



FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #: <u>132</u>	Study #
Follow-up Visit	<u>07/28/03</u> mm dd yy	<u>B/A/G</u> F M L	Permanent #: <u>44</u>	03-122085-106

Date Subject Entered the Study: <u>07/15/03</u> mm dd yy	Follow-Up Visit Date: <u>07/28/03</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.)

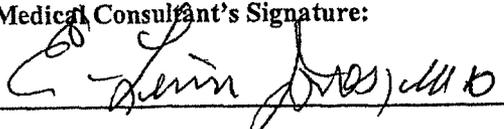
Two red papules on hand and forearm

Comments:

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

YES     NO    If yes, complete below

Comments:

Medical Consultant's Signature: 	Date <u>7/28/03</u> mm dd yy
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## Data Collection Form 1

## DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 107	Study #
Subject Qualification	07/15/03 mm dd yy	J.V.H. F M L	Permanent #: 45	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>50</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: Stacey E BorcheringDate: 07/15/03

mm

dd

yy

Data Collection Form 2  
INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106  
Page No.: IV-465

Visit Code	Date	Subject Initials	Subject Screen #: <u>107</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>J, V, H</u> f m l	Permanent #: <u>45</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 - $\beta$ -HCG Test Results: <input checked="" type="checkbox"/> negative <input type="checkbox"/> positive <u>7/23/03</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: SPB, 7/15/03

Investigator's Signature: \_\_\_\_\_

Ann L. Brady

Date: 08 10 03  
mm dd yy

**INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM**

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
			<u>107</u>	
Test Period	<u>07/23/03</u> mm dd yy	<u>J/V/H</u> F M L	Permanent #:	03-122085-106
			<u>45</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: Erin L. Harris Date: 07 / 23 / 03  
 mm dd yy

③ 8.6.03  
gfr

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

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/23/03</u> mm dd yy	<u>J.V.H</u> F. M L	<u>107</u> Permanent #: <u>45</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>	10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>
TNTC	<u>210</u>	<u>23</u>	TNTC	<u>200</u>	<u>18</u>
TNTC	<u>235</u>	<u>23</u>	TNTC	<u>284<sup>(*)</sup></u>	<u>32</u>
CFU/mL <u>2.2 x 10<sup>7</sup></u> Counted by: <u>ARB 17.25.03</u>			CFU/mL <u>2.5 x 10<sup>7</sup></u> Counted by: <u>ARB 17.25.03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>
TNTC	TNTC	TNTC	<u>36</u>	TNTC	TNTC	<u>235</u>	<u>14</u>	TNTC	TNTC	<u>209</u>	<u>31</u>
TNTC	TNTC	TNTC	<u>39</u>	TNTC	TNTC			TNTC	TNTC		
CFU/mL <u>3.3 x 10<sup>5</sup></u> Counted by: <u>ARB 17.25.03</u>				CFU/mL <u>2.2 x 10<sup>5</sup></u> Counted by: <u>ARB 17.25.03</u>							

LEFT HAND				WASH 11				RIGHT HAND			
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>
TNTC	TNTC	<u>142</u>	<u>17</u>	TNTC	TNTC	<u>147</u>	<u>19</u>	TNTC	TNTC	<u>145</u>	<u>18</u>
TNTC	TNTC	<u>167</u>	<u>18</u>	TNTC	TNTC			TNTC	TNTC		
CFU/mL <u>1.5 x 10<sup>5</sup></u> Counted by: <u>ARB 17.25.03</u>				CFU/mL <u>1.5 x 10<sup>5</sup></u> Counted by: <u>ARB 17.25.03</u>							

(\*) Did not estimate due to the countability of the plate. ARB 17.25.03

Calculations by: TL 17.26.03 Raw data reviewed by JNB 108.01.03

Calculations Verified by: JNB 107.29.03

\*10<sup>-1</sup> dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

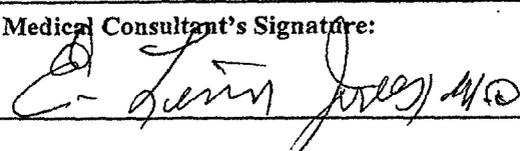
TNTC - Too Numerous To Count

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>07/28/03</u> mm dd yy	<u>J V H</u> F M L	<u>107</u> Permanent #: <u>45</u>	03-122085-106

Date Subject Entered the Study: <u>07/15/03</u> mm dd yy	Follow-Up Visit Date: <u>07/28/03</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/> <hr/> <p>Comments: _____</p> <hr/> <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/> <hr/>	

Medical Consultant's Signature: 	Date <u>7/28/03</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>263</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>K1-1R</u> F M L	Permanent #: <u>46</u>	03-122085-106

Gender:  Male  Female . Age: 54 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>high cholesterol</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>Zocor 10mg 1x day high cholesterol</u>		✓	

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-470

Visit Code	Date	Subject Initials	Subject Screen #: <u>263</u>	Study #
Subject Qualification	<u>07, 21, 03</u> mm dd yy	<u>K, - , R</u> f m i	Permanent #: <u>46</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>1985</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: JNB 107.21.03

Investigator's Signature: Ann R. Brady

Date: 08 / 10 / 03  
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>263</u>	Study #
Test Period	<u>07/30/03</u> mm dd yy	<u>K1-R</u> F M L	Permanent #: <u>46</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>K-1-R</u> F. M L	<u>263</u>	03-122085-106
		Permanent #:	
		<u>46</u>	

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>	10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>
TNTC	<u>240</u>	<u>23</u>	TNTC	<u>181</u>	<u>23</u>
TNTC	<u>225</u>	<u>17</u>	TNTC	<u>246</u>	<u>19</u>
CFU/mL <u>2.4 x 10<sup>7</sup></u> Counted by: <u>PS</u> / <u>8-1-03</u>			CFU/mL <u>2.1 x 10<sup>7</sup></u> Counted by: <u>PS</u> / <u>8-1-03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>
TNTC	TNTC	<u>82</u>	<u>3</u>	TNTC	TNTC	<u>52</u>	<u>6</u>	TNTC	TNTC	<u>61</u>	<u>4</u>
TNTC	TNTC	<u>69</u>	<u>5</u>	TNTC	TNTC	<u>61</u>	<u>4</u>	TNTC	TNTC	<u>61</u>	<u>4</u>
TNTC				TNTC				TNTC			
CFU/mL <u>7.6 x 10<sup>4</sup></u> Counted by: <u>PS</u> / <u>8-1-03</u>						CFU/mL <u>5.6 x 10<sup>4</sup></u> Counted by: <u>PS</u> / <u>8-1-03</u>					

LEFT HAND				WASH 11				RIGHT HAND			
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>
TNTC	<u>66</u>	<u>8</u>	<u>1</u>	TNTC	<u>98</u>	<u>10</u>	<u>2</u>	TNTC	<u>98</u>	<u>10</u>	<u>2</u>
TNTC	<u>130</u>	<u>10</u>	<u>1</u>	TNTC	<u>95</u>	<u>18</u>	<u>0</u>	TNTC	<u>95</u>	<u>18</u>	<u>0</u>
TNTC				TNTC				TNTC			
CFU/mL <u>1.1 x 10<sup>4</sup></u> Counted by: <u>PS</u> / <u>8-1-03</u>						CFU/mL <u>9.6 x 10<sup>3</sup></u> Counted by: <u>PS</u> / <u>8-1-03</u>					

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

Calculations Verified by: AS / 8-1-03

\*10<sup>-1</sup> dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

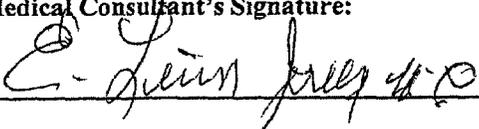
TNTC - Too Numerous To Count

Investigator's Signature: <u>Ann R. Brady</u>	Date: <u>08 / 10 / 03</u> mm dd yy
---	---------------------------------------

FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #: <u>263</u>	Study #
Follow-up Visit	<u>08/04/03</u> mm dd yy	<u>K - R</u> F M L	Permanent #: <u>46</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/> <hr/> <p>Comments: _____</p> <hr/> <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/> <hr/>	

Medical Consultant's Signature: 	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>245</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>C1-1C</u> F M L	Permanent #: <u>47</u>	03-122085-106

Gender:  Male  Female Age: 62 Years Subject error new 7-21-03

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: Mary M. Werten Date: 07/21/03  
mm dd yy

Data Collection Form 2  
INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106  
Page No.: IV-475

Visit Code	Date	Subject Initials	Subject Screen #: <u>245</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>e, - 1 e</u> f m l	Permanent #: <u>47</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 <u>4yr</u> <input checked="" type="checkbox"/> Surgically Sterile, year <u>1983</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - $\beta$ -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:

*Ann R. Brady*

Date: 08/10/03  
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>245</u>	Study #
Test Period	<u>07/30/03</u> mm dd yy	<u>C/M/C</u> F M L	Permanent #: <u>47</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. Warkent Date: 07 / 30 / 03  
mm dd yy

③  
8.7.03 gm

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/M/C</u> F. M L	<u>245</u>	03-122085-106
		Permanent #: <u>47</u>	

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>	10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>
TNTC	<u>192</u>	<u>23</u>	TNTC	<u>154</u>	<u>27</u>
TNTC	<u>156</u>	<u>26</u>	TNTC	<u>186</u>	<u>24</u>
CFU/mL <u>2.1 x 10<sup>7</sup></u> Counted by: <u>SP / 8/1/03</u>			CFU/mL <u>2.1 x 10<sup>7</sup></u> Counted by: <u>SP / 8/1/03</u>		

LEFT HAND				WASH I		RIGHT HAND	
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>
TNTC	TNTC	<u>32</u>	<u>41</u>	TNTC	TNTC	<u>155</u>	<u>16</u>
TNTC	TNTC	<u>249</u>	<u>31</u>	TNTC	TNTC	<u>182</u>	<u>19</u>
TNTC				TNTC			
CFU/mL <u>3.2 x 10<sup>5</sup></u> Counted by: <u>SP / 8/1/03</u>				CFU/mL <u>1.7 x 10<sup>5</sup></u> Counted by: <u>SP / 8/1/03</u>			

⊕ Value not estimated due to countability of plate. SP 8/1/03

LEFT HAND				WASH II		RIGHT HAND	
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>
TNTC	TNTC	<u>39</u>	<u>2</u>	TNTC	<u>213</u>	<u>20</u>	<u>0</u>
TNTC	TNTC	<u>33</u>	<u>2</u>	TNTC	<u>178</u>	<u>15</u>	<u>2</u>
TNTC				TNTC			
CFU/mL <u>3.6 x 10<sup>4</sup></u> Counted by: <u>SP / 8/1/03</u>				CFU/mL <u>2.0 x 10<sup>4</sup></u> Counted by: <u>SP / 8/1/03</u>			

Calculations by: ARS / 8.1.03 Raw data reviewed by JNB / 08.01.03

Calculations Verified by: JNB / 08.01.03

\*10<sup>-1</sup> 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>Ann R. Brady</u>	Date: <u>08 / 10 / 03</u> mm dd yy
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FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #: <u>245</u>	Study #
Follow-up Visit	<u>08</u> / <u>04</u> / <u>03</u> mm dd yy	<u>C.M.C</u> F M L	Permanent #: <u>47</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>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.)

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Comments:

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

YES  NO If yes, complete below

Comments:

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Medical Consultant's Signature: <u>E. Levin JMD, M.D.</u>	Date <u>8</u> / <u>4</u> / <u>03</u> mm dd yy
--	---

## Data Collection Form 1

## DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 266	Study #
Subject Qualification	07/21/03 mm dd yy	T/L/R F M L	Permanent #: 48	03-122085-106

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

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-490

Visit Code	Date	Subject Initials	Subject Screen #: <u>246</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>T I R</u> f m l	Permanent #: <u>48</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>1994</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - $\beta$ -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 / 07.21.03

Investigator's Signature: Ann R. Brady

Date: 08/10/03  
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>266</u>	Study #
Test Period	<u>07/30/03</u> mm dd yy	<u>T / L / R</u> F M L	Permanent #: <u>48</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. Waltham 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>T/L/R</u> F M L	<u>266</u> Permanent #: <u>48</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>	10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>
TNTC	<u>182</u>	<u>24</u>	TNTC	<u>189</u>	<u>16</u>
TNTC	<u>145</u>	<u>15</u>	TNTC	<u>100</u>	<u>12</u>
CFU/mL <u>1.7x10<sup>7</sup></u> Counted by: <u>PS / 8-1-03</u>			CFU/mL <u>1.4x10<sup>7</sup></u> Counted by: <u>PS / 8-1-03</u>		

LEFT HAND				WASH 1		RIGHT HAND			
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>		
TNTC	TNTC	<u>135</u>	<u>14</u>	TNTC	TNTC	<u>122</u>	<u>13</u>		
TNTC	TNTC	<u>172</u>	<u>16</u>	TNTC	TNTC	<u>132</u>	<u>19</u>		
TNTC				TNTC					
CFU/mL <u>1.5x10<sup>5</sup></u> Counted by: <u>PS / 8-1-03</u>				CFU/mL <u>1.3x10<sup>5</sup></u> Counted by: <u>PS / 8-1-03</u>					

LEFT HAND				WASH 11		RIGHT HAND			
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>		
TNTC	TNTC	<u>52</u>	<u>6</u>	TNTC	TNTC	<u>62</u>	<u>3</u>		
TNTC	TNTC	<u>32</u>	<u>5</u>	TNTC	TNTC	<u>55</u>	<u>5</u>		
TNTC				TNTC					
CFU/mL <u>4.2x10<sup>7</sup></u> Counted by: <u>PS / 8-1-03</u>				CFU/mL <u>5.8x10<sup>4</sup></u> Counted by: <u>PS / 8-1-03</u>					

Calculations by: PS / 8-1-03 Raw data reviewed by JNB / 08-01-03  
 Calculations Verified by: JNB / 08-01-03  
 \*10<sup>-1</sup> 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>Ann P. Brady</u>	Date: <u>08 / 10 / 03</u> mm dd yy
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Data Collection Form 5A

Subject Initials TLR Subject # 48

Study No. 03-122085-106  
Page No. IV-483

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
red bump	7/31/03	8/4/03	N	1	1	1	4*	<i>[Signature]</i> 8-21-03
Entry Date	Comment/Note: *Probably due to lost organism.							Initials
8/1/03	red bump on left hand							gr

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
see above	for dates							8/4/03 gr
Entry Date	Comment/Note:							Initials
8-4-03	Hands are clear today							<i>[Signature]</i>

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> 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

<sup>1</sup>Serious Adverse Event/Experience

FOLLOW-UP VISIT

Page No.: IV-4874  
③ 8.6.03  
982

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>08, 04, 03</u> mm dd yy	<u>T, L, R</u> F M L	<u>266</u> Permanent #: <u>48</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.)

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Comments:

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

YES  NO If yes, complete below

Comments:

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Medical Consultant's Signature: <i>E. Lynn 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 #: 157	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>K, E, J</u> F M L	Permanent #: 49	03-122085-106

Gender:  Male  Female. Age: 20 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. Barcherdin Date: 07/15/03  
mm dd yy

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

HTR Study No.: 03-122085-106  
Page No.: IV-486

Visit Code	Date	Subject Initials	Subject Screen #: 157	Study #
Subject Qualification	07/15/03 mm dd yy	K, E, J f m l	Permanent #: 49	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>7/24/03 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: SAB, 7/15/03

Investigator's Signature: \_\_\_\_\_

*Arnold Brady*

Date: 08/10/03  
mm dd yy

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>157</u>	Study #
Test Period	<u>07/24/03</u> mm dd yy	<u>KIEIJ</u> F M L	Permanent #: <u>49</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: Betty M. Conover Date: 07/24/03  
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/24/03</u> mm dd yy	<u>K/E/J</u> F M L	<u>157</u> Permanent #: <u>49</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>	10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>
TNTC	<u>128</u>	<u>25</u>	TNTC	<u>179</u>	<u>20</u>
TNTC	<u>159</u>	<u>14</u>	TNTC	<u>185</u>	<u>22</u>
CFU/mL <u>1.4 x 10<sup>7</sup></u> Counted by: <u>ARS 17.28.03</u>			CFU/mL <u>1.8 x 10<sup>7</sup></u> Counted by: <u>ARS 17.28.03</u>		

~~① JNB 07.28.03~~  
② 2 errors JNB 07.29.03

LEFT HAND				WASH 1	RIGHT HAND			
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	
TNTC	<del>TNTC</del>	<u>70</u>	<u>13</u>	TNTC	TNTC	<u>114</u>	<u>12</u>	
TNTC	TNTC	<u>64</u>	<u>6</u>	TNTC	TNTC	<u>107</u>	<u>11</u>	
TNTC	<del>X</del> ① ARS 17.28.03			TNTC				
CFU/mL <u>6.7 x 10<sup>4</sup></u> Counted by: <u>ARS 17.28.03</u>				CFU/mL <u>1.1 x 10<sup>5</sup></u>	Counted by: <u>ARS 17.28.03</u>			

LEFT HAND				WASH 11	RIGHT HAND			
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	
TNTC	TNTC	<u>71</u>	<u>6</u>	TNTC	TNTC	<u>146</u>	<u>11</u>	
TNTC	TNTC	<u>75</u>	<u>11</u>	TNTC	TNTC	<u>132</u>	<u>13</u>	
TNTC				TNTC				
CFU/mL <u>7.3 x 10<sup>4</sup></u> Counted by: <u>ARS 17.28.03</u>				CFU/mL <u>1.4 x 10<sup>5</sup></u>	Counted by: <u>ARS 17.28.03</u>			

Calculations by: JNB 107.29.03 Raw data reviewed by: ARB 18.1.03

Calculations Verified by: TU 17.29.03

\*10<sup>-1</sup> 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>07/29/03</u> mm dd yy	<u>K   E   J</u> F M L	<u>157</u> Permanent #: <u>49</u>	03-122085-106

Date Subject Entered the Study: <u>07/15/03</u> mm dd yy	Follow-Up Visit Date: <u>07/29/03</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.)

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Comments:

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

YES  NO If yes, complete below

Comments:

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Medical Consultant's Signature: <i>E. Lewis Jones, M.D.</i>	Date <u>7/29/03</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>237</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>R/J/D</u> F M L	Permanent #: <u>50</u>	03-122085-106

Gender:  Male  Female. Age: 53 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>dust</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 ? <u>Risperidone (11)</u>	✓		
5. Other ? <u>Risperidone 2mg 1x day depression</u>		✓	

Comments: Cyrteline 100mg 1 x day depression \* (11) JNB 07.21.03  
(11) mg added 7/22/03 gfn

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

Interviewer's Signature: Jamie Busmeyer Date: 07/21/03  
mm dd yy

Data Collection Form 2  
INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106  
Page No.: IV-491

Visit Code	Date	Subject Initials	Subject Screen #: <u>237</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>R J D</u> f m i	Permanent #: <u>50</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 - $\beta$ -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: JNB 107-21-03

Investigator's Signature: Ann R. Brady

Date: 08 10 03  
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: 237	Study #
Test Period	<u>07/29/03</u> mm dd yy	<u>R, J, D</u> F M L	Permanent #: 50	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. Bocheidig 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>R/J/D</u> F. M L	<u>237</u> Permanent #: <u>50</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>	10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>
TNTC	<u>170</u>	<u>9</u>	TNTC	<u>291</u> <sup>Δ</sup>	<u>25</u>
TNTC	<u>143</u>	<u>14</u>	TNTC	<u>228</u>	<u>23</u>
CFU/mL <u>6 × 10<sup>7</sup></u> Counted by: <u>TG</u> <u>17-31-03</u>			CFU/mL <u>2.5 × 10<sup>7</sup></u> Counted by: <u>TG</u> <u>17-31-03</u>		

Δ Unable to estimate due to uneven distribution of colonies. TG 7-31-03

LEFT HAND				WASH 1				RIGHT HAND			
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>
TNTC	TNTC	TNTC	<u>60</u>	TNTC	TNTC	TNTC	<u>32</u>	TNTC	TNTC	TNTC	<u>40</u>
TNTC	TNTC	TNTC	<u>41</u>	TNTC	TNTC	TNTC		TNTC	TNTC	TNTC	
TNTC				TNTC				TNTC			
CFU/mL <u>5.0 × 10<sup>5</sup></u> Counted by: <u>TG</u> <u>17-31-03</u>				CFU/mL <u>3.9 × 10<sup>5</sup></u> Counted by: <u>TG</u> <u>17-31-03</u>							

LEFT HAND				WASH 11				RIGHT HAND			
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>
TNTC	TNTC	TNTC	<u>50</u>	TNTC	TNTC	<u>119</u>	<u>17</u>	TNTC	TNTC	<u>109</u>	<u>18</u>
TNTC	TNTC	TNTC	<u>48</u>	TNTC	TNTC			TNTC	TNTC		
TNTC				TNTC				TNTC			
CFU/mL <u>4.9 × 10<sup>5</sup></u> Counted by: <u>JNB</u> <u>107-31-03</u>				CFU/mL <u>1.1 × 10<sup>5</sup></u> Counted by: <u>JNB</u> <u>107-31-03</u>							

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

Calculations Verified by: CAS 1-8-03

\*10<sup>-1</sup> 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>Ann R. Brady</u>	Date: <u>08/10/03</u> mm dd yy
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FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #: 237	Study #
Follow-up Visit	08/04/03 mm dd yy	R, J, D F M L	Permanent #: 50	03-122085-106

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

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Comments:

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

YES  NO If yes, complete below

Comments:

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Medical Consultant's Signature: <i>E. Lynn Jones</i>	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 #: 101	Study #
Subject Qualification	07/15/03 mm dd yy	W/T/S F M L	Permanent #: 51	03-122085-106

Gender:  Male  Female      Age: 37 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 Borchering      Date: 07/15/03  
mm      dd      yy

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

HTR Study No.: 03-122085-106  
Page No.: IV-496

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
	<u>07/15/03</u> mm dd yy	<u>W, T, S</u> f m l	<u>101</u> Permanent #: <u>51</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 - $\beta$ -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: SOB, 7/15/03

Investigator's Signature: Ann P. Brady Date: 08/10/03  
mm dd yy

**Data Collection Form 3**  
**INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM**

Visit Code	Date	Subject Initials	Subject Screen #: <u>101</u>	Study #
Test Period	<u>07/23/03</u> mm dd yy	<u>W T S</u> F M L	Permanent #: <u>51</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: Betty M. Conover Date: 07/23/03  
 mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/23/03</u> mm dd yy	<u>W/T/S</u> F. M L	<u>101</u> Permanent #:	03-122085-106
		<u>51</u>	

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>	10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>
TNTC	TNTC	<u>28</u>	TNTC	<u>240</u>	<u>24</u>
TNTC	TNTC	<u>24</u>	TNTC	<u>236</u>	<u>21</u>
CFU/mL <u>2.6 x 10<sup>7</sup></u> Counted by: <u>SEB 17/25/03</u>			CFU/mL <u>2.4 x 10<sup>7</sup></u> Counted by: <u>SEB 17/25/03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>
TNTC	TNTC	TNTC	<u>75</u>	TNTC	TNTC	TNTC	<u>109</u>	TNTC	TNTC	TNTC	<u>92</u>
TNTC	TNTC	TNTC	<u>81</u>	TNTC	TNTC	TNTC		TNTC	TNTC	TNTC	
TNTC				TNTC				TNTC			
CFU/mL <u>7.8 x 10<sup>5</sup></u> Counted by: <u>SEB 17/25/03</u>				CFU/mL <u>1.0 x 10<sup>6</sup></u> Counted by: <u>SEB 17/25/03</u>							

LEFT HAND				WASH 11				RIGHT HAND			
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>
TNTC	TNTC	TNTC	<u>48</u>	TNTC	TNTC	TNTC	<u>49</u>	TNTC	TNTC	TNTC	<u>41</u>
TNTC	TNTC	TNTC	<u>55</u>	TNTC	TNTC	TNTC		TNTC	TNTC	TNTC	
TNTC				TNTC				TNTC			
CFU/mL <u>5.2 x 10<sup>5</sup></u> Counted by: <u>SEB 17/25/03</u>				CFU/mL <u>4.5 x 10<sup>5</sup></u> Counted by: <u>SEB 17/25/03</u>							

Calculations by: TW 17/26/03 Raw data reviewed by: ALB 18-1-03

Calculations Verified by: JNB 107-29-03

\*10<sup>-1</sup> 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>9/11/03</u> mm dd yy
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Data Collection Form 5A

Subject Initials WTS Subject # 51

Study No. 03-122085-106

Page No. IV-499

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
red bumps w/ itching	7/23/03	7/29/03	N	1	4(1)	1	4(2)	E. J. [Signature]
Entry Date	Comment/Note: 1) Used Hum Hc Hydrocortisone cream - 2) Duct to lot ointment							
7/25/03	red bumps and itching on both hands gr							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
see above for dates	7/28/03							gr
Entry Date	Comment/Note:							
7-28-03	Clear today used hydrocortisone cream E. J. [Signature]							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> 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

<sup>1</sup>Serious Adverse Event/Experience

FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>07/28/03</u> mm dd yy	<u>W T S</u> F M L	<u>101</u> Permanent #: <u>51</u>	03-122085-106

Date Subject Entered the Study: <u>07/15/03</u> mm dd yy	Follow-Up Visit Date: <u>07/28/03</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.)

*used hydrocortisone cream*

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, M.D.*

Date

7/28/03  
mm dd yy

## Data Collection Form 1

## DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 182	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>M F M</u> F M L	Permanent #: 52	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>65</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 ? <u>unknown</u> (11)		✓	
4. Insulin ?	✓		
5. Other ?	✓		

Comments: (11) can not reach subject by phone had phone # 3/4/03 gsu

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

Interviewer's Signature: <u>Mary M. Wickett</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 - 502

Visit Code	Date	Subject Initials	Subject Screen #: <u>182</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>M / F / M</u> f m l	Permanent #: <u>52</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 <u>4yr</u> <input checked="" type="checkbox"/> Surgically Sterile, year <u>1992</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: Ann R. Brady

Date: 08/19/03  
mm dd yy

**Data Collection Form 3**  
**INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM**

Visit Code	Date	Subject Initials	Subject Screen #: 182	Study #
Test Period	<u>07/29/03</u> mm dd yy	<u>M, F, M</u> F M L	Permanent #: <u>52</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. Bochenko 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>M.F.M</u> F. M L	<u>182</u> Permanent #: <u>52</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>	10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>
TNTC	TNTC	<u>37</u>	TNTC	TNTC	<u>27</u>
TNTC	TNTC	<u>37</u>	TNTC	TNTC	<u>34</u>
CFU/mL <u>3.7x10<sup>7</sup></u> Counted by: <u>TK 17-31-03</u>			CFU/mL <u>3.0x10<sup>7</sup></u> Counted by: <u>TK 17-31-03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>
TNTC	TNTC	<u>236</u>	<u>19</u>	TNTC	TNTC	<u>81</u>	<u>10</u>	TNTC	TNTC	<u>87</u>	<u>7</u>
TNTC	TNTC	<u>174</u>	<u>23</u>	TNTC	TNTC	<u>87</u>	<u>7</u>	TNTC	TNTC	<u>87</u>	<u>7</u>
TNTC				TNTC				TNTC			
CFU/mL <u>2.0x10<sup>5</sup></u> Counted by: <u>SAS 17-31-03</u>						CFU/mL <u>8.4x10<sup>4</sup></u> Counted by: <u>SAS 17-31-03</u>					

LEFT HAND				WASH 11				RIGHT HAND			
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>
TNTC	TNTC	<u>64</u>	<u>8</u>	TNTC	TNTC	<u>63</u>	<u>9</u>	TNTC	TNTC	<u>46</u>	<u>4</u>
TNTC	TNTC	<u>76</u>	<u>6</u>	TNTC	TNTC	<u>46</u>	<u>4</u>	TNTC	TNTC	<u>46</u>	<u>4</u>
TNTC				TNTC				TNTC			
CFU/mL <u>7.0x10<sup>4</sup></u> Counted by: <u>SAS 17-31-03</u>						CFU/mL <u>5.4x10<sup>4</sup></u> Counted by: <u>SAS 17-31-03</u>					

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

Calculations Verified by: SAS 18-1-03

\*10<sup>-1</sup> 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>Ann L. Brady</u>	Date: <u>08 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>M, F, M</u> F M L	<u>182</u> Permanent #: <u>52</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.)

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Comments:

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

YES  NO If yes, complete below

Comments:

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Medical Consultant's Signature: <i>E. Lynn Gray, MD</i>	Date <u>8, 9, 03</u> mm dd yy
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## DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 244	Study #
Subject Qualification	07/21/03 mm dd yy	S/S/M F M L	Permanent #: 53	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>43</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:

*Betty M. Conover*Date: 07/21/03  
mm dd yy

Data Collection Form 2  
INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122084  
Page No.: IV -

Visit Code	Date	Subject Initials	Subject Screen #: 244	Study #
Subject Qualification	07/21/03 mm dd yy	S/S/M f m l	Permanent #: 53	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 <input type="checkbox"/>	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 7/29/03
<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: \_\_\_\_\_

*Paul R. Brad*

Date: 08/10/03  
mm dd yy

## INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: 244	Study #
Test Period	07/29/03 mm dd yy	S, S, M F M L	Permanent #: 53	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>S/S/M</u> F. M L	<u>244</u> Permanent #: <u>53</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>	10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>
TNTC	<u>246</u>	<u>24</u>	TNTC	<u>258<sup>Δ</sup></u>	<u>20</u>
TNTC	<u>275<sup>Δ</sup></u>	<u>12</u>	TNTC	<u>267<sup>Δ</sup></u>	<u>50</u>
CFU/mL <u>2.6 × 10<sup>7</sup></u> Counted by: <u>TG 17-31-03</u>			CFU/mL <u>3.5 × 10<sup>7</sup></u> Counted by: <u>TG 17-31-03</u>		

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

LEFT HAND				WASH 1		RIGHT HAND		
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-5</sup>
TNTC	TNTC	<u>64</u>	<u>3</u>	TNTC	TNTC	<u>37</u>	<u>1</u>	<u>1</u>
TNTC	TNTC	<u>67</u>	<u>7</u>	TNTC	TNTC	<u>49</u>	<u>3</u>	<u>3</u>
TNTC				TNTC				
CFU/mL <u>6.6 × 10<sup>4</sup></u> Counted by: <u>TG 17-31-03</u>				CFU/mL <u>4.3 × 10<sup>4</sup></u> Counted by: <u>TG 17-31-03</u>				

LEFT HAND				WASH 11		RIGHT HAND		
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-5</sup>
TNTC	TNTC	<u>35</u>	<u>2</u>	TNTC	<u>222</u>	<u>24</u>	<u>3</u>	<u>3</u>
TNTC	TNTC	<u>33</u>	<u>2</u>	TNTC	<u>202</u>	<u>30</u>	<u>2</u>	<u>2</u>
TNTC				TNTC				
CFU/mL <u>3.4 × 10<sup>4</sup></u> Counted by: <u>JNB 107-31-03</u>				CFU/mL <u>2.4 × 10<sup>4</sup></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<sup>-1</sup> 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>Ann L. Brady</u>	Date: <u>08/10/03</u> mm dd yy
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FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #: <u>244</u>	Study #
Follow-up Visit	<u>08</u> / <u>04</u> / <u>03</u> mm dd yy	<u>S S M</u> F M L	Permanent #: <u>53</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>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.)

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Comments:

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

YES  NO If yes, complete below

Comments:

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Medical Consultant's Signature: <u>E. Levin Jones, MD</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 #: 218	Study #
Subject Qualification	07/21/03 mm dd yy	D/S/B F M L	Permanent #: 54	03-122085-106

Gender:  Male  Female. Age: 42 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: Jami Buxemeyer Date: 07 / 21 / 03  
mm dd yy

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

HTR Study No.: 03-122085-106  
Page No.: IV-512

Visit Code	Date	Subject Initials	Subject Screen #: <u>218</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>D, S, B</u> f m l	Permanent #: <u>54</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 checked="" 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>1996</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - $\beta$ -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: \_\_\_\_\_

*Ann L. Budy*

Date: 08/10/03  
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>D, S, B</u> F M L	<u>218</u> Permanent #: <u>54</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. Barchetti 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/S/B</u> F M L	<u>218</u>	
		Permanent #:	03-122085-106
		<u>54</u>	

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>	10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>
TNTC	<u>229</u>	<u>19</u>	TNTC	<u>184</u>	<u>21</u>
TNTC	<u>231</u>	<u>29</u>	TNTC	<u>210</u>	<u>18</u>
CFU/mL <u>2.4x10<sup>7</sup></u> Counted by: <u>TG 17-31-03</u>			CFU/mL <u>2.0x10<sup>7</sup></u> Counted by: <u>TG 17-31-03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>
TNTC	TNTC	<u>41</u>	<u>1</u>	TNTC	TNTC	<u>55</u>	<u>5</u>	TNTC	TNTC	<u>60</u>	<u>6</u>
TNTC	TNTC	<u>49</u>	<u>3</u>	TNTC	TNTC			TNTC	TNTC		
TNTC				TNTC				TNTC			
CFU/mL <u>4.5x10<sup>4</sup></u> Counted by: <u>TG 17-31-03</u>				CFU/mL <u>5.8x10<sup>4</sup></u> Counted by: <u>TG 17-31-03</u>							

LEFT HAND				WASH 11				RIGHT HAND			
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>
TNTC	<u>246</u>	<u>16</u>	<u>1</u>	TNTC	TNTC	<u>29</u>	<u>1</u>	TNTC	TNTC	<u>27</u>	<u>2</u>
TNTC	<u>216</u>	<u>29</u>	<u>2</u>	TNTC	TNTC			TNTC	TNTC		
TNTC				TNTC				TNTC			
CFU/mL <u>2.3x10<sup>4</sup></u> Counted by: <u>TG 17-31-03</u>				CFU/mL <u>2.8x10<sup>4</sup></u> Counted by: <u>TG 17-31-03</u>							

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

Calculations Verified by: NS 18-1-03

\*10<sup>-1</sup> 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>Ann R. Brady</u>	Date: <u>08/10/03</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>DISIB</u> F M L	<u>218</u> Permanent #: <u>54</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.)

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Comments:

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

YES  NO If yes, complete below

Comments:

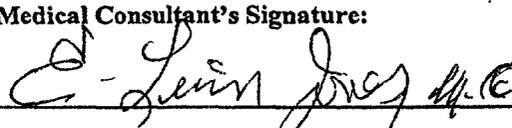
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Medical Consultant's Signature: 	Date <u>8/4/03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>282</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>L/D/I</u> F M L	Permanent #: <u>55</u>	03-122085-106

Gender:  Male  Female . Age: 41 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: Jami Busmer Date: 07/21/03  
mm dd yy

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

HTR Study No.: 03-122085-106  
Page No.: IV-517

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
	<u>07/21/03</u>	<u>L/D/I</u>	<u>282</u>	
Subject Qualification	<u>mm dd yy</u>	<u>f m l</u>	Permanent #:	03-122085-106
			<u>55</u>	

**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>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: JNB, 07-21-03

Investigator's Signature: \_\_\_\_\_

Date: 01/11/03  
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>282</u>	Study #
Test Period	<u>07/30/03</u> mm dd yy	<u>L/D/I</u> F M L	Permanent #: <u>55</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>L/D/I</u> F. M L	<u>282</u>	
		Permanent #:	03-122085-106
		<u>55</u>	

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>	10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>
TNTC	<u>144</u>	<u>22</u>	TNTC	TNTC	<u>39</u>
TNTC	<u>163</u>	<u>20</u>	TNTC	TNTC	<u>40</u>
CFU/mL <u>1.5 x 10<sup>7</sup></u> Counted by: <u>PS</u> / 8-1-03			CFU/mL <u>4.0 x 10<sup>7</sup></u> Counted by: <u>PS</u> / <del>8-1-06</del> <sup>8-1-03</sup> (3) PS 8-1-		

LEFT HAND				WASH 1				RIGHT HAND			
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>
TNTC	TNTC	TNTC	<u>38</u>	TNTC	TNTC	<u>104</u>	<u>12</u>	TNTC	TNTC	<u>47</u>	<u>13</u>
TNTC	TNTC	TNTC	<u>25</u>	TNTC	TNTC	<u>47</u>	<u>13</u>	TNTC	TNTC	<u>47</u>	<u>13</u>
TNTC				TNTC				TNTC			
CFU/mL <u>3.2 x 10<sup>5</sup></u> Counted by: <u>PS</u> / 8-1-03				CFU/mL <u>1.1 x 10<sup>5</sup></u> Counted by: <u>PS</u> / <del>PS</del> 8-1-03				(3) PS 8-1-0			

LEFT HAND				WASH 11				RIGHT HAND			
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>
TNTC	TNTC	<u>143</u>	<u>24</u>	TNTC	TNTC	<u>135</u>	<u>10</u>	TNTC	TNTC	<u>148</u>	<u>14</u>
TNTC	TNTC	<u>163</u>	<u>24</u>	TNTC	TNTC	<u>148</u>	<u>14</u>	TNTC	TNTC	<u>148</u>	<u>14</u>
TNTC				TNTC				TNTC			
CFU/mL <u>1.5 x 10<sup>5</sup></u> Counted by: <u>PS</u> / 8-1-03				CFU/mL <u>1.4 x 10<sup>5</sup></u> Counted by: <u>PS</u> / 8-1-03							

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

Calculations Verified by: JNB / 08-01-03

\*10<sup>-1</sup> 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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Data Collection Form 5A

Subject Initials LDI Subject # 55

Study No. 03-122085-106

Page No. IV-519a

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
cold	7/31/03	8/12/03	N	1	1	1	4	<i>[Signature]</i> 8/12/03

Entry Date	Comment/Note:	Initials
8/7/03	stuffy nose and chest congestion taking tylenol cold medication OTC 4x day started on 8/1/03	QK
8/12/03	ended medication on 8/11/03, all clear on 8/12/03	QK

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date

Entry Date	Comment/Note:	Initials

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> 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

<sup>1</sup>Serious Adverse Event/Experience

FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>08/04/03</u> mm dd yy	<u>L D I</u> F M L	<u>282</u> Permanent #: <u>55</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.)

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Comments:

---



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

YES  NO If yes, complete below

Comments: a cold. Onset 7-31-03

---



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Medical Consultant's Signature: <u>E. Lein Jones MD</u>	Date: <u>8/4/03</u> mm dd yy
--	------------------------------------

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 274	Study #
Subject Qualification	07/21/03 mm dd yy	K, A, L F M L	Permanent #: 56	03-122085-106

Gender:  Male  Female      Age: 39 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 C. Barchetti      Date: 07/21/03  
mm      dd      yy

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

HTR Study No.: 03-122085-106  
Page No.: IV-522

Visit Code	Date	Subject Initials	Subject Screen #: 274	Study #
Subject Qualification	07/21/03 mm dd yy	K, A, L f m l	Permanent #: 56	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 1994 <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

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>274</u>	Study #
Test Period	<u>07/30/03</u> mm dd yy	<u>K I A I L</u> F M L	Permanent #: <u>56</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: Glenn D. Heles 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>K.A.L</u> F. M L	<u>274</u> Permanent #: <u>56</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>	10 <sup>-4</sup>	(*) 10 <sup>-5</sup>	10 <sup>-6</sup>
TNTC	TNTC	<u>25</u>	TNTC	<u>257</u>	<u>25</u>
TNTC	TNTC	<u>26</u>	TNTC	<u>180</u>	<u>22</u>
CFU/mL <u>2.6 × 10<sup>7</sup></u> Counted by: <u>PS</u> / 8-1-03			CFU/mL <u>2.3 × 10<sup>7</sup></u> Counted by: <u>PS</u> / 8-1-03		

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

LEFT HAND				WASH 1				RIGHT HAND			
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>
TNTC	TNTC	<u>185</u>	<u>19</u>	TNTC	TNTC	<u>106</u>	<u>6</u>	TNTC	TNTC	<u>63</u>	<u>10</u>
TNTC	TNTC	<u>111</u>	<u>16</u>	TNTC	TNTC	<u>63</u>	<u>10</u>	TNTC	TNTC	<u>63</u>	<u>10</u>
TNTC				TNTC				TNTC			
CFU/mL <u>1.5 × 10<sup>5</sup></u> Counted by: <u>PS</u> / 8-1-03				CFU/mL <u>8.4 × 10<sup>4</sup></u> Counted by: <u>PS</u> / 8-1-03				CFU/mL <u>8.4 × 10<sup>4</sup></u> Counted by: <u>PS</u> / 8-1-03			

LEFT HAND				WASH 11				RIGHT HAND			
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>
TNTC	TNTC	<u>152</u>	<u>14</u>	TNTC	TNTC	<u>114</u>	<u>16</u>	TNTC	TNTC	<u>71</u>	<u>16</u>
TNTC	TNTC	<u>134</u>	<u>17</u>	TNTC	TNTC	<u>71</u>	<u>16</u>	TNTC	TNTC	<u>71</u>	<u>16</u>
TNTC				TNTC				TNTC			
CFU/mL <u>1.4 × 10<sup>5</sup></u> Counted by: <u>PS</u> / 8-1-03				CFU/mL <u>9.2 × 10<sup>4</sup></u> Counted by: <u>PS</u> / 8-1-03				CFU/mL <u>9.2 × 10<sup>4</sup></u> Counted by: <u>PS</u> / 8-1-03			

Calculations by: PS / 8-1-03 Raw data reviewed by PS / 8-1-03

Calculations Verified by: PS / 8-1-03

\*10<sup>-1</sup> 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>0</u> / <u>11</u> / <u>03</u> mm dd yy
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Data Collection Form 5A

Subject Initials KAL Subject # 56

Study No. 03-122085-106  
Page No. IV-524a

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Headache	8/2/03	8/2/03	N	2	2	5	4*	<i>[Signature]</i> 8-21-03

Entry Date	Comment/Note:	Initials
	* Unrelated illness.	
8/4/03	Headache, cough, chest pain, and sinus. Took 500mg amoxicillin on 8/2/03.	gh
8/7/03	Dr Jones prescribed 500mg of amoxicillin for 5 days 1 tablet per day. - symptoms persist	

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
	see above for dates			8/7/03	gh			

Entry Date	Comment/Note:	Initials
8/7/03	but feeling better.	gh
8/21/03	Subject contacted on 8.7.03 and 8.11.03 without response	gh

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> 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

<sup>1</sup>Serious Adverse Event/Experience  
5= Lost to follow up

FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	08/04/03 mm dd yy	KIAL F M L	274 Permanent #: 56	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: Onset 7-30-03 Headache, cough, chest pain, sinus, Took amoxicillin 8-2-03, 500mg tid.

Medical Consultant's Signature: E. Lynn [Signature]	Date 8/4/03 mm dd yy
--	----------------------------

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 255	Study #
Subject Qualification	07/21/03 mm dd yy	I-IG F M L	Permanent #: 57	03-122085-106

Gender:  Male  Female. Age: 21 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>codeine</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 ? <u>Ortho-Tricyclen (birth control)</u>		/	

Comments:

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

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

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

HTR Study No.: 03-122085-106  
Page No.: IV-527

Visit Code	Date	Subject Initials	Subject Screen #: <u>255</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>I-1-G</u> f m l	Permanent #: <u>57</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>7/30/03 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: SOB, 7/21/03

Investigator's Signature: G. Spalding

Date: 9-1-03  
mm dd yy

## Data Collection Form 3

## INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>255</u>	Study #
Test Period	<u>07/30/03</u> mm dd yy	<u>I 1 - 1 G</u> F M L	Permanent #: <u>57</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: Maury M. Wooten

Date: 07 / 30 / 03  
mm dd yy

Data Collection Form 4

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>I - IG</u> F. M L	<u>255</u> Permanent #: <u>57</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>	10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>
TNTC	<u>146</u>	<u>17</u>	TNTC	<u>198</u>	<u>33</u>
TNTC	<u>132</u>	<u>22</u>	TNTC	<u>135</u>	<u>22</u>
CFU/mL <u>1.4 × 10<sup>7</sup></u> Counted by: <u>PS</u> / 8-1-03			CFU/mL <u>2.2 × 10<sup>7</sup></u> Counted by: <u>PS</u> / 8-1-03		

LEFT HAND				WASH 1				RIGHT HAND			
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>
TNTC	TNTC	<u>76</u>	<u>8</u>	TNTC	TNTC	<u>55</u>	<u>1</u>	TNTC	TNTC	<u>42</u>	<u>7</u>
TNTC	TNTC	<u>61</u>	<u>7</u>	TNTC	TNTC	<u>42</u>	<u>7</u>	TNTC	TNTC	<u>42</u>	<u>7</u>
TNTC				TNTC				TNTC			
CFU/mL <u>6.8 × 10<sup>4</sup></u> Counted by: <u>PS</u> / 8-1-03				CFU/mL <u>4.8 × 10<sup>4</sup></u> Counted by: <u>PS</u> / 8-1-03							

LEFT HAND				WASH 11				RIGHT HAND			
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>
<u>179</u>	<u>62</u>	<u>5</u>	<u>0</u>	<u>209</u>	<u>52</u>	<u>LA<sup>Ⓢ</sup>Ⓢ</u>	<u>0</u>	<u>209</u>	<u>52</u>	<u>LA<sup>Ⓢ</sup>Ⓢ</u>	<u>0</u>
<u>199</u>	<u>51</u>	<u>9</u>	<u>0</u>	<u>187</u>	<u>56</u>	<u>LA<sup>Ⓢ</sup>Ⓢ</u>	<u>LA<sup>Ⓢ</sup>Ⓢ</u>	<u>159</u>	<u>56</u>	<u>LA<sup>Ⓢ</sup>Ⓢ</u>	<u>LA<sup>Ⓢ</sup>Ⓢ</u>
<u>67</u>				<u>159</u>							
CFU/mL <u>5.4 × 10<sup>3</sup></u> Counted by: <u>PS</u> / 8-1-03				CFU/mL <u>5.4 × 10<sup>3</sup></u> Counted by: <u>PS</u> / 8-1-03							

ⓈⓈ LA: LAB ACCIDENT. PS 8-1-03

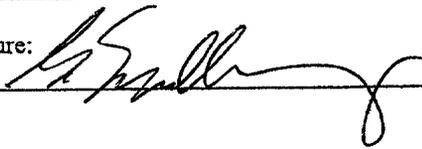
Calculations by: PS / 8-1-03 Raw data reviewed by PS 18.1.03

Calculations Verified by: PS 18.1.03

\*10<sup>-1</sup> 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: 	Date: <u>8/11/03</u> mm dd yy
---	----------------------------------

Subject Initials I-G Subject # 57

Study No. 03-122085-106  
Page No. IV-53 D

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
red bumps	7/30/03	8/4/03	N	1			4*	E.J.G. 8/21/03
Entry Date	Comment/Note: * probably due to test organism, E.J.G.							
8/1/03	red bumps w/ itching on hands							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
see above for dates		8/4/03						E.J.G.
Entry Date	Comment/Note:							
8-4-03	Hands are clear today.							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> 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

<sup>1</sup>Serious Adverse Event/Experience

FOLLOW-UP VISIT

8/6/03  
8m

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	08/04/03 mm dd yy	I - G F M L	255 Permanent #: 57	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.)

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Comments:

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

YES  NO If yes, complete below

Comments:

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Medical Consultant's Signature: E. Linn Jones, M.D.	Date 8/4/04 mm dd yy
--	----------------------------

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 247	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>TIEIH</u> F M L	Permanent #: <u>50 NA</u>	03-122085-106

7/30/03 gk

Gender:  Male  Female Age: 39 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>Codine</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: 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-533

Visit Code	Date	Subject Initials	Subject Screen #: 247	Study #
Subject Qualification	07/21/03 mm dd yy	TIEIH f m l	Permanent #: 58 NA	03-122085-106

INCLUSION CRITERIA

7/30/03 gk

Check one

YES

NO

Subject:

<input checked="" type="checkbox"/>		1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>		2. Has signed informed consent ?
<input checked="" type="checkbox"/>		3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>		4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>		5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" 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"/>		7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" 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"/>		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"/>		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"/>		11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one

YES

NO

N/A

Subject:

	<input checked="" type="checkbox"/>		1. Is currently participating in another clinical study at this or any other facility ?
	<input checked="" type="checkbox"/>		2. Has participated in any type of hand or arm wash study within the past 7 days ?
	<input checked="" type="checkbox"/>		3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
	<input checked="" type="checkbox"/>		4. Has artificial nails or nail tips ?
	<input checked="" type="checkbox"/>		5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
	<input checked="" 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
	<input checked="" type="checkbox"/>		8. Is currently lactating ?
	<input checked="" 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"/>		10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
	<input checked="" 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"/>		12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

7/30/03 gk

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:

*[Handwritten Signature]*

Date:

8/11/03  
mm dd yy

## INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: 247	Study #
Test Period	07/30/03 mm dd yy	T/E/H F M L	Permanent #: 58	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. Wautton*

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>T/E/H</u> F. M L	<u>247</u> Permanent #: <u>58</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>	10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>
TNTC	<u>176</u>	17	TNTC	<u>233</u>	<u>28</u>
TNTC	<u>241</u>	16	TNTC	<u>189</u>	<u>20</u>
CFU/mL <u>2.1 × 10<sup>7</sup></u> Counted by: <u>SP 10/1/03</u>			CFU/mL <u>2.2 × 10<sup>7</sup></u> Counted by: <u>SP 10/1/03</u> <i>SP 8-1-03</i>		

LEFT HAND			WASH 1			RIGHT HAND		
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-1</sup> <i>SP 8/1/03</i>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	
TNTC	TNTC	<u>63</u>	<u>289</u>	TNTC	TNTC	<u>132</u>	<u>10</u>	
TNTC	TNTC	<u>64</u>	<u>10</u>	TNTC	TNTC	<u>111</u>	<u>10</u>	
TNTC				TNTC				
CFU/mL <u>6.4 × 10<sup>4</sup></u> Counted by: <u>SP 10/1/03</u>			CFU/mL <u>1.2 × 10<sup>5</sup></u> Counted by: <u>SP 10/1/03</u>					

LEFT HAND			WASH 11			RIGHT HAND		
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	
<del>TNTC</del> <u>190</u>	<del>113</del> <u>152</u>	<del>43</del> <u>89</u>	<del>8</del> <u>2</u>	TNTC	<u>101</u>	<u>8</u>	<u>14</u>	
<del>TNTC</del> <u>139</u>	<u>68</u>	<u>16</u>	<u>4</u>	TNTC	<u>98</u>	<u>5</u>	<u>0</u>	
<del>TNTC</del> <u>201</u>				TNTC				
CFU/mL <u>1.8 × 10<sup>4</sup></u> Counted by: <u>PS 10/1/03</u>			CFU/mL <u>1.0 × 10<sup>3</sup></u> Counted by: <u>SP 10/1/03</u>					

Counted thru contamination on Wash 11 Left hand. PS 8-1-03  
 Unable to count thru contamination on the 10<sup>-1</sup> PS 8-1-03  
 Estimated counts. PS 8-1-03 Did not use counts in calculations  
 Calculations by: SPS 10/1/03 Raw data reviewed by PS 10/1/03  
 Calculations Verified by: PS 8-1-03  
 \*10<sup>-1</sup> 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

*SPS 8-1-03*

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>247</u>	Study #
Follow-up Visit	<u>08/04/03</u> mm dd yy	<u>T E H</u> F M L	Permanent #: <u>58</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. Lewis 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>258</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>AIRIV</u> F M L	Permanent #: <u>59</u>	03-122085-106

Gender:  Male  Female. Age: 19 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 Busemeyer Date: 07/21/03  
mm dd yy

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

HTR Study No.: 03-122085-106  
Page No.: IV-538

Visit Code	Date	Subject Initials	Subject Screen #: <u>258</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>A.R.I.V</u> f m l	Permanent #: <u>59</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>7/30/03 gr</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: 07/21/03  
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>258</u>	Study #
Test Period	<u>07/30/03</u> mm dd yy	<u>A/R/V</u> F M L	Permanent #: <u>59</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. Warten 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>A/R/V</u> F. M L	<u>258</u>	
		Permanent #:	03-122085-106
		<u>59</u>	

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>	10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>
TNTC	<u>165</u>	<u>23</u>	TNTC	<u>206</u>	<u>14</u>
TNTC	<u>199</u>	<u>21</u>	TNTC	<u>259</u>	<u>30</u>
CFU/mL <u>1.8 x 10<sup>7</sup></u> Counted by: <u>SP / 8/1/03</u>			CFU/mL <u>2.3 x 10<sup>7</sup></u> Counted by: <u>SP / 8/1/03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>
TNTC	TNTC	<u>172</u>	<u>21</u>	TNTC	TNTC	<u>216</u>	<u>22</u>	TNTC	TNTC	<u>216</u>	<u>22</u>
TNTC	TNTC	<u>190</u>	<u>18</u>	TNTC	TNTC	<u>182</u>	<u>16</u>	TNTC	TNTC	<u>182</u>	<u>16</u>
TNTC				TNTC				TNTC			
CFU/mL <u>1.8 x 10<sup>5</sup></u> Counted by: <u>SP / 8/1/03</u>				CFU/mL <u>2.9 x 10<sup>5</sup></u> Counted by: <u>SP / 8/1/03</u>				CFU/mL <u>2.9 x 10<sup>5</sup></u> Counted by: <u>SP / 8/1/03</u>			

LEFT HAND				WASH 11				RIGHT HAND			
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>
<u>598</u> ESPC	<u>LA*</u>	<u>24</u>	<u>1</u>	TNTC	TNTC	<u>74</u>	<u>1</u>	TNTC	TNTC	<u>74</u>	<u>1</u>
<u>855</u> ESPC	<u>LA*</u>	<u>27</u>	<u>1</u>	TNTC	TNTC	<u>44</u>	<u>3</u>	TNTC	TNTC	<u>44</u>	<u>3</u>
<u>570</u> ESPC				TNTC				TNTC			
CFU/mL <u>2.6 x 10<sup>4</sup></u> Counted by: <u>SP / 8/1/03</u>				CFU/mL <u>5.9 x 10<sup>4</sup></u> Counted by: <u>SP / 8/1/03</u>				CFU/mL <u>5.9 x 10<sup>4</sup></u> Counted by: <u>SP / 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<sup>-1</sup> 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

⊛ LA = LAB ACCIDENT SP 8/1/03

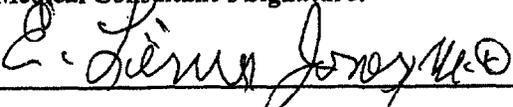
ESPC = Estimated Standard Plate Count SP 8/1/03

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>258</u>	Study #
Follow-up Visit	<u>08, 04, 03</u> mm dd yy	<u>A, R, V</u> F M L	Permanent #: <u>59</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 type="checkbox"/> YES <input checked="" type="checkbox"/> 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? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO    If yes, complete below	
Comments: _____ _____ _____	

Medical Consultant's Signature: 	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 #
			07-21-03 249	
Subject Qualification	07/21/03 mm dd yy	J1-10 F M L	Permanent #: 60	03-122085-106

Gender:  Male  Female Age: 50 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 ? ZIBAN - ANTI-SMOKING (II)		✓	

Comments: (I) mg unknown 7.22.03 gr

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-543

Visit Code	Date	Subject Initials	Subject Screen #: <u>249</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>J/W/O</u> f m l	Permanent #: <u>60</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>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>07/21/03</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	<input checked="" type="checkbox"/>	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 - $\beta$ -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 / 07.21.03

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>249</u>	Study #
Test Period	<u>07/30/03</u> mm dd yy	<u>J W O</u> F M L	Permanent #: <u>60</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. Wether 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>J/W/O</u> F. M L	<u>249</u>	
		Permanent #:	03-122085-106
		<u>60</u>	

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>	10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>
TNTC	<u>62</u>	<u>30</u>	TNTC	<u>219</u>	<u>20</u>
TNTC	<u>181</u>	<u>20</u>	TNTC	<u>167</u>	<u>16</u>
CFU/mL <u>2.1x10<sup>7</sup></u> Counted by: <u>SP 8/1/03</u>			CFU/mL <u>1.9x10<sup>7</sup></u> Counted by: <u>SP 8/1/03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>
TNTC	TNTC	TNTC	<u>40</u>	TNTC	TNTC	<u>227</u>	<u>24</u>	TNTC	TNTC	<u>274</u>	<u>29</u>
TNTC	TNTC	TNTC	<u>40</u>	TNTC	TNTC	<u>274</u>	<u>29</u>	TNTC	TNTC	<u>274</u>	<u>29</u>
TNTC				TNTC				TNTC			
CFU/mL <u>4.0x10<sup>5</sup></u> Counted by: <u>SP 8/1/03</u>						CFU/mL <u>2.6x10<sup>5</sup></u> Counted by: <u>SP 8/1/03</u>					

LEFT HAND				WASH 11				RIGHT HAND			
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>
TNTC	TNTC	TNTC	<u>32</u>	TNTC	TNTC	<u>287</u>	<u>45</u>	TNTC	TNTC	<u>369</u>	<u>2324</u>
TNTC	TNTC	TNTC	<u>28</u>	TNTC	TNTC	<u>369</u>	<u>2324</u>	TNTC	TNTC	<u>369</u>	<u>2324</u>
TNTC				TNTC				TNTC			
CFU/mL <u>3.0x10<sup>5</sup></u> Counted by: <u>SP 8/1/03</u>						CFU/mL <u>3.4x10<sup>5</sup></u> Counted by: <u>SP 8/1/03</u>					

underlined in error  
③ 8-5 8-1-03

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

Calculations Verified by: JNB 108-01-03

\*10<sup>-1</sup> 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 countabili. of plate  
SP 8/1/03

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

Data Collection Form 5A

Subject Initials JW O Subject # 60

Study No. 03-122085-106

Page No. II-546

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
red bumps w/itching	7/30/03	8/11/03	N	1	1	1	4*	<i>[Signature]</i> 8-21-03 Initials <i>[Signature]</i>
Entry Date	Comment/Note: * Probably due to lost organisms, @-J.G.							
7/31/03	red bumps with itching on both hands subject plans to use bacitracin on hands for three days							
8/11/03	hand clear <sup>① 8.11.03</sup> <i>[Signature]</i>							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
see above for dates				3	7	03		<i>[Signature]</i>
Entry Date	Comment/Note:							
8-4-03	Three red macules on the dorsal of the hands <i>[Signature]</i>							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> 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

<sup>1</sup>Serious Adverse Event/Experience

FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>08 04 03</u> mm dd yy	<u>J. W. O</u> F M L	<u>249</u> Permanent #: <u>60</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.)

Three red macules on dorsa 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 Jones MD</u>	Date <u>8 9 03</u> mm dd yy
---	-----------------------------------

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 210	Study #
Subject Qualification	07/21/03 mm dd yy	R / L / M F M L	Permanent #: 61	03-122085-106

Gender:  Male  Female . Age: 61 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>high cholesterol</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>Lipitor 20mg 1x day high cholesterol</u>		✓	

Comments:

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

Interviewer's Signature: Jamie Buseneyer Date: 07/21/03  
mm dd yy

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

HTR Study No.: 03-122085-106  
Page No.: IV-549

Visit Code	Date	Subject Initials	Subject Screen #: <u>210</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>R/L/M</u> f m l	Permanent #: <u>61</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: JNB 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 #: 210	Study #
Test Period	<u>07/29/03</u> mm dd yy	<u>R, L, M</u> F M L	Permanent #: 61	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. Bacherdiz*

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>R/L/M</u> F. M L	<u>210</u> Permanent #: <u>61</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>	10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>
TNTC	<u>227</u>	<u>21</u>	TNTC	<u>270<sup>Δ</sup></u>	<u>22</u>
TNTC	<u>232</u>	<u>15</u>	TNTC	<u>260<sup>Δ</sup></u>	<u>25</u>
CFU/mL <u>2.3x10<sup>7</sup></u> Counted by: <u>TG 17-31-03</u>			CFU/mL <u>2.4x10<sup>7</sup></u> Counted by: <u>TG 17-31-03</u>		

Δ Not countable estimated due to countability of the plate. TG 7-31-03

LEFT HAND				WASH 1				RIGHT HAND			
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>
TNTC	TNTC	<u>187</u>	<u>12</u>	TNTC	TNTC	<u>202</u>	<u>17</u>	TNTC	TNTC	<u>193</u>	<u>20</u>
TNTC	TNTC	<u>147</u>	<u>30</u>	TNTC	TNTC			TNTC	TNTC		
TNTC				TNTC				TNTC			
CFU/mL <u>1.7x10<sup>5</sup></u> Counted by: <u>JNB 07-31-03</u>						CFU/mL <u>2.0x10<sup>5</sup></u> Counted by: <u>JNB 07-31-03</u>					

LEFT HAND				WASH 11				RIGHT HAND			
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>
TNTC	TNTC	TNTC	<u>25</u>	TNTC	TNTC	TNTC	<u>40</u>	TNTC	TNTC	TNTC	<u>44</u>
TNTC	TNTC	TNTC	<u>49</u>	TNTC	TNTC	TNTC		TNTC	TNTC	TNTC	
TNTC				TNTC				TNTC			
CFU/mL <u>3.7x10<sup>5</sup></u> Counted by: <u>TG 17-31-03</u>						CFU/mL <u>4.2x10<sup>5</sup></u> Counted by: <u>TG 17-31-03</u>					

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

Calculations Verified by: EAS 18-1-03

\*10<sup>-1</sup> 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>B. Spalding</u>	Date: <u>8/1/03</u> mm dd yy
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Data Collection Form 5A

Subject Initials R.L.M. Subject # 01

Study No. 03-122085-106

Page No. IV-552

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
<u>Pustule</u>	<u>7-31-03</u>	<u>8/12/03</u>	<u>N</u>	<u>1</u>	<u>4 (U)</u>	<u>1</u>	<u>4 (2)</u>	<u>[Signature]</u> 8/21/03
Entry Date	Comment/Note:							Initials
<u>8-4-03</u>	<u>1) Used Non-Rx Neosporin 2) Ducts to organism</u>							<u>[Initials]</u>
	<u>One pustule on forearm and three red macules on the backs of the hands</u>							<u>[Initials]</u>
<u>8/12/03</u>	<u>Hands and forearm clear</u>							<u>[Initials]</u>

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
<u>see above</u>	<u>for dates</u>			<u>8/12/03</u>		<u>qr</u>		
Entry Date	Comment/Note:							Initials
<u>8/12/03</u>	<u>neosporin used on bumps from 8/4/03 to 8/10/03 1 to 2 times a day</u>							<u>qr</u>

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> 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

<sup>1</sup>Serious Adverse Event/Experience

FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #: <u>210</u>	Study #
Follow-up Visit	<u>08, 04, 03</u> mm dd yy	<u>R, L, M</u> F M L	Permanent #: <u>61</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.)

One pustule on fore arm and 3 red  
nodules on backs of hands  
Onset 7-31-04  
DB E.K.J.

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>Dr. L. J. 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 #: 221	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>M/R/P</u> F M L	Permanent #: 62	03-122085-106

Gender:  Male     Female    Age: 21 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. Barcheidi    Date: 07/21/03  
mm    dd    yy

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

HTR Study No.: 03-122085-106  
Page No.: IV-555

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
	<u>07/21/03</u>	<u>M, R, P</u>	<u>221</u>	
Subject Qualification	<u>mm dd yy</u>	<u>f m l</u>	Permanent #:	03-122085-106
			<u>62</u>	

**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 - $\beta$ -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: JSB, 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 #:	Study #
			221	
Test Period	<u>07/29/03</u> mm dd yy	<u>M, R, P</u> F M L	Permanent #: 62	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. Bachevaldi

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>M/R/P</u> F. M L	<u>221</u> Permanent #: <u>62</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>	10 <sup>-4</sup>	10 <sup>-5</sup>	10 <sup>-6</sup>
TNTC	<u>197</u>	<u>10</u>	TNTC	<u>239</u>	<u>21</u>
TNTC	<u>189</u>	<u>19</u>	TNTC	<u>196</u>	<u>12</u>
CFU/mL <u>1.9 x 10<sup>7</sup></u> Counted by: <u>TC 17-31-03</u>			CFU/mL <u>2.2 x 10<sup>7</sup></u> Counted by: <u>TC 17-31-03</u>		

LEFT HAND				WASH 1		RIGHT HAND	
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>
TNTC	TNTC	TNTC	<u>28</u>	TNTC	TNTC	<u>114</u>	<u>11</u>
TNTC	TNTC	TNTC	<u>28</u>	TNTC	TNTC	<u>121</u>	<u>11</u>
TNTC				TNTC			
CFU/mL <u>2.8 x 10<sup>5</sup></u> Counted by: <u>JNB 107-31-03</u>				CFU/mL <u>1.2 x 10<sup>5</sup></u> Counted by: <u>JNB 107-31-03</u>			

LEFT HAND				WASH 11		RIGHT HAND	
10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>
TNTC	TNTC	<u>153</u>	<u>17</u>	TNTC	TNTC	<u>191</u>	<u>15</u>
TNTC	TNTC	<u>168</u>	<u>23</u>	TNTC	TNTC	<u>158</u>	<u>24</u>
TNTC				TNTC			
CFU/mL <u>1.6 x 10<sup>5</sup></u> Counted by: <u>TC 17-31-03</u>				CFU/mL <u>1.7 x 10<sup>5</sup></u> Counted by: <u>TC 17-31-03</u>			

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

Calculations Verified by: DS 18-1-03

\*10<sup>-1</sup> dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

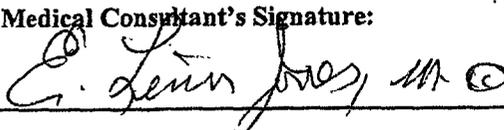
TNTC - Too Numerous To Count

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

Visit Code	Date	Subject Initials	Subject Screen #: <u>221</u>	Study #
Follow-up Visit	<u>08, 04, 03</u> mm dd yy	<u>M, R, P</u> F M L	Permanent #: <u>62</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/> <hr/> <p>Comments:</p> <hr/> <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/> <hr/>	

Medical Consultant's Signature: 	Date <u>8, 14, 03</u> mm dd yy
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