

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>265</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>S-I-P</u> F M L	Permanent #: <u>63</u>	03-122085-106

Gender: Male Female. Age: 44 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. <u>ragweed</u>		✓	
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: Jami Busmeyer Date: 07/21/03
mm dd yy

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

HTR Study No.: 03-122085-106
Page No.: IV-560

Visit Code	Date	Subject Initials	Subject Screen #: <u>265</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>S1-1P</u> f m l	Permanent #: <u>63</u>	03-122085-106

INCLUSION CRITERIA

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

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input checked="" type="checkbox"/> negative <input type="checkbox"/> positive <u>7/20/03 gk</u>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

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

Reasons for disqualification: _____ Interviewer's Initials/Date: JNB 07.21.03

Investigator's Signature: _____

Date: 9 / 11 / 03
mm dd yy

Data Collection Form 3
INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>265</u>	Study #
Test Period	<u>07 / 30 / 03</u> mm dd yy	<u>S I E I P</u> F M L	Permanent #: <u>63</u>	03-122085-106

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 new 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:

Interviewer's Signature: Mary M. Warrham Date: 07 / 30 / 03
 mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/30/03</u> mm dd yy	<u>S-I-P</u> F. M L	<u>265</u> Permanent #: <u>63</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	<u>(*)</u> 10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>263</u>	<u>18</u>	TNTC	TNTC	<u>75</u>
TNTC	<u>220</u>	<u>33</u>	TNTC	TNTC	<u>43</u>
CFU/mL <u>2.5 x 10⁷</u> Counted by: <u>PS / 8-1-03</u>			CFU/mL <u>5.9 x 10⁷</u> Counted by: <u>PS / 8-1-03</u>		

(*) Did not estimate due to countability of plates. PS 8-6-03

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>29</u>	<u>2</u>	TNTC	TNTC	<u>40</u>	<u>1</u>	TNTC	TNTC	<u>36</u>	<u>1</u>
TNTC	TNTC	<u>42</u>	<u>0</u>	TNTC	TNTC	<u>36</u>	<u>1</u>	TNTC	TNTC	<u>36</u>	<u>1</u>
TNTC				TNTC				TNTC			
CFU/mL <u>3.6 x 10⁴</u> Counted by: <u>PS / 8-1-03</u>				CFU/mL <u>3.8 x 10⁴</u> Counted by: <u>PS / 8-1-03</u>				CFU/mL <u>3.8 x 10⁴</u> Counted by: <u>PS / 8-1-03</u>			

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
<u>52</u>	<u>29</u>	<u>2</u>	<u>0</u>	<u>115</u>	<u>20</u>	<u>2</u>	<u>0</u>	<u>52</u>	<u>20</u>	<u>2</u>	<u>0</u>
<u>57</u>	<u>23</u>	<u>2</u>	<u>0</u>	<u>94</u>	<u>31</u>	<u>2</u>	<u>0</u>	<u>57</u>	<u>31</u>	<u>2</u>	<u>0</u>
<u>66</u>				<u>106</u>				<u>66</u>			
CFU/mL <u>2.3 x 10³</u> Counted by: <u>PS / 8-1-03</u>				CFU/mL <u>3.0 x 10³</u> Counted by: <u>PS / 8-1-03</u>				CFU/mL <u>3.0 x 10³</u> Counted by: <u>PS / 8-1-03</u>			

Calculations by: SAS / 8-1-03 Raw data reviewed by JNB / 08-01-03

Calculations Verified by: JNB / 08-01-03

*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>8 / 11 / 03</u> mm dd yy
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FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #: <u>265</u>	Study #
Follow-up Visit	<u>08</u> / <u>04</u> / <u>03</u> mm dd yy	<u>S E C P</u> F M L	Permanent #: <u>63</u>	03-122085-106

3/4/03 g&v

Date Subject Entered the Study: <u>07</u> / <u>21</u> / <u>03</u> mm dd yy	Follow-Up Visit Date: <u>08</u> / <u>04</u> / <u>03</u> mm dd yy
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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: <u>E. Lewis Jones M.D.</u>	Date <u>8</u> / <u>4</u> / <u>03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 220	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>C I A I B</u> F M L	Permanent #: 64	03-122085-106

Gender: <input checked="" type="checkbox"/> Male <input type="checkbox"/> Female	Age: <u>44</u> Years
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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: <u>Betty M. Conover</u>	Date: <u>07/21/03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-565

Visit Code	Date	Subject Initials	Subject Screen #: 220	Study #
Subject Qualification	07/21/03 mm dd yy	CIAIB f m l	Permanent #: 64	03-122085-106

INCLUSION CRITERIA

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

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	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, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

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

Reasons for disqualification: _____ Interviewer's Initials/Date: BC 107-21-03

Investigator's Signature: [Signature]

Date: 8/11/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: 220	Study #
Test Period	<u>07/29/03</u> mm dd yy	<u>C, A, B</u> F M L	Permanent #: 64	03-122085-106

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 new 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:

Interviewer's Signature: Stacey Buckendy Date: 07, 29, 03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/29/03</u> mm dd yy	<u>C/A/B</u> F M L	<u>220</u>	03-122085-106
		Permanent #:	
		<u>64</u>	

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>118</u>	<u>17</u>	TNTC	<u>103</u>	<u>6</u>
TNTC	<u>144</u>	<u>17</u>	TNTC	<u>91</u>	<u>6</u>
CFU/mL <u>1.3x10⁷</u> Counted by: <u>JNB /07-31-03</u>			CFU/mL <u>9.7x10⁶</u> Counted by: <u>JNB /07-31-03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>217</u>	<u>22</u>	TNTC	TNTC	TNTC	<u>36</u>	TNTC	TNTC	TNTC	<u>34</u>
TNTC	TNTC	<u>189</u>	<u>23</u>	TNTC	TNTC	TNTC		TNTC	TNTC	TNTC	
TNTC				TNTC				TNTC			
CFU/mL <u>2.0x10⁵</u> Counted by: <u>JNB /07-31-03</u>						CFU/mL <u>3.5x10⁵</u> Counted by: <u>JNB /07-31-03</u>					

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>309</u>	<u>22</u>	TNTC	TNTC	TNTC	<u>33</u>	TNTC	TNTC	TNTC	<u>26</u>
TNTC	TNTC	<u>272</u>	<u>25</u>	TNTC	TNTC	TNTC		TNTC	TNTC	TNTC	
TNTC				TNTC				TNTC			
CFU/mL <u>2.4x10⁵</u> Counted by: <u>EAS /7-31-03</u>						CFU/mL <u>3.0x10⁵</u> Counted by: <u>EAS /7-31-03</u>					

Ⓢ Did not estimate due to countability of plate EAS 7-31-03

Calculations by: JNB /08-01-03 Raw data reviewed by SRH /8-6-03

Calculations Verified by: EAS /8-1-03

*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>8 / 11 / 03</u> mm dd yy
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Data Collection Form 5A

Subject Initials C.A.B. Subject # 64

Study No. 03-122085-106

Page No. IV-568

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
<i>Papules</i>	<i>7-31/03</i>	<i>8/14/03</i>	<i>N</i>	<i>1</i>			<i>4*</i>	<i>E.S.J. 8/21/03</i>
Entry Date	Comment/Note: <i>* Probably due to test organism. E.S.J.</i>							
<i>8/4/03</i>	<i>Six red papules on the hands and forearms</i>							
<i>8/14/03</i>	<i>Hands & forearms clear no medications used</i>							

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

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

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 #: <u>220</u>	Study #
Follow-up Visit	<u>08/04/03</u> mm dd yy	<u>C, A, B</u> F M L	Permanent #: <u>64</u>	03-122085-106

Date Subject Entered the Study: <u>07.21.03</u> mm dd yy	Follow-Up Visit Date: <u>08.04.03</u> mm dd yy
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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.)

Six red papules on hands + fore arm.
Onset: 7-31-03

Comments:

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

YES NO If yes, complete below

Comments:

Medical Consultant's Signature:		Date ____/____/____ mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 239	Study #
Subject Qualification	07/21/03 mm dd yy	BIL 10 F M L	Permanent #: 65	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>46</u> Years
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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 ? <u>Da lip 1996</u>		✓	
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify: <u>Hypo-thyroidism</u>		✓	

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 ? <u>Synthroid 150mg 1x day for Hypothyroidism</u>		✓	

Comments:

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

Interviewer's Signature: <u>Graig M. Warkham</u>	Date: <u>07/21/03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-571

Visit Code	Date	Subject Initials	Subject Screen #: <u>239</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>B/K/O</u> f m l	Permanent #: <u>65</u>	03-122085-106

INCLUSION CRITERIA

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

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <u>72</u> <input checked="" type="checkbox"/> Surgically Sterile, year <u>1996</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β-HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

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

Reasons for disqualification: _____ Interviewer's Initials/Date: MMW 17-21-03

Investigator's Signature: [Signature] Date: 8/1/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: 239	Study #
Test Period	07/29/03 mm dd yy	B, L, O F M L	Permanent #: 65	03-122085-106

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 new 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:

Interviewer's Signature: Stacey E. Backlund Date: 07/29/03
mm dd yy

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

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/29/03</u> mm dd yy	<u>B/L/O</u> F M L	<u>239</u> Permanent #: <u>65</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>170</u>	10	TNTC	<u>182</u>	<u>28</u>
TNTC	<u>187</u>	17	TNTC	<u>207</u>	<u>32</u>
CFU/mL <u>1.8x10⁷</u> Counted by: <u>TG 17-31-03</u>			CFU/mL <u>2.5x10⁷</u> Counted by: <u>TG 17-31-03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	TNTC	<u>50</u>	TNTC	TNTC	TNTC	<u>44</u>	TNTC	TNTC	TNTC	<u>31</u>
TNTC	TNTC	TNTC	<u>52</u>	TNTC	TNTC	TNTC	<u>31</u>	TNTC	TNTC	TNTC	<u>31</u>
TNTC				TNTC				TNTC			
CFU/mL <u>5.1x10⁵</u> Counted by: <u>TG 17-31-03</u>				CFU/mL <u>3.8x10⁵</u> Counted by: <u>TG 17-31-03</u>				CFU/mL <u>3.8x10⁵</u> Counted by: <u>TG 17-31-03</u>			

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	TNTC	<u>47</u>	TNTC	TNTC	TNTC	<u>37</u>	TNTC	TNTC	TNTC	<u>37</u>
TNTC	TNTC	TNTC	<u>44</u>	TNTC	TNTC	TNTC	<u>37</u>	TNTC	TNTC	TNTC	<u>37</u>
TNTC				TNTC				TNTC			
CFU/mL <u>4.6x10⁵</u> Counted by: <u>JNB 107-31-03</u>				CFU/mL <u>3.7x10⁵</u> Counted by: <u>JNB 107-31-03</u>				CFU/mL <u>3.7x10⁵</u> Counted by: <u>JNB 107-31-03</u>			

Calculations by: JNB 108-01-03 Raw data reviewed by SRLH 8-6-03

Calculations Verified by: SAS 8-1-03

*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>8/11/03</u> mm dd yy
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FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>08.04.03</u> mm dd yy	<u>B, L, D</u> F M L	<u>239</u> Permanent #: <u>65</u>	03-122085-106

Date Subject Entered the Study: <u>07.21.03</u> mm dd yy	Follow-Up Visit Date: <u>08.04.03</u> mm dd yy
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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: <i>E. Levin</i>	Date <u>8.4.03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>231</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>K, E, G</u> F M L	Permanent #: <u>66</u>	03-122085-106

Gender: Male Female Age: 46 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: <u>depression</u>		/	

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 ? <u>Prozac 20mg 1/day (depression)</u>		/	

Comments:

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

Interviewer's Signature: Stacy E. Bachendy Date: 07/21/03
mm dd yy

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

HTR Study No.: 03-122085-106
Page No.: IV-576

Visit Code	Date	Subject Initials	Subject Screen #: <u>231</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>K, E, S</u> f m i	Permanent #: <u>66</u>	03-122085-106

INCLUSION CRITERIA

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

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year <u> </u> <input type="checkbox"/> Post-menopausal, year <u> </u> If of child bearing potential - β -HCG Test Results: <input checked="" type="checkbox"/> negative <input type="checkbox"/> positive <u>7/29/03 ga</u>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

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

Reasons for disqualification: _____ Interviewer's Initials/Date: SEP 7/21/03

Investigator's Signature: [Signature] Date: 8/11/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>231</u>	Study #
Test Period	<u>07/29/03</u> mm dd yy	<u>KIEIG</u> F M L	Permanent #: <u>666</u>	03-122085-106

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 new 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: _____

Interviewer's Signature: Stacy E. Barchard Date: 07/29/03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/29/03</u> mm dd yy	<u>KIEG</u> F. M L	<u>231</u> Permanent #: <u>66</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	* 10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>215</u>	<u>291^Δ</u>	TNTC	<u>198</u>	<u>39</u>
TNTC	<u>289^Δ</u>	<u>252^Δ</u>	TNTC	<u>215</u>	<u>42</u>
CFU/mL <u>2.5 x 10⁷</u> Counted by: <u>TG 17-31-03</u>			CFU/mL <u>3.0 x 10⁷</u> Counted by: <u>TG 17-31-03</u>		

Δ Not estimated due to uneven distribution of colonies. TG 7-31-03
* Probable dilution error. Do not use in calculation. TG 7-31-03

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	TNTC	<u>31</u>	TNTC	TNTC	TNTC	<u>52</u>	TNTC	TNTC	TNTC	<u>52</u>
TNTC	TNTC	TNTC	<u>53</u>	TNTC	TNTC	TNTC	<u>52</u>	TNTC	TNTC	TNTC	<u>52</u>
TNTC				TNTC				TNTC			
CFU/mL <u>4.2 x 10⁵</u> Counted by: <u>ES 17-31-03</u>						CFU/mL <u>5.7 x 10⁵</u> Counted by: <u>ES 17-31-03</u>					

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	TNTC	<u>62</u>	TNTC	TNTC	TNTC	<u>49</u>	TNTC	TNTC	TNTC	<u>98</u>
TNTC	TNTC	TNTC	<u>90</u>	TNTC	TNTC	TNTC	<u>98</u>	TNTC	TNTC	TNTC	<u>98</u>
TNTC				TNTC				TNTC			
CFU/mL <u>7.6 x 10⁵</u> Counted by: <u>ES 17-31-03</u>						CFU/mL <u>7.4 x 10⁵</u> Counted by: <u>ES 17-31-03</u>					

Calculations by: JNB 108-01-03 Raw data reviewed by SRH 18-6-03

Calculations Verified by: ES 18-1-03

*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

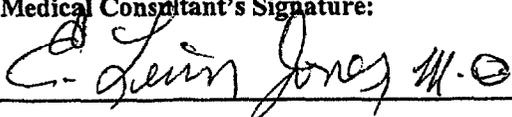
TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>8/1/03</u> mm dd yy
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FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
	<u>08.04.03</u>	<u>KIEIG</u>	<u>231</u>	
Follow-up Visit	mm dd yy	F M L	Permanent #:	03-122085-106
			<u>66</u>	

Date Subject Entered the Study: <u>07.21.03</u> mm dd yy	Follow-Up Visit Date: <u>08.04.03</u> 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? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, complete below:	
Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.) <hr/> <hr/> <hr/>	
Comments: <hr/> <hr/> <hr/>	
Has the subject had any health related issues since the treatment procedure? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, complete below	
Comments: <hr/> <hr/> <hr/>	

Medical Consultant's Signature: 	Date <u>8.9.03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 225	Study #
Subject Qualification	07/21/03 mm dd yy	GIEB F M L	Permanent #: 67	03-122085-106

Gender: Male Female Age: 60 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 ? <i>osteoporosis EVISTA 60mg 1xday</i>		✓	

Comments: *Ⓜ added 7/22/03 gr as per subject*

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

Interviewer's Signature: *Betty M. Conover* Date: 07/21/03
mm dd yy

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

HTR Study No.: 03-122085-106
Page No.: IV-581

Visit Code	Date	Subject Initials	Subject Screen #: <u>225</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>GIEIB</u> f m l	Permanent #: <u>67</u>	03-122085-106

INCLUSION CRITERIA

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

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	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 checked="" type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year <u>1993</u> If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:

Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: BC 107-21-03

Investigator's Signature: _____

Date: 9 11 03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Test Period	<u>07/29/03</u> mm dd yy	<u>G, E, B</u> F M L	<u>225</u> Permanent #: <u>67</u>	03-122085-106

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 new 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:

Interviewer's Signature: Stacey E. Backlund Date: 07/29/03
mm dd yy

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

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/29/03</u> mm dd yy	<u>G/E/B</u> F M L	<u>225</u> Permanent #: <u>67</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>154</u>	<u>19</u>	TNTC	<u>172</u>	<u>24</u>
TNTC	<u>11</u>	<u>14</u>	TNTC	<u>124</u>	<u>17</u>
CFU/mL <u>1.5x10⁷</u> Counted by: <u>JNB 107-31-03</u>			CFU/mL <u>5x10⁷</u> Counted by: <u>JNB 107-31-03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>125</u>	<u>9</u>	TNTC	TNTC	<u>49</u>	<u>5</u>	TNTC	TNTC	<u>179</u>	<u>3</u>
TNTC	TNTC	<u>123</u>	<u>13</u>	TNTC	TNTC			TNTC	TNTC		
TNTC				TNTC				TNTC			
CFU/mL <u>1.2x10⁵</u> Counted by: <u>JNB 107-31-03</u>						CFU/mL <u>1.1x10⁵</u> Counted by: <u>JNB 107-31-03</u>					

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>147</u>	<u>8</u>	TNTC	TNTC	<u>116</u>	<u>15</u>	TNTC	TNTC	<u>128</u>	<u>7</u>
TNTC	TNTC	<u>90</u>	<u>16</u>	TNTC	TNTC			TNTC	TNTC		
TNTC				TNTC				TNTC			
CFU/mL <u>1.2x10⁵</u> Counted by: <u>SAS 17-31-03</u>						CFU/mL <u>1.2x10⁵</u> Counted by: <u>SAS 17-31-03</u>					

Calculations by: JNB 108-01-03 Raw data reviewed by SRH 18-6-03
 Calculations Verified by: SAS 18-1-03
 *10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.
 Underlined values are used for calculation of CFU/mL
 TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>8/14/03</u> mm dd yy
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FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>08/04/03</u> mm dd yy	<u>G I E I B</u> F M L	<u>225</u> Permanent #: <u>67</u>	03-122085-106

Date Subject Entered the Study: <u>07/21/03</u> mm dd yy	Follow-Up Visit Date: <u>08/04/03</u> 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: <i>E. Levin Jones, M.D.</i>	Date <u>8/4/03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 217	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>D, J, H</u> F M L	Permanent #: 68	03-122085-106

Gender: Male Female. Age: 52 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 ? <u>Ovarian 1975</u> <u>7/6/03</u> (3) ✓	✓	✓	
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: Stacy C. Beckwith

Date: 07/21/03
mm dd yy

Data Collection Form 2
INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106
Page No.: IV-586

Visit Code	Date	Subject Initials	Subject Screen #: <u>217</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>D, J, H</u> f m l	Permanent #: <u>68</u>	03-122085-106

INCLUSION CRITERIA

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

EXCLUSION CRITERIA

Check one ...			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Surgically Sterile, year <u>1975</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β-HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:

Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: SEB, 7/21/03

Investigator's Signature: [Signature]

Date: 07/21/03
mm dd yy

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: 217	Study #
Test Period	<u>07/29/03</u> mm dd yy	<u>D.S.H</u> F M L	Permanent #: 68	03-122085-106

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 new 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: _____

Interviewer's Signature: Jacey E. Barchewitz Date: 07/29/03
 mm dd yy

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

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/29/03</u> mm dd yy	<u>D/J/H</u> F. M L	<u>217</u>	
		Permanent #: <u>68</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>237</u>	<u>30</u>	TNTC	<u>170</u>	<u>17</u>
TNTC	<u>233</u>	<u>16</u>	TNTC	<u>164</u>	<u>15</u>
CFU/mL <u>2.3x10⁷</u> Counted by: <u>TG 17-31-03</u>			CFU/mL <u>1.7x10⁷</u> Counted by: <u>TG 17-31-03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	TNTC	<u>55</u>	TNTC	TNTC	<u>206</u>	<u>20</u>	TNTC	TNTC	<u>195</u>	<u>24</u>
TNTC	TNTC	TNTC	<u>62</u>	TNTC	TNTC			TNTC	TNTC		
TNTC				TNTC				TNTC			
CFU/mL <u>5.8x10⁵</u> Counted by: <u>JNB 107-31-03</u>						CFU/mL <u>2.0x10⁵</u> Counted by: <u>JNB 107-31-03</u>					

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>243</u>	<u>19</u>	TNTC	TNTC	TNTC	<u>33</u>	TNTC	TNTC	TNTC	<u>34</u>
TNTC	TNTC	<u>233</u>	<u>42</u>	TNTC	TNTC	TNTC		TNTC	TNTC	TNTC	
TNTC				TNTC				TNTC			
CFU/mL <u>2.7x10⁵</u> Counted by: <u>SAS 17-31-03</u>						CFU/mL <u>3.4x10⁵</u> Counted by: <u>SAS 17-31-03</u>					

Calculations by: JNB 108-01-03 Raw data reviewed by SELH 18-6-03

Calculations Verified by: SAS 18-1-03

*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>8</u> / <u>11</u> / <u>03</u> mm dd yy
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FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #: <u>217</u>	Study #
Follow-up Visit	<u>08, 04, 03</u> mm dd yy	<u>D, J, H</u> F M L	Permanent #: <u>68</u>	03-122085-106

Date Subject Entered the Study: <u>07, 21, 03</u> mm dd yy	Follow-Up Visit Date: <u>08, 04, 03</u> 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: <i>E. Linn Jones, MD</i>	Date <u>8, 4, 03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>268</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>K I J I P</u> F M L	Permanent #: <u>69</u>	03-122085-106

Gender: Male Female. Age: 51 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. <u>Seasonal</u>		✓	
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: <u>Hypo-thyroidism</u>		✓	

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 ? <u>Synthroid 100 mcg 1x day for Hypothyroidism</u>		✓	

Comments: Effexor 75mg 1x day + 35.9 1x day for depression

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

Interviewer's Signature: Mary M. Wathen

Date: 07/21/03
mm dd yy

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

HTR Study No.: 03-122085-106
Page No.: IV-591

Visit Code	Date	Subject Initials	Subject Screen #: <u>268</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>K/J/P</u> f m l	Permanent #: <u>69</u>	03-122085-106

INCLUSION CRITERIA

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

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <i>Hyst</i> <input checked="" type="checkbox"/> Surgically Sterile, year <u>1998</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β-HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

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

Reasons for disqualification: _____ Interviewer's Initials/Date: MMW 17.21.03

Investigator's Signature: [Signature] Date: 01/10/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
	<u>07/29/03</u>	<u>K, J, P</u>	<u>268</u>	
Test Period	<u>mm dd yy</u>	<u>F M L</u>	Permanent #:	03-122085-106
			<u>69</u>	

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 new 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:

Interviewer's Signature: Stacy E Borcheidin Date: 07, 29, 03
 mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/29/03</u> mm dd yy	<u>K, J, P</u> F. M L	<u>268</u> Permanent #: <u>69</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>245</u>	<u>29</u>	TNTC	<u>215</u>	<u>35</u>
TNTC	<u>240</u>	<u>34</u>	TNTC	<u>266^Δ</u>	<u>23</u>
CFU/mL <u>2.8 x 10⁷</u> Counted by: <u>TG 17-31-03</u>			CFU/mL <u>2.6 x 10⁷</u> Counted by: <u>TG 17-31-03</u>		

Δ Did not estimate due to countability of the plate. TG 7-31-03

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>66</u>	<u>6</u>	TNTC	TNTC	<u>81</u>	<u>7</u>	TNTC	TNTC	<u>57</u>	<u>3</u>
TNTC	TNTC	<u>74</u>	<u>11</u>	TNTC	TNTC			TNTC	TNTC		
TNTC				TNTC				TNTC			
CFU/mL <u>7.0 x 10⁴</u> Counted by: <u>TG 17-31-03</u>				CFU/mL <u>6.9 x 10⁴</u> Counted by: <u>TG 17-31-03</u>							

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	<u>FTNTC</u>	<u>63</u>	<u>7</u>	TNTC	TNTC	<u>68</u>	<u>9</u>	TNTC	TNTC	<u>49</u>	<u>7</u>
TNTC	TNTC	<u>45</u>	<u>9</u>	TNTC	TNTC			TNTC	TNTC		
TNTC				TNTC				TNTC			
CFU/mL <u>5.4 x 10⁴</u> Counted by: <u>JNB 107-31-03</u>				CFU/mL <u>5.8 x 10⁴</u> Counted by: <u>JNB 107-31-03</u>							

Calculations by: JNB 108-01-03 Raw data reviewed by SRH 18-6-03

Calculations Verified by: SAS 8-1-03

*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>8 / 11 / 03</u> mm dd yy
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FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #: <u>268</u>	Study #
Follow-up Visit	<u>08.04.03</u> mm dd yy	<u>K.I.P</u> F M L	Permanent #: <u>69</u>	03-122085-106

Date Subject Entered the Study: <u>07.21.03</u> mm dd yy	Follow-Up Visit Date: <u>08.04.03</u> mm dd yy
<p>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?</p> <p><input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, complete below:</p> <p>Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)</p> <hr/> <hr/> <hr/>	
<p>Comments:</p> <hr/> <hr/> <hr/>	
<p>Has the subject had any health related issues since the treatment procedure?</p> <p><input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, complete below</p> <p>Comments:</p> <hr/> <hr/> <hr/>	

Medical Consultant's Signature: <u>E. Lynn Jones, MD</u>	Date <u>8.4.03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>250</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>DIMH</u> F M L	Permanent #: <u>70</u>	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>40</u> Years
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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: <u>Anxiety</u>		✓	

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? <u>Effexor 37.5mg 2x day for anxiety</u>		✓	

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.Interviewer's Signature: Mary M. WarrhamDate: 07/21/03
mm dd yy

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

HTR Study No.: 03-122085-106
Page No.: IV-596

Visit Code	Date	Subject Initials	Subject Screen #: <u>250</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>DIMIH</u> f m l	Permanent #: <u>70</u>	03-122085-106

INCLUSION CRITERIA

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

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female <input checked="" type="checkbox"/>	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year <u> </u> <input type="checkbox"/> Post-menopausal, year <u> </u> If of child bearing potential - β-HCG Test Results: <input checked="" type="checkbox"/> negative <input type="checkbox"/> positive <u>7/29/03 gsn</u>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

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

Reasons for disqualification: _____ Interviewer's Initials/Date: MMW 107-21-03

Investigator's Signature: G. Malby Date: 01/11/03
mm dd yy

Data Collection Form 3
INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>250</u>	Study #
Test Period	<u>07/29/03</u> mm dd yy	<u>D/M/H</u> F M L	Permanent #: <u>70</u>	03-122085-106

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 new 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: _____

Interviewer's Signature: Stacy E. Bachendy Date: 07/29/03
 mm dd yy

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

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/29/03</u> mm dd yy	<u>D.M.H</u> F. M L	<u>250</u> Permanent #: <u>70</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>160</u>	<u>24</u>	TNTC	<u>174</u>	<u>20</u>
TNTC	<u>276</u> Ⓢ	<u>15</u>	TNTC	<u>175</u>	<u>15</u>
CFU/mL <u>2.2x10⁷</u> Counted by: <u>JNB 107-31-03</u>			CFU/mL <u>1.7x10⁷</u> Counted by: <u>JNB 107-31-03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	TNTC	<u>36</u>	TNTC	TNTC	TNTC	<u>44</u>	TNTC	TNTC	TNTC	<u>34</u>
TNTC	TNTC	TNTC	<u>29</u>	TNTC	TNTC	TNTC		TNTC	TNTC	TNTC	
TNTC				TNTC							
CFU/mL <u>3.2x10⁵</u> Counted by: <u>JNB 107-31-03</u>				CFU/mL <u>3.9x10⁵</u> Counted by: <u>JNB 107-31-03</u>							

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>19</u>	<u>14</u>	TNTC	TNTC	<u>170</u>	<u>14</u>	TNTC	TNTC	<u>182</u>	<u>15</u>
TNTC	TNTC	<u>129</u>	<u>12</u>	TNTC	TNTC			TNTC	TNTC		
TNTC				TNTC				TNTC			
CFU/mL <u>1.6x10⁵</u> Counted by: <u>TG 17-31-03</u>				CFU/mL <u>1.8x10⁵</u> Counted by: <u>TG 17-31-03</u>							

Calculations by: JNB 108-01-03 Raw data reviewed by SKH / 8-6-03

Calculations Verified by: SAS / 8-1-03

*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Ⓢ Did not estimate due to countability of the plate. JNB 07-31-03

Investigator's Signature: <u>[Signature]</u>	Date: <u>8 / 11 / 03</u> mm dd yy
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Data Collection Form 5A

Subject Initials DMH Subject # 70

Study No. 03-122085-106

Page No. IV-599

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
bumps	7/3/03	8/2/03	N	1	1	5	4*	<i>[Signature]</i> 8-21-03 Initials
Entry Date	Comment/Note: * Probably due to test organism.							
7/1/03	red bumps on fingers with soreness							
8/2/03	Subject contacted on 8-7-03 and 8-11-03 without response							

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
use above for dates 8-7-03 gn								
Entry Date	Comment/Note:							
8-4-03	Two papules on the back of the left hand							

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

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 *5= Int to follow up*

FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>08.04.03</u> mm dd yy	<u>D.M.H</u> F M L	<u>250</u> Permanent #: <u>70</u>	03-122085-106

Date Subject Entered the Study: <u>07.21.03</u> mm dd yy	Follow-Up Visit Date: <u>08.04.03</u> 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? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO If yes, complete below:	
Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.) <u>Two papules on back of left hand</u>	
Comments: _____ _____ _____	
Has the subject had any health related issues since the treatment procedure? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, complete below	
Comments: _____ _____ _____	

Medical Consultant's Signature: <u>E. Lynn Jones, M.D.</u>	Date: <u>8.4.03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
			238	
Subject Qualification	07/21/03 mm dd yy	JITIF F M L	Permanent #: 71	03-122085-106

Gender: <input checked="" type="checkbox"/> Male <input type="checkbox"/> Female	Age: <u>37</u> 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: <u>depression</u>	✓	✓	

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 ? <u>WE/butrin - depression 200mg</u>		✓	

Comments:

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

Interviewer's Signature: <u>Betty M. Conover</u>	Date: <u>07/21/03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-602

Visit Code	Date	Subject Initials	Subject Screen #: <u>238</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>J I T I F</u> f m l	Permanent #: <u>71</u>	03-122085-106

INCLUSION CRITERIA

21-03
3

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

EXCLUSION CRITERIA

Check one ...			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	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, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

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

Reasons for disqualification: _____ Interviewer's Initials/Date: BC 107.21.03

Investigator's Signature: <u>[Signature]</u>	Date: <u>01/11/03</u> mm dd yy
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Data Collection Form 3
INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: 238	Study #
Test Period	<u>07/29/03</u> mm dd yy	<u>J / T / F</u> F M L	Permanent #: 71	03-122085-106

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 new 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: _____

Interviewer's Signature: Stacy E. Bachendy Date: 07/29/03
 mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/29/03</u> mm dd yy	<u>J I T F</u> F. M L	<u>238</u> Permanent #: <u>71</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>207</u>	<u>18</u>	TNTC	LA	<u>20</u>
TNTC	<u>188</u>	<u>16</u>	TNTC	LA	<u>20</u>
CFU/mL <u>2.0x10⁷</u> Counted by: <u>TR 17-31-03</u>			CFU/mL <u>2.0x10⁷</u> Counted by: <u>TR 17-31-03</u>		

LA = Lab Accident; Gross Contamination. Unable to count. TR 7.31.03

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>204</u>	<u>16</u>	TNTC	TNTC	TNTC	<u>45</u>	TNTC	TNTC	TNTC	<u>33</u>
TNTC	TNTC	<u>190</u>	<u>22</u>	TNTC	TNTC	TNTC		TNTC	TNTC	TNTC	
TNTC				TNTC				TNTC			
CFU/mL <u>2.1x10⁵</u> Counted by: <u>TR 17-31-03</u>				CFU/mL <u>3.9x10⁵</u> Counted by: <u>TR 17-31-03</u>							

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>125</u>	<u>20</u>	TNTC	TNTC	<u>107</u>	<u>15</u>	TNTC	TNTC	<u>102</u>	<u>4</u>
TNTC	TNTC	<u>76</u>	<u>18</u>	TNTC	TNTC			TNTC	TNTC		
TNTC				TNTC				TNTC			
CFU/mL <u>1.0x10⁵</u> Counted by: <u>JNB 107-31-03</u>				CFU/mL <u>1.0x10⁵</u> Counted by: <u>JNB 107-31-03</u>							

Calculations by: JNB 108-01-03 Raw data reviewed by SRH 18-6-03

Calculations Verified by: EAS 18-1-03

*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>8/11/03</u> mm dd yy
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Data Collection Form 5A

Subject Initials JTF Subject # 71

Study No. 03-122085-106

Page No. IV-605

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
red bumps/swelling	7/29/03	8/7/03	N	1	1	1	4*	<i>[Signature]</i> 8-21-03
Entry Date	Comment/Note: *Probable due to test organism E.L.J. As Reported by subject by phone conversation of red bumps on both hands with itching and swelling. Jadded 8-21-03 gr							
7/31/03								
8/7/03	wrist clear - no medications used gr							

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
see above for dates	8.7.03							gr
Entry Date	Comment/Note:							
8-4-03	Two papules on the left wrist E.L.J.							

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

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 #: <u>238</u>	Study #
Follow-up Visit	<u>08/04/03</u> mm dd yy	<u>JITIF</u> F M L	Permanent #: <u>71</u>	03-122085-106

Date Subject Entered the Study: <u>07/21/03</u> mm dd yy	Follow-Up Visit Date: <u>08/04/03</u> 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.)

Two papules on left wrist.

Comments:

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

YES NO If yes, complete below

Comments:

Medical Consultant's Signature: <u>E. Levin Jones M.D.</u>	Date <u>8/4/03</u> mm dd yy
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DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 2801	Study #
Subject Qualification	07/21/03 mm dd yy	C/C/S F M L	Permanent #: 72	03-122085-106

Gender: Male Female Age: 31 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 @ 7/21/03 gh	No	Yes	Don't Know
1. Allergies? Please specify. <u>no reflex</u>		✓	
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: <u>depression</u>		✓	

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 ? <u>welbutin 60mg 1xday depression</u>		✓	

Comments: welbutin 400mg 1xday depression

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

Interviewer's Signature: Jenna D. Hiles Date: 07/21/03
mm dd yy

Data Collection Form 2
INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106
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Visit Code	Date	Subject Initials	Subject Screen #: <u>231</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>C,C,S</u> f m l	Permanent #: <u>72</u>	03-122085-106

INCLUSION CRITERIA

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

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input checked="" type="checkbox"/> negative <input type="checkbox"/> positive <u>7/30/03gr</u>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

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

Reasons for disqualification: _____ Interviewer's Initials/Date: gr 7/21/03

Investigator's Signature: [Signature]

Date: 07/21/03
mm dd yy

Data Collection Form 3
INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>281</u>	Study #
Test Period	<u>07/30/03</u> mm dd yy	<u>C/C/S</u> F M L	Permanent #: <u>72</u>	03-122085-106

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 new 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:

Interviewer's Signature: Mary M. Wacetham Date: 07/30/03
 mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/30/03</u> mm dd yy	<u>C/C/S</u> F M L	<u>281</u> Permanent #: <u>72</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>228</u>	16	TNTC	<u>148</u>	16
TNTC	<u>196</u>	20	TNTC	<u>272</u>	23
CFU/mL <u>2.1 x 10⁷</u> Counted by: <u>SP 8/1/03</u>			CFU/mL <u>2.1 x 10⁷</u> Counted by: <u>SP 8/1/03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	TNTC	<u>42</u>	TNTC	TNTC	TNTC	<u>27</u>	TNTC	TNTC	TNTC	<u>29</u>
TNTC	TNTC	TNTC	<u>44</u>	TNTC	TNTC	TNTC	<u>29</u>	TNTC	TNTC	TNTC	<u>29</u>
TNTC	F ³ SP 8/1/03			TNTC				TNTC			
CFU/mL <u>4.3 x 10⁵</u> Counted by: <u>SP 8/1/03</u>						CFU/mL <u>2.8 x 10⁵</u> Counted by: <u>SP 8/1/03</u>					

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>380</u> ⁴	<u>23</u>	TNTC	TNTC	<u>145</u>	<u>29</u>	TNTC	TNTC	<u>264</u> ⁴	<u>19</u>
TNTC	TNTC	<u>288</u> ⁴	<u>28</u>	TNTC	TNTC	<u>264</u> ⁴	<u>19</u>	TNTC	TNTC	<u>264</u> ⁴	<u>19</u>
TNTC				TNTC				TNTC			
CFU/mL <u>2.6 x 10⁵</u> Counted by: <u>SP 8/1/03</u>						CFU/mL <u>2.2 x 10⁵</u> Counted by: <u>SP 8/1/03</u>					

⁴ Did not estimate due to countability of pl
SP 8/1/03

03/04/03

Calculations by: SAS 18-1-03 Raw data reviewed by JNB 108-01-03

Calculations Verified by: JNB 108-01-03

*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>8/1</u> / <u>1</u> / <u>103</u> mm dd yy
--	--

Subject Initials CCS Subject # 72

Study No. 03-122085-106
Page No. IV-611

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
red bumps	7/31/03	8/11/03	N	1	1	1	4*	<i>[Signature]</i> 8/21/03 Initials
Entry Date	Comment/Note: * I probably due to test organism.							Initials
8/1/03	red bumps on right & left hands							gn
8/4/03	cold w/ head & chest congestion							gn
8/7/03	cold clear							gn
8/11/03	Hands clear no medications used							gn

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Macules	see above for dates				8/7/03			
Entry Date	Comment/Note:							Initials
8-4-03	Faces red macules on left hand and forearm.							<i>[Signature]</i>

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	08/04/03 mm dd yy	C, C, S F M L	281 Permanent #: 72	03-122085-106

Date Subject Entered the Study: 07/21/03 mm dd yy	Follow-Up Visit Date: 08/04/03 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.)

4 red macules on left hand and forearm

Comments:

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

YES NO If yes, complete below

Comments: a cold: Head + chest congestion.

Medical Consultant's Signature: E. Lynn Jones M.D.	Date: 8/9/03 mm dd yy
---	-----------------------------

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 251	Study #
Subject Qualification	07/21/03 mm dd yy	S, W F M L	Permanent #: 73	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>40</u> 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? Dist [] 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: Stacey E. BorchardtDate: 07/21/03

mm

dd

yy

Data Collection Form 2
INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106
Page No.: IV-64

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
	07/21/03 mm dd yy	S-I-W f m l	251 Permanent #: 73	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
/		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 body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products 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			Subject:
YES	NO	N/A	
	/		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, antibiotic, Polysporin® 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 checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Surgically Sterile, year 1999 <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β-HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
	/		8. Is currently lactating ?
	/		9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
	/		10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
	/		11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
	/		12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

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

Reasons for disqualification: _____ Interviewer's Initials/Date: SSB 17/01/03

Investigator's Signature: _____

Date: 8/1/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>251</u>	Study #
Test Period	<u>07/30/03</u> mm dd yy	<u>S1-1W</u> F M L	Permanent #: <u>73</u>	03-122085-106

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 new 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:

Interviewer's Signature: Mary M. Wooten Date: 07/30/03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/30/03</u> mm dd yy	<u>S1 - 1W</u> F. M L	<u>251</u> Permanent #: <u>73</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTZ	<u>195</u>	<u>14</u>	TNTZ	<u>160</u>	<u>17</u>
TNTZ	<u>212</u>	<u>31</u>	TNTZ	<u>240</u>	<u>16</u>
CFU/mL <u>2.6 × 10⁷</u> Counted by: <u>SP 1 8/1/03</u>			CFU/mL <u>2.0 × 10⁷</u> Counted by: <u>SP 1 8/1/03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTZ	TNTZ	<u>114</u>	<u>7</u>	TNTZ	TNTZ	<u>119</u>	<u>10</u>	TNTZ	TNTZ	<u>92</u>	<u>2</u>
TNTZ	TNTZ	<u>108</u>	<u>9</u>	TNTZ	TNTZ			TNTZ	TNTZ		
TNTZ				TNTZ				TNTZ			
CFU/mL <u>1.1 × 10⁵</u> Counted by: <u>SP 1 8/1/03</u>				CFU/mL <u>1.0 × 10⁵</u> Counted by: <u>SP 1 8/1/03</u>							

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTZ	TNTZ	<u>76</u>	<u>8</u>	TNTZ	TNTZ	<u>70</u>	<u>9</u>	TNTZ	TNTZ	<u>91</u>	<u>4</u>
TNTZ	TNTZ	<u>71</u>	<u>7</u>	TNTZ	TNTZ			TNTZ	TNTZ		
TNTZ				TNTZ				TNTZ			
CFU/mL <u>7.4 × 10⁴</u> Counted by: <u>SP 1 8/1/03</u>				CFU/mL <u>8.0 × 10⁴</u> Counted by: <u>SP 1 8/1/03</u>							

Calculations by: SAS / 8-1-03 Raw data reviewed by JNB / 108-01-03

Calculations Verified by: JNB / 108-01-03

*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>8/1/03</u> mm dd yy
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Data Collection Form 5A

Subject Initials S-W Subject # 73

Study No. 03-122085-106

Page No. IV-6167

③ 8.6.03
gn

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
rash on wrist	7/31/03	8/7/03	N	1	4(1)	1	4(2)	E.L. Q. 8-21-03
Entry Date	Comment/Note: 1) Used 10mg of cortisone 2) Due to test organization							
8/1/03	red rash on wrist with itching 8-21-03 gn							
8/7/03	Sands & forearms cream - used gn							
	cortisone-10 2 to 3 times a day from 7/31/03 to 8/7/03							

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Popules	see above for dates						gn	
Entry Date	Comment/Note:							
8-4-03	Three red popules on forearm. E.L. Q.							

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

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 #: 251	Study #
Follow-up Visit	08, 04, 03 mm dd yy	S - 1 - W F M L	Permanent #: 73	03-122085-106

Date Subject Entered the Study: 07, 21, 03 mm dd yy	Follow-Up Visit Date: 08, 04, 03 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.)

Three red papules on forearm.

Comments:

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

YES NO If yes, complete below

Comments:

Medical Consultant's Signature: E. Linn Jones, M.D.	Date 8, 4, 03 mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 252	Study #
Subject Qualification	07/21/03 mm dd yy	D/A/J F M L	Permanent #: 74	03-122085-106

Gender: <input checked="" type="checkbox"/> Male <input type="checkbox"/> Female	Age: <u>42</u> 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: <u>Betty M. Conover</u>	Date: <u>07/21/03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-620

Visit Code	Date	Subject Initials	Subject Screen #: <u>252</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>DIAI</u> f m l	Permanent #: <u>74</u>	03-122085-106

INCLUSION CRITERIA

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

EXCLUSION CRITERIA

Check one ..			Subject:
YES	NO	N/A	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

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

Reasons for disqualification: _____ Interviewer's Initials/Date: BC 107-21-03

Investigator's Signature: [Signature] Date: 01/1/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>252</u>	Study #
Test Period	<u>07/30/03</u> mm dd yy	<u>D/A/J</u> F M L	Permanent #: <u>74</u>	03-122085-106

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 new 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:

Interviewer's Signature: Mary M. Wathen Date: 07/30/03
 mm dd yy

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

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/30/03</u> mm dd yy	<u>D/A/J</u> F. M L	<u>252</u> Permanent #: <u>74</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	TNTC	<u>25</u>	TNTC	<u>182</u>	18
TNTC	TNTC	<u>31</u>	TNTC	<u>210</u> 210	19
CFU/mL <u>2.8 × 10⁷</u> Counted by: <u>PS</u> / 8-1-03			CFU/mL <u>2.0 × 10⁷</u> Counted by: <u>PS</u> / 8-1-03		

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>203</u>	<u>19</u>	TNTC	TNTC	TNTC	<u>29</u>	TNTC	TNTC	TNTC	<u>27</u>
TNTC	TNTC	<u>110</u>	<u>28</u>	TNTC	TNTC	TNTC	<u>27</u>	TNTC	TNTC	TNTC	<u>27</u>
TNTC				TNTC				TNTC			
CFU/mL <u>2.1 × 10⁵</u> Counted by: <u>PS</u> / 8-1-03				CFU/mL <u>2.8 × 10⁵</u> Counted by: <u>PS</u> / 8-1-03				CFU/mL <u>2.8 × 10⁵</u> Counted by: <u>PS</u> / 8-1-03			

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>247</u>	<u>30</u>	TNTC	TNTC	LA [Ⓢ]	<u>11</u>	TNTC	TNTC	<u>121</u>	<u>39</u>
TNTC	TNTC	<u>197</u>	<u>24</u>	TNTC	TNTC			TNTC	TNTC		
TNTC				TNTC				TNTC			
CFU/mL <u>2.5 × 10⁵</u> Counted by: <u>PS</u> / 8-1-03				CFU/mL <u>2.1 × 10⁵</u> Counted by: <u>PS</u> / 8-1-03				CFU/mL <u>2.1 × 10⁵</u> Counted by: <u>PS</u> / 8-1-03			

Ⓢ LA: LAB ACCIDENT, 03 8-1-03

Calculations by: AS / 8-1-03 Raw data reviewed by AS 18-1-03

Calculations Verified by: AS / 8-1-03

*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>8/11/03</u> mm dd yy
--	----------------------------------

FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #: 252	Study #
Follow-up Visit	08/04/03 mm dd yy	D, A, J F M L	Permanent #: 74	03-122085-106

Date Subject Entered the Study: 07/21/03 mm dd yy	Follow-Up Visit Date: 08/04/03 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: E. Quinn Jones, MD	Date 8/4/03 mm dd yy
---	----------------------------

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>256</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>G I - I M</u> F M L	Permanent #: <u>75</u>	03-122085-106

Gender: Male Female Age: 62 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: Betty M. Conover Date: 07/21/03
mm dd yy

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

HTR Study No.: 03-122085-106
Page No.: IV-625

Visit Code	Date	Subject Initials	Subject Screen #: <u>256</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>G1-1M</u> f m l	Permanent #: <u>75</u>	03-122085-106

INCLUSION CRITERIA

Check one			Subject:
YES	NO		
<input checked="" type="checkbox"/>	<input type="checkbox"/>		1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<u>BC 07.21.03</u>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<u>②</u>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		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 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one				Subject:
YES	NO	N/A		
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male		7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Surgically Sterile, year <u>1997</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β-HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:

Qualified Not Qualified for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: _____

BC 107.21.03

Investigator's Signature: _____

Date: 07 21 03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>256</u>	Study #
Test Period	<u>07/30/03</u> mm dd yy	<u>G / - / M</u> F M L	Permanent #: <u>75</u>	03-122085-106

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 new 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: _____

Interviewer's Signature: Mary M. Watham Date: 07 / 30 / 03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/30/03</u> mm dd yy	<u>G - M</u> F. M L	<u>256</u> Permanent #: <u>75</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>293/42</u>	<u>24/39</u>	TNTC	<u>170</u>	<u>18</u>
TNTC	<u>26+200</u>	<u>32/16</u>	TNTC	<u>194</u>	<u>14</u>
CFU/mL <u>2.2 × 10⁷</u> Counted by: <u>SP 8/1/03</u>			CFU/mL <u>1.8 × 10⁷</u> Counted by: <u>SP 8/1/03</u>		

LEFT HAND				WASH 1		RIGHT HAND		
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	
TNTC	TNTC	<u>293</u> ⊕	<u>24</u>	TNTC	TNTC	<u>220</u>	<u>31</u>	
TNTC	TNTC	<u>26</u> ⊕	<u>32</u>	TNTC	TNTC	<u>229</u>	<u>24</u>	
TNTC				TNTC				
CFU/mL <u>2.8 × 10⁵</u> Counted by: <u>SP 8/1/03</u>				CFU/mL <u>2.5 × 10⁵</u> Counted by: <u>SP 8/1/03</u>				

⊕ Did not estimate due to countability of plate SP 8/6/03
Δ underlined error. SAS 8-1-03

LEFT HAND				WASH 11		RIGHT HAND		
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	
TNTC	TNTC	<u>86</u>	<u>5</u>	TNTC	TNTC	<u>62</u>	<u>6</u>	
TNTC	TNTC	<u>67</u>	<u>17</u>	TNTC	TNTC	<u>127</u>	<u>9</u>	
TNTC				TNTC				
CFU/mL <u>7.6 × 10⁴</u> Counted by: <u>SP 8/1/03</u>				CFU/mL <u>9.4 × 10⁴</u> Counted by: <u>SP 8/1/03</u>				

Calculations by: SAS 8-1-03 Raw data reviewed by AS 8.1.03

Calculations Verified by: AS 8.1.03

*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>8/1/03</u> mm dd yy
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FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	08/04/03 mm dd yy	G, - M F M L	256 Permanent #: 75	03-122085-106

Date Subject Entered the Study: 07/21/03 mm dd yy	Follow-Up Visit Date: 08/04/03 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: <i>E. Lynn Jones, MD</i>	Date 8/4/03 mm dd yy
---	----------------------------

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 168	Study #
Subject Qualification	07/21/03 mm dd yy	C/L/C F M L	Permanent #: 76	03-122085-106

Gender: Male Female Age: 30 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: Stacey E. Bacheidin Date: 07/21/03
mm dd yy

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

HTR Study No.: 03-122085-106
Page No.: IV - 630

Visit Code	Date	Subject Initials	Subject Screen #: 168	Study #
Subject Qualification	07/21/03 mm dd yy	CILIC f m l	Permanent #: 74	03-122085-106

INCLUSION CRITERIA

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

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	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, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:

Qualified **Not Qualified**

for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: SEB, 7/21/03

Investigator's Signature: [Signature]

Date: 8/1/03
mm dd yy

Data Collection Form 3
INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>168</u>	Study #
Test Period	<u>07 / 28 / 03</u> mm dd yy	<u>C / L / C</u> F M L	Permanent #: <u>76</u>	03-122085-106

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 new 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:

Interviewer's Signature: Mary M. Wortham Date: 07 / 28 / 03
 mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/28/03</u> mm dd yy	<u>CILIC</u> F. M L	<u>168</u> Permanent #: <u>76</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>216</u>	<u>34</u>	TNTC	<u>215</u>	<u>32</u>
TNTC	<u>209</u>	<u>28</u>	TNTC	<u>220</u>	<u>31</u>
CFU/mL <u>2.6 x 10⁷</u> Counted by: <u>JNB 107-30-03</u>			CFU/mL <u>2.7 x 10⁷</u> Counted by: <u>JNB 107-30-03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>191</u>	<u>18</u>	TNTC	TNTC	TNTC	<u>41</u>	TNTC	TNTC	TNTC	<u>38</u>
TNTC	TNTC	<u>190</u>	<u>16</u>	TNTC	TNTC	TNTC		TNTC	TNTC	TNTC	
TNTC				TNTC				TNTC			
CFU/mL <u>1.9 x 10⁵</u> Counted by: <u>JNB 107-30-03</u>				CFU/mL <u>4.2 x 10⁵</u> Counted by: <u>JNB 107-30-03</u>							

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>36</u>	<u>3</u>	TNTC	TNTC	<u>136</u>	<u>23</u>	TNTC	TNTC	<u>142</u>	<u>13</u>
TNTC	TNTC	<u>29</u>	<u>3</u>	TNTC	TNTC			TNTC	TNTC		
TNTC				TNTC				TNTC			
CFU/mL <u>3.2 x 10⁴</u> Counted by: <u>JNB 107-30-03</u>				CFU/mL <u>1.4 x 10⁵</u> Counted by: <u>JNB 107-30-03</u>							

Calculations by: TG 107-31-03 Raw data reviewed by SLH 18-6-03

Calculations Verified by: JNB 108-01-03 08-01-03

*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates. ©JNB 08-01-03

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>G. Spiller</u>	Date: <u>8/11/03</u> mm dd yy
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FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>08/01/03</u> mm dd yy	<u>C/L/C</u> F M L	<u>168</u> Permanent #: <u>76</u>	03-122085-106

Date Subject Entered the Study: <u>07/21/03</u> mm dd yy	Follow-Up Visit Date: <u>08/01/03</u> 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: <u>E. Lynn Jones M-D</u>	Date <u>8/1/03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>169</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>E I J B</u> F M L	Permanent #: <u>77</u>	03-122085-106

Gender: Male Female Age: 49 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: Jamie Bussemeyer Date: 07/21/03
mm dd yy

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

HTR Study No.: 03-122085-106
Page No.: IV-1635

Visit Code	Date	Subject Initials	Subject Screen #: <u>1169</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>E J B</u> f m l	Permanent #: <u>77</u>	03-122085-106

INCLUSION CRITERIA

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

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input checked="" type="checkbox"/> Post-menopausal, year <u>2002</u> If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:

Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: JNB 107-21-03

Investigator's Signature: _____

Date: 9/18/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: 169	Study #
Test Period	<u>07/28/03</u> mm dd yy	<u>E/S B</u> F M L	Permanent #: <u>77</u>	03-122085-106

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 new 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:

Interviewer's Signature: Stacey E. Backlund Date: 07/28/03
 mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/28/03</u> mm dd yy	<u>EJB</u> F. M L	<u>1109</u>	03-122085-106
		Permanent #: <u>77</u>	

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>138</u>	<u>21</u>	TNTC	<u>152</u>	<u>21</u>
TNTC	<u>179</u>	<u>23</u>	TNTC	<u>175</u>	<u>5</u>
CFU/mL <u>1.6 x 10⁷</u> Counted by: <u>JNB 107-30-03</u>			CFU/mL <u>1.6 x 10⁷</u> Counted by: <u>JNB 107-30-03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>38</u>	<u>6</u>	TNTC	TNTC	<u>59</u>	<u>6</u>	TNTC	TNTC	<u>74</u>	<u>11</u>
TNTC	TNTC	<u>38</u>	<u>7</u>	TNTC	TNTC	<u>74</u>	<u>11</u>	TNTC	TNTC	<u>74</u>	<u>11</u>
TNTC				TNTC				TNTC			
CFU/mL <u>3.8 x 10⁴</u> Counted by: <u>JNB 107-30-03</u>				CFU/mL <u>6.6 x 10⁴</u> Counted by: <u>JNB 107-30-03</u>				CFU/mL <u>6.6 x 10⁴</u> Counted by: <u>JNB 107-30-03</u>			

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
<u>135</u>	<u>59</u>	<u>3</u>	<u>0</u>	TNTC	<u>76</u>	<u>9</u>	<u>0</u>	TNTC	<u>90</u>	<u>7</u>	<u>3</u>
<u>140</u>	<u>47</u>	<u>7</u>	<u>1</u>	TNTC	<u>90</u>	<u>7</u>	<u>3</u>	TNTC	<u>90</u>	<u>7</u>	<u>3</u>
<u>124</u>				TNTC				TNTC			
CFU/mL <u>4.9 x 10³</u> Counted by: <u>JNB 107-30-03</u>				CFU/mL <u>8.3 x 10³</u> Counted by: <u>JNB 107-30-03</u>				CFU/mL <u>8.3 x 10³</u> Counted by: <u>JNB 107-30-03</u>			

Calculations by: TB 17-31-03 Raw data reviewed by SLH 18-6-03

Calculations Verified by: JNB 108-01-03

*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>8/11/03</u> mm dd yy
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Data Collection Form 5A

Subject Initials EJB Subject # 77

Study No. 03-122085-106

Page No. IV-638

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
red bumps	7/29/03	8/6/03	N	1	4(1)	1	4(2)	<i>[Signature]</i> 8/21/03
Entry Date	Comment/Note: 1) Used 10mg of cortisone 10 2) Due to test organism							
7/31/03	red bumps on right hand.							
8/6/03	hands clear - used cortisone 10 2 times a day from 7/31/03 to 8/3/03							

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
see above	for dates	8/5/03						<i>[Signature]</i>
Entry Date	Comment/Note:							
8-1-03	Four pink macules on the backs of the hands							

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

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	<u>07/21/03</u> mm dd yy	<u>E J B</u> F M L	<u>169</u> Permanent #: <u>77</u>	03-122085-106

7/28/03 gr

Date Subject Entered the Study:

07/21/03

mm dd yy

Follow-Up Visit Date:

08/01/03

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.)

Four pink macules on the backs of hands

Comments:

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

YES NO If yes, complete below

Comments:

Medical Consultant's Signature: <u>E. Levin</u>	Date <u>8/1/03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 171	Study #
Subject Qualification	07/21/03 mm dd yy	M, A, N F M L	Permanent #: 78	03-122085-106

Gender: Male Female Age: 59 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: <u>HRT, thyroid, osteo-arthritis</u>		✓	

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

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? <u>Premanin 0.3mg 1xday (HRT)</u> <u>7/21/03</u> <u>SSB (3)</u>	✓	✓	

Comments: Synthroid 0.1mg 1xday (thyroid)
Vioxx 0.3mg 1xday (o osteo-arthritis)
SSB 7/21/03

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

Interviewer's Signature: Stacey E. Backlund Date: 07, 21, 03
mm dd yy

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

HTR Study No.: 03-122085-106
Page No.: IV-691

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>M, A, N</u> f m l	<u>171</u> Permanent #: <u>78</u>	03-122085-106

INCLUSION CRITERIA

Check one

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

EXCLUSION CRITERIA

Check one

YES	NO	N/A	Subject:
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input checked="" type="checkbox"/> Post-menopausal, year <u>1970</u> If of child bearing potential - β-HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:

Qualified **Not Qualified**

for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: SEB, 7/21/03

Investigator's Signature: [Signature]

Date: 07/21/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>171</u>	Study #
Test Period	<u>07 / 28 / 03</u> mm dd yy	<u>M / A / N</u> F M L	Permanent #: <u>78</u>	03-122085-106

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 new 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:

Interviewer's Signature: Stacey E. Bocheiding Date: 07 / 28 / 03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07 / 28 / 03</u> mm dd yy	<u>M / A / N</u> F. M L	<u>171</u>	
		Permanent #:	03-122085-106
		<u>78</u>	

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>194</u>	<u>31</u>	TNTC	<u>281</u> [Ⓢ]	<u>21</u>
TNTC	<u>231</u>	<u>25</u>	TNTC	<u>209</u>	<u>26</u>
CFU/mL <u>2.5 x 10⁷</u> Counted by: <u>JNB 07-30-03</u>			CFU/mL <u>2.4 x 10⁷</u> Counted by: <u>JNB 07-30-03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	<u>122</u>	<u>12</u>	<u>3</u>	TNTC	<u>115</u>	<u>17</u>	<u>2</u>	TNTC	<u>114</u>	<u>15</u>	<u>0</u>
TNTC	<u>111</u>	<u>16</u>	<u>1</u>	TNTC	<u>114</u>	<u>15</u>	<u>0</u>	TNTC	<u>114</u>	<u>15</u>	<u>0</u>
TNTC				TNTC				TNTC			
CFU/mL <u>1.2 x 10⁴</u> Counted by: <u>JNB 07-30-03</u>				CFU/mL <u>1.1 x 10⁴</u> Counted by: <u>JNB 07-30-03</u>				CFU/mL <u>1.1 x 10⁴</u> Counted by: <u>JNB 07-30-03</u>			

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
<u>26</u>	<u>12</u>	<u>3</u>	<u>30</u>	<u>40</u>	<u>17</u>	<u>1</u>	<u>0</u>	<u>40</u>	<u>17</u>	<u>1</u>	<u>0</u>
<u>29</u>	<u>11</u>	<u>0</u>	<u>0</u>	<u>47</u>	<u>15</u>	<u>0</u>	<u>0</u>	<u>40</u>	<u>15</u>	<u>0</u>	<u>0</u>
<u>23</u>				<u>40</u>				<u>40</u>			
CFU/mL <u>7.8 x 10²</u> Counted by: <u>JNB 07-30-03</u>				CFU/mL <u>1.3 x 10³</u> Counted by: <u>JNB 07-30-03</u>				CFU/mL <u>1.3 x 10³</u> Counted by: <u>JNB 07-30-03</u>			

Calculations by: TG 07-31-03 Raw data reviewed by SRH 08-6-03

Calculations Verified by: JNB 108-01-03

*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

[Ⓢ] Did not estimate due to countability of the plate. JNB 07-30-03

Investigator's Signature: <u>[Signature]</u>	Date: <u>08 / 11 / 03</u> mm dd yy
--	---------------------------------------

FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #: 171	Study #
Follow-up Visit	08/01/03 mm dd yy	M/A/N F M L	Permanent #: 78	03-122085-106

Date Subject Entered the Study: 07/21/03 mm dd yy	Follow-Up Visit Date: 08/01/03 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: <i>E. Simon Jones, M.D.</i>	Date: 8/1/03 mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>170</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>L I J 15</u> F M L	Permanent #: <u>79</u>	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>53</u> 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: <u>Mary M. Warkem</u>	Date: <u>07/21/03</u> mm dd yy
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Data Collection Form 2
INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106
Page No.: IV-646

Visit Code	Date	Subject Initials	Subject Screen #: <u>170</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>LJS15</u> f m l	Permanent #: <u>79</u>	03-122085-106

INCLUSION CRITERIA

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

EXCLUSION CRITERIA

Check one ...			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input type="checkbox"/> No <u>TL</u> <input checked="" type="checkbox"/> Surgically Sterile, year <u>1978</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ? <u>MMW 7-21-03</u>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

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

Reasons for disqualification: _____ Interviewer's Initials/Date: MMW 11-21-03

Investigator's Signature: [Signature] Date: 07/21/03
mm dd yy

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>170</u>	Study #
Test Period	<u>07/28/03</u> mm dd yy	<u>KJS/5</u> F M L	Permanent #: <u>79</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? Yes No ③MMW
7-28-03

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 new 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:

Interviewer's Signature: Mary M. Wacikow Date: 07/28/03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/28/03</u> mm dd yy	<u>LJS</u> F. M L	<u>170</u> Permanent #: <u>79</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>198</u>	<u>37</u>	TNTC	<u>205</u>	<u>15</u>
TNTC	<u>254</u> [Ⓢ]	<u>33</u>	TNTC	<u>129</u>	<u>23</u>
CFU/mL <u>2.9 x 10⁷</u> Counted by: <u>JNB 107-30-03</u>			CFU/mL <u>1.7 x 10⁷</u> Counted by: <u>JNB 107-30-03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	<u>200</u>	<u>23</u>	<u>6</u>	TNTC	<u>185</u>	<u>21</u>	<u>4</u>	TNTC	<u>124</u>	<u>10</u>	<u>3</u>
TNTC	<u>163</u>	<u>27</u>	<u>4</u>	TNTC	<u>124</u>	<u>10</u>	<u>3</u>	TNTC	<u>124</u>	<u>10</u>	<u>3</u>
TNTC				TNTC				TNTC			
CFU/mL <u>2.2 x 10⁴</u> Counted by: <u>JNB 107-30-03</u>						CFU/mL <u>1.5 x 10⁴</u> Counted by: <u>JNB 107-30-03</u>					

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
<u>88</u>	<u>33</u>	<u>4</u>	<u>0</u>	<u>69</u>	<u>18</u>	<u>5</u>	<u>2</u>	<u>69</u>	<u>18</u>	<u>5</u>	<u>2</u>
<u>82</u>	<u>29</u>	<u>3</u>	<u>1</u>	<u>51</u>	<u>15</u>	<u>1</u>	<u>1</u>	<u>51</u>	<u>15</u>	<u>1</u>	<u>1</u>
<u>60</u>				<u>60</u>				<u>60</u>			
CFU/mL <u>2.8 x 10³</u> Counted by: <u>JNB 107-30-03</u>						CFU/mL <u>1.8 x 10³</u> Counted by: <u>JNB 107-30-03</u>					

Calculations by: TL 17-31-03 Raw data reviewed by SLH 8-6-03

Calculations Verified by: JNB 108-01-03

*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

[Ⓢ] [Ⓢ] Did not estimate due to countability of the plate. JNB 07-30-03

Investigator's Signature: <u>[Signature]</u>	Date: <u>0</u> / <u>11</u> / <u>03</u> mm dd yy
--	--

FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #: <u>170</u>	Study #
Follow-up Visit	<u>08 01 03</u> mm dd yy	<u>L / J / S</u> F M L	Permanent #: <u>79</u>	03-122085-106

Date Subject Entered the Study: <u>07 21 03</u> mm dd yy	Follow-Up Visit Date: <u>08 01 03</u> ^{7.28.03} 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: <u>E. Lynn Jones, MD</u>	Date <u>8 1 03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 193	Study #
Subject Qualification	07/21/03 mm dd yy	E L J F M L	Permanent #: 80	03-122085-106

Gender: Male Female . Age: 55 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? <u>hbp</u>		/	
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 ? <u>Diovan 80mg 1xday</u>		/	
4. Insulin ?	/		
5. Other ?	/		

Comments:

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

Interviewer's Signature: Stacey E. Beckwith Date: 07/21/03
mm dd yy

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

HTR Study No.: 03-122085-106
Page No.: IV-1051

Visit Code	Date	Subject Initials	Subject Screen #: <u>193</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>E L I J</u> f m l	Permanent #: <u>80</u>	03-122085-106

INCLUSION CRITERIA

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

EXCLUSION CRITERIA

Check one ...			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	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, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

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

Reasons for disqualification: _____ Interviewer's Initials/Date: SFB , 7/21/03

Investigator's Signature: [Signature]

Date: 8 / 11 / 03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>193</u>	Study #
Test Period	<u>07/28/03</u> mm dd yy	<u>E/L/J</u> F M L	Permanent #: <u>80</u>	03-122085-106

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 new 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:

Interviewer's Signature: Stacy E. Barcheiding Date: 07 / 28 / 03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/28/03</u> mm dd yy	<u>E.L.J.</u> F. M L	<u>193</u> Permanent #: <u>80</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	TNTC	<u>30</u>	TNTC	TNTC	<u>28</u>
TNTC	TNTC	<u>39</u>	TNTC	TNTC	<u>29</u>
CFU/mL <u>3.4 x 10⁷</u> Counted by: <u>SAS</u> / <u>7-24-03</u>			CFU/mL <u>2.8 x 10⁷</u> Counted by: <u>SAS</u> / <u>7-24-03</u>		

LEFT HAND				WASH 1		RIGHT HAND	
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>38</u>	<u>38</u>	TNTC	TNTC	<u>39</u>	<u>6</u>
TNTC	TNTC	<u>26</u>	<u>0</u>	TNTC	TNTC	<u>40</u>	<u>6</u>
TNTC				TNTC			
CFU/mL <u>3.2 x 10⁴</u> Counted by: <u>SAS</u> / <u>7-24-03</u>				CFU/mL <u>4.0 x 10⁴</u> Counted by: <u>SAS</u> / <u>7-24-03</u>			

SAS / 7-24-03

LEFT HAND				WASH 11		RIGHT HAND	
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
<u>34</u>	<u>0</u>	<u>4</u>	<u>0</u>	<u>44</u>	<u>21</u>	<u>2</u>	<u>1</u>
<u>32</u>	<u>11</u>	<u>1</u>	<u>0</u>	<u>65</u>	<u>20</u>	<u>0</u>	<u>0</u>
<u>46</u>				<u>64</u>			
CFU/mL <u>1.1 x 10³</u> Counted by: <u>SAS</u> / <u>7-30-03</u>				CFU/mL <u>1.7 x 10³</u> Counted by: <u>SAS</u> / <u>7-30-03</u>			

Calculations by: TG / 7-31-03 Raw data reviewed by SLH / 8-6-03

Calculations Verified by: JNB / 108-01-03

*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>9</u> / <u>11</u> / <u>03</u> mm dd yy
--	--

Data Collection Form 5A

Subject Initials E.L.J. Subject # 80

Study No. 03-122085-106

Page No. IV-654

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date	
<u>Papule</u>		<u>8/13/03</u>	<u>N</u>	<u>1</u>	<u>1</u>	<u>1</u>	<u>4*</u>	<u>E.L.J. 8-21-03</u>	
Entry Date	Comment/Note: <u>* Probably due to test organism E.L.J.</u>								Initials
<u>8-1-03</u>	<u>One papule on the back of the left hand</u>								<u>E.L.J.</u>
<u>8/13/03</u>	<u>Hand clear no medications used</u>								<u>gk</u>

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 #: <u>193</u>	Study #
Follow-up Visit	<u>08/01/03</u> mm dd yy	<u>E/L/J</u> F M L	Permanent #: <u>80</u>	03-122085-106

Date Subject Entered the Study: <u>07/21/03</u> mm dd yy	Follow-Up Visit Date: <u>08/01/03</u> 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.)

One papule on the back of the left hand

Comments: _____

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

YES NO If yes, complete below

Comments: _____

Medical Consultant's Signature: <u>E. Leon J...</u>	Date <u>8/1/03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>186</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>EICIE</u> F M L	Permanent #: <u>81</u>	03-122085-106

Gender: Male Female Age: 58 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. <u>bee stings</u>		/	
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: <u>HRT</u>		/	

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 ? <u>Prempro 25mg / 0.065mg 1xday</u>		/	

Comments:

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

Interviewer's Signature: Stacey E. Berchard

Date: 07/21/03
mm dd yy

Data Collection Form 2
INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106
Page No.: II-657

Visit Code	Date	Subject Initials	Subject Screen #: 186	Study #
Subject Qualification	07/21/03 mm dd yy	E I C I E f m l	Permanent #: 81	03-122085-106

INCLUSION CRITERIA

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

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Surgically Sterile, year 1990 <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

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

Reasons for disqualification: _____

Interviewer's Initials/Date: SEB, 7/21/03

Investigator's Signature: [Signature]

Date: 9/11/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: 186	Study #
Test Period	<u>07/28/03</u> mm dd yy	<u>E / C / E</u> F M L	Permanent #: 81	03-122085-106

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 new 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:

Interviewer's Signature: Mary M. Wacchar Date: 07 / 28 / 03
 mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/28/03</u> mm dd yy	<u>RICIE</u> F. M L	<u>186</u> Permanent #: <u>81</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>266</u>	<u>19</u>	TNTC	TNTC	<u>30</u>
TNTC	<u>234</u>	<u>24</u>	TNTC	TNTC	<u>27</u>
CFU/mL <u>2.3 x 10⁷</u> Counted by: <u>SAS / 7-30-03</u> <u>2.5 x 10⁷</u>			CFU/mL <u>2.8 x 10⁷</u> Counted by: <u>SAS / 7-30-03</u>		

③ SAS 8-1-03

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>52</u>	<u>2</u>	TNTC	TNTC	<u>89</u>	<u>5</u>	TNTC	TNTC	<u>83</u>	<u>11</u>
TNTC	TNTC	<u>49</u>	<u>2</u>	TNTC	TNTC	<u>83</u>	<u>11</u>	TNTC	TNTC	<u>83</u>	<u>11</u>
TNTC				TNTC				TNTC			
CFU/mL <u>5.6 x 10⁴</u> Counted by: <u>SAS / 7-30-03</u>				CFU/mL <u>8.6 x 10⁴</u> Counted by: <u>SAS / 7-30-03</u>							

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
<u>182</u>	<u>60</u>	<u>3</u>	<u>0</u>	TNTC	<u>97</u>	<u>16</u>	<u>0</u>	TNTC	<u>97</u>	<u>16</u>	<u>0</u>
<u>234</u>	<u>67</u>	<u>5</u>	<u>0</u>	TNTC	<u>123</u>	<u>5</u>	<u>2</u>	TNTC	<u>123</u>	<u>5</u>	<u>2</u>
<u>204</u>				TNTC				TNTC			
CFU/mL <u>6.3 x 10³</u> Counted by: <u>SAS / 7-30-03</u>				CFU/mL <u>1.1 x 10⁴</u> Counted by: <u>SAS / 7-30-03</u>							

⑩ Did not estimate due to the countability of the plate. SAS 7-30-03

Calculations by: TG 17-31-03 Raw data reviewed by SRH 18-6-03

Calculations Verified by: JNB 108-01-03

*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>8/11/03</u> mm dd yy
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FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>08</u> / <u>01</u> / <u>03</u> mm dd yy	<u>EIC/E</u> F M L	<u>186</u> Permanent #: <u>81</u>	03-122085-106

Date Subject Entered the Study: <u>07</u> / <u>21</u> / <u>03</u> mm dd yy	Follow-Up Visit Date: <u>08</u> / <u>01</u> / <u>03</u> mm dd yy
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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: <i>E. Lynn Jones MD</i>	Date <u>8</u> / <u>1</u> / <u>03</u> mm dd yy
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