left and right hands).

The GLM Procedure

Tukey's Studentized Range (HSD) Test for lgavg

NOTE: This test controls the Type I experimentwise error rate.

Alpha	0.05
Error Degrees of Freedom	72
Error Mean Square	0.009799
Critical Value of Studentized Range	3.38440

Comparisons significant at the 0.05 level are indicated by ***.

HTRCode Comparison	Difference Between Means	Simultaneous 95% Confidence Limits
HTR Code A - HTR Code B	0.04789	-0.01328 0.10906
HTR Code A - HTR Code C	0.05875	-0.01616 0.13366
HTR Code B - HTR Code A	-0.04789	-0.10906 0.01328
HTR Code B - HTR Code C	0.01086	-0.06405 0.08577
HTR Code C - HTR Code A	-0.05875	-0.13366 0.01616
HTR Code C - HTR Code B	-0.01086	-0.08577 0.06405

Table 5. Analysis of variance to evaluate the effectiveness of each treatment as a function of the number of treatments (using the log10 count differences from baseline for each test article).

----- HTRCode=HTR Code A -----

The GLM Procedure

Class Level Information

Class	Levels	Values
Subject	30	3 4 6 11 17 19 22 23 25 27 28 29 32 33 35 36 37 38 39 42 43 46 50 51 52 55 56 57 58 61
Eval	2	Wash 1 Wash 11

Number of observations 60

Table 5. Analysis of variance to evaluate the effectiveness of each treatment as a function of the number of treatments (using the log10 count differences from baseline for each test article).

HTRCode=HTR Code A

The GLM Procedure

Dependent Variable: lgdiff

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	30	16.35136926	0.54504564	7.17	<.0001
Error	29	2.20457936	0.07601998		
Corrected Total	59	18.55594863			

R-Square Coeff Var Root MSE lgdiff Mean
 0.881193 7.159064 0.275717 3.851303

Source	DF	Type I SS	Mean Square	F Value	Pr > F
Subject	29	15.47116678	0.53348851	7.02	<.0001
Eval	1	0.88020248	0.88020248	11.58	0.0020

Source	DF	Type III SS	Mean Square	F Value	Pr > F
Subject	29	15.47116678	0.53348851	7.02	<.0001
Eval	1	0.88020248	0.88020248	11.58	0.0020

Table 5. Analysis of variance to evaluate the effectiveness of each treatment as a function of the number of treatments
(using the log₁₀ count differences from baseline for each test article).

----- HTRCode=HTR Code A -----

The GLM Procedure

Tukey's Studentized Range (HSD) Test for lgdiff

NOTE: This test controls the Type I experimentwise error rate, but it generally has a higher Type II error rate than REGWQ.

Alpha	0.05
Error Degrees of Freedom	29
Error Mean Square	0.07602
Critical Value of Studentized Range	2.89240
Minimum Significant Difference	0.1456

Means with the same letter are not significantly different.

Tukey Grouping	Mean	N	Eval
A	3.97242	30	Wash 11
B	3.73018	30	Wash 1

Table 5. Analysis of variance to evaluate the effectiveness of each treatment as a function of the number of treatments
 (using the log10 count differences from baseline for each test article).

----- HTRCode=HTR Code B -----

The GLM Procedure

Class Level Information

Class	Levels	Values
Subject	30	1 12 15 16 18 21 24 26 30 31 34 40 41 45 47 48 49 53 54 59 60 62 63 65 66 67 69 70 74 75
Eval	2	Wash 1 Wash 11

Number of observations 60

Table 5. Analysis of variance to evaluate the effectiveness of each treatment as a function of the number of treatments (using the log10 count differences from baseline for each test article).

----- HTRCode=HTR Code B -----

The GLM Procedure

Dependent Variable: lgdiff

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	30	14.23297901	0.47443263	2.86	0.0029
Error	29	4.80671640	0.16574884		
Corrected Total	59	19.03969541			

R-Square	Coeff Var	Root MSE	lgdiff Mean
0.747542	10.96127	0.407123	3.714193

Source	DF	Type I SS	Mean Square	F Value	Pr > F
Subject	29	13.87700209	0.47851731	2.89	0.0028
Eval	1	0.35597692	0.35597692	2.15	0.1535

Source	DF	Type III SS	Mean Square	F Value	Pr > F
Subject	29	13.87700209	0.47851731	2.89	0.0028
Eval	1	0.35597692	0.35597692	2.15	0.1535

Table 5. Analysis of variance to evaluate the effectiveness of each treatment as a function of the number of treatments (using the log10 count differences from baseline for each test article).

----- HTRCode=HTR Code B -----

The GLM Procedure

Tukey's Studentized Range (HSD) Test for lgdiff

NOTE: This test controls the Type I experimentwise error rate, but it generally has a higher Type II error rate than REGWQ.

Alpha	0.05
Error Degrees of Freedom	29
Error Mean Square	0.165749
Critical Value of Studentized Range	2.89240
Minimum Significant Difference	0.215

Means with the same letter are not significantly different.

Tukey Grouping	Mean	N	Eval
A	3.7912	30	Wash 11
A	3.6372	30	Wash 1

Table 5. Analysis of variance to evaluate the effectiveness of each treatment as a function of the number of treatments (using the log10 count differences from baseline for each test article).

----- HTRCode=HTR Code C -----

The GLM Procedure

Class Level Information

Class	Levels	Values
Subject	15	2 5 7 8 9 10 13 14 20 44 64 68 71 72 73
Eval	2	Wash 1 Wash 11

Number of observations 30

Table 5. Analysis of variance to evaluate the effectiveness of each treatment as a function of the number of treatments (using the log10 count differences from baseline for each test article).

----- HTRCode=HTR Code C -----

The GLM Procedure

Dependent Variable: lgdiff

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	15	9.95329362	0.66355291	7.97	0.0002
Error	14	1.16567749	0.08326268		
Corrected Total	29	11.11897111			

R-Square	Coeff Var	Root MSE	lgdiff Mean
0.895163	9.543809	0.288553	3.023455

Source	DF	Type I SS	Mean Square	F Value	Pr > F
Subject	14	2.17661704	0.15547265	1.87	0.1274
Eval	1	7.77667658	7.77667658	93.40	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
Subject	14	2.17661704	0.15547265	1.87	0.1274
Eval	1	7.77667658	7.77667658	93.40	<.0001

Table 5. Analysis of variance to evaluate the effectiveness of each treatment as a function of the number of treatments (using the log10 count differences from baseline for each test article).

----- HTRCode=HTR Code C -----

The GLM Procedure

Tukey's Studentized Range (HSD) Test for lgdiff

NOTE: This test controls the Type I experimentwise error rate, but it generally has a higher Type II error rate than REGWQ.

Alpha	0.05
Error Degrees of Freedom	14
Error Mean Square	0.083263
Critical Value of Studentized Range	3.03319
Minimum Significant Difference	0.226

Means with the same letter are not significantly different.

Tukey Grouping	Mean	N	Eval
A	3.5326	15	Wash 11
B	2.5143	15	Wash 1