

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>205</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>S I A I S</u> F M L	Permanent #: <u>82</u>	03-122085-106

Gender: Male Female Age: 44 Years

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

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

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

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify. <u>environmental</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: Jamie Basemeyer Date: 07/21/03
mm dd yy

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

HTR Study No.: 03-122085-106
Page No.: IV-662

Visit Code	Date	Subject Initials	Subject Screen #: <u>205</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>S I A S</u> f m l	Permanent #: <u>82</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>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: [Signature] Date: 8/1/03
mm dd yy

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>205</u>	Study #
Test Period	<u>07 / 28 / 03</u> mm dd yy	<u>S / A / J</u> F M L	Permanent #: <u>82</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 / 28 / 03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07 / 28 / 03</u> mm dd yy	<u>S / A / S</u> F. M L	<u>205</u> Permanent #: <u>82</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>152</u>	<u>23</u>	TNTC	<u>167</u>	<u>25</u>
TNTC	<u>183</u>	<u>23</u>	TNTC	<u>122</u>	<u>18</u>
CFU/mL <u>1.7 x 10⁷</u> Counted by: <u>JNB / 07.30.03</u>			CFU/mL <u>1.8 x 10⁷</u> Counted by: <u>JNB / 07.30.03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	<u>187</u>	<u>22</u>	<u>1</u>	TNTC	<u>238</u>	<u>28</u>	<u>5</u>	TNTC	<u>160</u>	<u>22</u>	<u>3</u>
TNTC	<u>192</u>	<u>21</u>	<u>1</u>	TNTC	<u>160</u>	<u>22</u>	<u>3</u>	TNTC	<u>160</u>	<u>22</u>	<u>3</u>
TNTC				TNTC				TNTC			
CFU/mL <u>2.1 x 10⁴</u> Counted by: <u>JNB / 07.30.03</u>				CFU/mL <u>2.2 x 10⁴</u> Counted by: <u>JNB / 07.30.03</u>							

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
<u>84</u>	<u>28</u>	<u>3</u>	<u>1</u>	<u>162</u>	<u>20</u>	<u>3</u>	<u>0</u>	<u>162</u>	<u>20</u>	<u>3</u>	<u>0</u>
<u>10</u>	<u>32</u>	<u>3</u>	<u>0</u>	<u>64</u>	<u>19</u>	<u>1</u>	<u>0</u>	<u>64</u>	<u>19</u>	<u>1</u>	<u>0</u>
<u>63</u>				<u>59</u>				<u>59</u>			
CFU/mL <u>2.7 x 10³</u> Counted by: <u>JNB / 07.30.03</u>				CFU/mL <u>9.2 x 10²</u> Counted by: <u>JNB / 07.30.03</u>				CFU/mL <u>1.8 x 10³</u> Counted by: <u>JNB / 07.30.03</u>			

Calculations by: TG / 17.31.03 Raw data reviewed by JRH / 8.6.03

Calculations Verified by: JNB / 08.01.05

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

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>8 / 11 / 03</u> mm dd yy
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Subject Initials SAS Subject # 82

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ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
red bumps	7-29/03	9/5/03	N	1	1	1	4*	<i>E. J. J.</i> 8-21-03
Entry Date	Comment/Note: <i>Probably due to test organism E. J. J. 8-21-03</i>							Initials
7/30/03	<i>red bumps on left hand and wrist</i>							<i>gr</i>
9/5/03	<i>hands clear - no medications used.</i>							<i>gr</i>

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
<i>see above for dates</i>								<i>gr</i>
Entry Date	Comment/Note:							Initials
8-1-03	<i>Three pink macules on back of left hoof</i>							<i>E. J. J.</i>

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

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

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

¹Serious Adverse Event/Experience

FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #: 205	Study #
Follow-up Visit	08/01/03 mm dd yy	S/A/S F M L	Permanent #: 82	03-122085-106

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

3 pink moles on back of left hand.
Onset 7-29-03

Comments:

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

YES NO If yes, complete below

Comments:

Medical Consultant's Signature: C. Lynn Jones MD	Date 8/1/03 mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 174	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>B I S</u> F M L	Permanent #: <u>83</u>	03-122085-106

Gender: <input checked="" type="checkbox"/> Male <input type="checkbox"/> Female	Age: <u>61</u> Years
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Does the subject have any of the following at the treatment sites?

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

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

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

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

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

Comments:

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

Interviewer's Signature: <u>Stacy C. Bachelder</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-1668

Visit Code	Date	Subject Initials	Subject Screen #: <u>174</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>B.S.S.</u> f m l	Permanent #: <u>83</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: SEB, 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 #: 174	Study #
Test Period	07 28 03 mm dd yy	B / J / S F M L	Permanent #: 83	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. Beckwith Date: 07 28 03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07 / 28 / 03</u> mm dd yy	<u>B. J. S</u> F. M. L	<u>174</u>	
		Permanent #:	03-122085-106
		<u>83</u>	

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>239</u>	<u>16</u>	TNTC	<u>161</u>	<u>24</u>
TNTC	<u>129</u>	<u>13</u>	TNTC	<u>235</u>	<u>22</u>
CFU/mL <u>1.8 x 10⁷</u> Counted by: <u>SAS / 7-30-03</u>			CFU/mL <u>2.0 x 10⁷</u> Counted by: <u>SAS / 7-30-03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>56</u>	<u>9</u>	TNTC	TNTC	<u>60</u>	<u>11</u>	TNTC	TNTC	<u>71</u>	<u>5</u>
TNTC	TNTC	<u>67</u>	<u>6</u>	TNTC	TNTC			TNTC	TNTC		
CFU/mL <u>6.2 x 10⁴</u> Counted by: <u>SAS / 7-30-03</u>						CFU/mL <u>6.6 x 10⁴</u> Counted by: <u>SAS / 7-30-03</u>					

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
<u>113</u>	<u>35</u>	<u>5</u>	<u>0</u>	<u>50</u>	<u>20</u>	<u>1</u>	<u>0</u>	<u>50</u>	<u>16</u>	<u>1</u>	<u>1</u>
<u>114</u>	<u>44</u>	<u>0</u>	<u>0</u>	<u>56</u>	<u>16</u>	<u>1</u>	<u>1</u>	<u>48</u>			
CFU/mL <u>3.8 x 10³</u> Counted by: <u>SAS / 7-30-03</u>						CFU/mL <u>1.5 x 10³</u> Counted by: <u>SAS / 7-30-03</u>					

Calculations by: TK / 7-31-03 Raw data reviewed by SKH / 8-6-03

Calculations Verified by: JNB / 08-01-03

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

Underlined values are used for calculation of CFU/mL

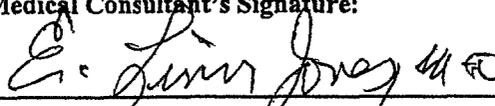
TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>07 / 11 / 03</u> mm dd yy
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FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>08/01/03</u> mm dd yy	<u>B / J / S</u> F M L	<u>174</u> Permanent #: <u>83</u>	03-122085-106

Date Subject Entered the Study: <u>07/21/03</u> mm dd yy	Follow-Up Visit Date: <u>08/01/03</u> mm dd yy
Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection? <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>8/1/03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 173	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>E I J 15</u> F M L	Permanent #: 84	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>62</u> Years
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Does the subject have any of the following at the treatment sites?

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

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

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

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

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

Comments:

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

Interviewer's Signature: <u>Mary M. Warden</u>	Date: <u>07/21/03</u> mm dd yy
--	-----------------------------------

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

HTR Study No.: 03-122085-106
Page No.: IV-673

Visit Code	Date	Subject Initials	Subject Screen #: <u>173</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>EJS</u> f m l	Permanent #: <u>84</u>	03-122085-106

INCLUSION CRITERIA

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 type="checkbox"/> Yes <input checked="" type="checkbox"/> No <u>Hyst</u> <input checked="" type="checkbox"/> Surgically Sterile, year <u>1976</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 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 ?

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

Qualified Not Qualified

for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: MMW 17-21-03

Investigator's Signature: [Signature]

Date: 01/11/03
mm dd yy

Data Collection Form 3
INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>173</u>	Study #
Test Period	<u>07/28/03</u> mm dd yy	<u>EJS</u> F M L	Permanent #: <u>84</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: <u>Mary M. Wooten</u>	Date: <u>07/28/03</u> mm dd yy
--	-----------------------------------

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/28/03</u> mm dd yy	<u>EJS</u> F. M L	<u>173</u>	
		Permanent #:	03-122085-106
		<u>84</u>	

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>222</u>	<u>23</u>	TNTC	<u>182</u>	<u>24</u>
TNTC	<u>210</u>	<u>30</u>	TNTC	<u>173</u>	<u>19</u>
CFU/mL <u>2.4 x 10⁷</u> Counted by: <u>JNB 1073003</u>			CFU/mL <u>1.8 x 10⁷</u> Counted by: <u>JNB 1073003</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>50</u>	<u>4</u>	TNTC	TNTC	<u>65</u>	<u>11</u>	TNTC	TNTC	<u>61</u>	<u>13</u>
TNTC	TNTC	<u>49</u>	<u>7</u>	TNTC	TNTC			TNTC	TNTC		
TNTC				TNTC				TNTC			
CFU/mL <u>5.0 x 10⁴</u> Counted by: <u>JNB 1073003</u>				CFU/mL <u>6.3 x 10⁴</u> Counted by: <u>JNB 1073003</u>							

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
<u>31</u>	<u>15</u>	<u>2</u>	<u>0</u>	<u>97</u>	<u>37</u>	<u>5</u>	<u>1</u>	<u>47</u>	<u>29</u>	<u>4</u>	<u>0</u>
<u>47</u>	<u>15</u>	<u>0</u>	<u>0</u>	<u>124</u>	<u>29</u>	<u>4</u>	<u>0</u>	<u>95</u>			
<u>34</u>											
CFU/mL <u>1.1 x 10³</u> Counted by: <u>JNB 1073003</u>				CFU/mL <u>3.2 x 10³</u> Counted by: <u>JNB 1073003</u>							

Calculations by: TG 17-31-03 Raw data reviewed by SLH 1 8-6-03

Calculations Verified by: JNB 108-01-03

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

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>01/11/03</u> mm dd yy
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FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #: 173	Study #
Follow-up Visit	08/01/03 mm dd yy	E, J, S F M L	Permanent #: 84	03-122085-106

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

Comments:

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

YES NO If yes, complete below

Comments:

Medical Consultant's Signature: <i>E. Lenin Jones, MD</i>	Date 8/1/03 mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
			177	
Subject Qualification	07/21/03 mm dd yy	L, M, H F M L	Permanent #: 85	03-122085-106

Gender: Male Female Age: 35 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 ? <u>Zovia 28days</u> <u>birth control</u>		✓	

Comments:

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

Interviewer's Signature: Jacey E Barcherdin Date: 07/21/03
mm dd yy

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

HTR Study No.: 03-122085-106
Page No.: IV-678

Visit Code	Date	Subject Initials	Subject Screen #: <u>177</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>L M, H</u> f m l	Permanent #: <u>85</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>7/28/03 gja</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: SEB, 7/21/03

Investigator's Signature: <u>[Signature]</u>	Date: <u>8/11/03</u> mm dd yy
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Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: 177	Study #
Test Period	07/28/03 mm dd yy	L, M, H F M L	Permanent #: 85	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 Bachredin Date: 07 / 28 / 03
 mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/28/03</u> mm dd yy	<u>L M H</u> F M L	<u>177</u> Permanent #: <u>85</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>132</u>	<u>18</u>	TNTC	<u>89</u>	<u>10</u>
TNTC	<u>85</u>	<u>17</u>	TNTC	<u>93</u>	<u>11</u>
CFU/mL <u>1.1 x 10⁷</u> Counted by: <u>JNB 107-30-03</u>			CFU/mL <u>2.1 x 10⁶</u> Counted by: <u>JNB 107-30-03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>36</u>	<u>5</u>	TNTC	TNTC	<u>56</u>	<u>10</u>	TNTC	TNTC	<u>56</u>	<u>10</u>
TNTC	TNTC	<u>32</u>	<u>3</u>	TNTC	TNTC	<u>58</u>	<u>7</u>	TNTC	TNTC	<u>58</u>	<u>7</u>
TNTC				TNTC				TNTC			
CFU/mL <u>3.4 x 10⁴</u> Counted by: <u>JNB 107-30-03</u>				CFU/mL <u>5.7 x 10⁴</u> Counted by: <u>JNB 107-30-03</u>							

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
<u>27</u>	<u>12</u>	<u>1</u>	<u>0</u>	<u>60</u>	<u>32</u>	<u>2</u>	<u>0</u>	<u>60</u>	<u>32</u>	<u>2</u>	<u>0</u>
<u>27</u>	<u>9</u>	<u>0</u>	<u>0</u>	<u>50</u>	<u>12</u>	<u>0</u>	<u>0</u>	<u>50</u>	<u>12</u>	<u>0</u>	<u>0</u>
<u>27</u>				<u>45</u>				<u>45</u>			
CFU/mL <u>2.7 x 10²</u> Counted by: <u>JNB 107-30-03</u>				CFU/mL <u>2.0 x 10³</u> Counted by: <u>JNB 107-30-03</u>							

8.1 x 10²

8395 8-1-03

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

Calculations Verified by: JNB 108-01-03

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

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

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

Visit Code	Date	Subject Initials	Subject Screen #: <u>177</u>	Study #
Follow-up Visit	<u>08/01/03</u> mm dd yy	<u>LIM/H</u> F M L	Permanent #: <u>85</u>	03-122085-106

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

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

YES NO If yes, complete below:

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

Comments:

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

YES NO If yes, complete below

Comments:

Medical Consultant's Signature: <i>E. Linn Jones, M.D.</i>	Date <u>8/1/03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 196	Study #
Subject Qualification	07/21/03 mm dd yy	L, R, C F M L	Permanent #: 86	03-122085-106

Gender: Male Female Age: 51 Years

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

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

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

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify. <u>poison ivy</u>	^{7/21/03} _{SEP} ③ X	/	
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 Borchardt Date: 07/21/03
mm dd yy

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

HTR Study No.: 03-122085-106
Page No.: IV-683

Visit Code	Date	Subject Initials	Subject Screen #: <u>196</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>L, R, C</u> f m l	Permanent #: <u>86</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>7/28/03 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: JB, 7/21/03

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

Data Collection Form 3
INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Test Period	<u>07/28/03</u> mm dd yy	<u>L R C</u> F M L	<u>196</u> Permanent #: <u>86</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. Bachevalier Date: 07/28/03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07 / 28 / 03</u> mm dd yy	<u>L / R / C</u> F M L	<u>196</u> Permanent #: <u>86</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	TNTC	<u>28</u>	TNTC	<u>243</u>	19
TNTC	TNTC	<u>33</u>	TNTC	<u>241</u>	24
CFU/mL <u>3.0 x 10⁷</u> Counted by: <u>SAS / 7-30-03</u>			CFU/mL <u>2.4 x 10⁷</u> Counted by: <u>SAS / 7-30-03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	<u>290</u>	24	3	TNTC	TNTC	<u>29</u>	5	TNTC	TNTC	<u>32</u>	4
TNTC	<u>230</u>	20	0	TNTC	TNTC	<u>32</u>	4	TNTC	TNTC	<u>32</u>	4
TNTC				TNTC				TNTC			
CFU/mL <u>2.6 x 10⁴</u> Counted by: <u>SAS / 7-30-03</u>				CFU/mL <u>3.0 x 10⁴</u> Counted by: <u>SAS / 7-30-03</u>				CFU/mL <u>3.0 x 10⁴</u> Counted by: <u>SAS / 7-30-03</u>			

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
<u>134</u>	<u>34</u>	0	0	TNTC	<u>96</u>	10	2	TNTC	<u>121</u>	12	1
<u>108</u>	<u>40</u>	5	0	TNTC	<u>121</u>	12	1	TNTC	<u>121</u>	12	1
<u>130</u>				TNTC				TNTC			
CFU/mL <u>3.7 x 10³</u> Counted by: <u>SAS / 7-30-03</u>				CFU/mL <u>1.1 x 10⁴</u> Counted by: <u>SAS / 7-30-03</u>				CFU/mL <u>1.1 x 10⁴</u> Counted by: <u>SAS / 7-30-03</u>			

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

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

Calculations Verified by: JNB / 08-01-03

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

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

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

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	08/01/03 mm dd yy	L, R, C F M L	196 Permanent #: 86	03-122085-106

Date Subject Entered the Study: 07/21/03 mm dd yy	Follow-Up Visit Date: 08/01/03 mm dd yy
---	---

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

YES NO If yes, complete below:

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

Comments:

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

YES NO If yes, complete below

Comments:

Medical Consultant's Signature: <i>E. Lenin Jones MD</i>	Date 8/1/03 mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 201	Study #
Subject Qualification	07/21/03 mm dd yy	S, D, D F M L	Permanent #: 87	03-122085-106

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

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

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

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

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify. <i>in past has used since with no problem Dial soaps, IP dye</i>		✓	
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

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

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ? <i>Ibuprofen 200mg taken as needed</i>		✓	

Comments:

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

Interviewer's Signature:

*Stacey E. Beckardin*Date: 07/21/03
mm dd yy

Data Collection Form 2
INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106
Page No.: IV-688

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
	<u>07/21/03</u> mm dd yy	<u>S/D/D</u> f m l	<u>201</u> Permanent #: <u>87</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>1987</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β-HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

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

Reasons for disqualification: _____

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

Investigator's Signature: [Signature]

Date: 8/11/03
mm dd yy

Data Collection Form 3
INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>201</u>	Study #
Test Period	<u>07/28/03</u> mm dd yy	<u>5/D/D</u> F M L	Permanent #: <u>87</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. Wacham Date: 07/28/03
 mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07 / 28 / 03</u> mm dd yy	<u>S/D/D</u> F. M L	<u>201</u>	
		Permanent #:	03-122085-106
		<u>87</u>	

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	TNTC	<u>22</u>	TNTC	TNTC	<u>26</u>
TNTC	TNTC	<u>34</u>	TNTC	TNTC	<u>29</u>
CFU/mL <u>3.0 x 10⁷</u> Counted by: <u>JNB 107-30-03</u>			CFU/mL <u>2.8 x 10⁷</u> Counted by: <u>JNB 107-30-03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>59</u>	<u>8</u>	TNTC	TNTC	<u>59</u>	<u>12</u>	TNTC	TNTC	<u>68</u>	<u>8</u>
TNTC	TNTC	<u>67</u>	<u>7</u>	TNTC	TNTC	<u>68</u>	<u>8</u>	TNTC	TNTC	<u>68</u>	<u>8</u>
TNTC				TNTC				TNTC			
CFU/mL <u>6.3 x 10⁴</u> Counted by: <u>JNB 107-30-03</u>						CFU/mL <u>6.4 x 10⁴</u> Counted by: <u>JNB 107-30-03</u>					

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	<u>214</u>	<u>23</u>	<u>4</u>	TNTC	TNTC	<u>24</u>	<u>3</u>	TNTC	TNTC	<u>38</u>	<u>2</u>
TNTC	<u>246</u>	<u>30</u>	<u>4</u>	TNTC	TNTC	<u>38</u>	<u>2</u>	TNTC	TNTC	<u>38</u>	<u>2</u>
TNTC				TNTC				TNTC			
CFU/mL <u>2.5 x 10⁴</u> Counted by: <u>JNB 107-30-03</u>						CFU/mL <u>3.1 x 10⁴</u> Counted by: <u>JNB 107-30-03</u>					

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

Calculations Verified by: JNB 108-01-03

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

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>01 / 11 / 03</u> mm dd yy
--	---------------------------------------

FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #: <u>201</u>	Study #
Follow-up Visit	<u>08/01/03</u> mm dd yy	<u>S/D/D</u> F M L	Permanent #: <u>87</u>	03-122085-106

Date Subject Entered the Study: <u>07.21.03</u> mm dd yy	Follow-Up Visit Date: <u>08.01.03</u> mm dd yy
--	--

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

YES NO If yes, complete below:

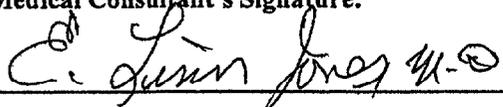
Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)

Comments:

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

YES NO If yes, complete below

Comments:

Medical Consultant's Signature: 	Date <u>8.1.03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>200</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>J/L/S</u> F M L	Permanent #: <u>88</u>	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>osteoporosis, depression</u>		✓	

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

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ? <u>Fosamax 70mg 1x week osteoporosis</u>		✓	

Comments: Other meds: Effexor 50mg 2x day depression

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

Interviewer's Signature: Jami Busemeyer Date: 07/21/03
mm dd yy

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

HTR Study No.: 03-122085-106

Page No.: IV-693

Visit Code	Date	Subject Initials	Subject Screen #: <u>200</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>J/L/S</u> f m l	Permanent #: <u>88</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

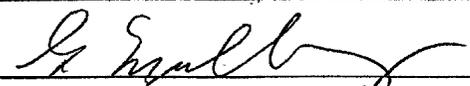
Check one ..			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has 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	<input checked="" type="checkbox"/>	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input checked="" type="checkbox"/> Post-menopausal, year <u>1993</u> If of child bearing potential - β-HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

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

Qualified Not Qualified for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: 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>200</u>	Study #
Test Period	<u>07/28/03</u> mm dd yy	<u>J L S</u> F M L	Permanent #: <u>88</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: 07/28/03
 mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/28/03</u> mm dd yy	<u>JILS</u> F. M L	<u>200</u>	
		Permanent #:	03-122085-106
		<u>88</u>	

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	TNTC	<u>26</u>	TNTC	TNTC	<u>36</u>
TNTC	TNTC	<u>29</u>	TNTC	TNTC	<u>27</u>
CFU/mL <u>2.8 x 10⁷</u> Counted by: <u>SAS</u> / 7-30-03			CFU/mL <u>3.2 x 10⁷</u> Counted by: <u>SAS</u> / 7-30-03		

ASAS 7-30-03

LEFT HAND				WASH 1		RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>275</u>	4	TNTC	TNTC	<u>65</u>	5	<u>65</u>	5
TNTC	TNTC	<u>50</u>	3	TNTC	TNTC	<u>58</u>	5	<u>58</u>	5
TNTC				TNTC					
CFU/mL <u>6.2 x 10⁴</u> Counted by: <u>SAS</u> / 7-30-03					CFU/mL <u>6.2 x 10⁴</u> Counted by: <u>SAS</u> / 7-30-03				

LEFT HAND				WASH 11		RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻³	10 ⁻⁴
TNTC	<u>85</u>	7	0	TNTC	<u>79</u>	5	0	<u>79</u>	0
TNTC	<u>80</u>	6	0	TNTC	<u>83</u>	2	0	<u>83</u>	0
TNTC				TNTC					
CFU/mL <u>8.2 x 10³</u> Counted by: <u>SAS</u> / 7-30-03					CFU/mL <u>8.1 x 10³</u> Counted by: <u>SAS</u> / 7-30-03				

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

Calculations Verified by: JNB 108-01-03

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

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

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

FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #: 200	Study #
Follow-up Visit	08/01/03 mm dd yy	J / L / S F M L	Permanent #: 88	03-122085-106

Date Subject Entered the Study: 07/21/03 mm dd yy	Follow-Up Visit Date: 08/01/03 mm dd yy
---	---

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

YES NO If yes, complete below:

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

Comments:

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

YES NO If yes, complete below

Comments:

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

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>180</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>M/F/M</u> F M L	Permanent #: <u>89</u>	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 ?	✓		

Comments:

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

Interviewer's Signature:

Joni Busmeyer

Date:

07/21/03
mm dd yy

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

HTR Study No.: 03-122085-106
Page No.: IV-698

Visit Code	Date	Subject Initials	Subject Screen #: <u>180</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>M, F/M</u> f m l	Permanent #: <u>89</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: E. Small

Date: 8/10/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: 180	Study #
Test Period	<u>07/28/03</u> mm dd yy	<u>M, F, M</u> F M L	Permanent #: 89	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? Yes No

If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? Yes No

If no, please explain: _____

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

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

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

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

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

Describe condition: _____

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

Action Taken: None Continued on study Withdrawn from the study Consulted physician

Medication taken (Complete below) Hospitalized Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

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

Comments:

Interviewer's Signature:

Stacey E Backlund

Date:

07/28/03
mm dd yy

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

Test Date	Subject Initials	Subject Screen #	Study #
<u>07 / 28 / 03</u> mm dd yy	<u>M / F / M</u> F. M L	<u>180</u> Permanent #: <u>89</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>171</u>	<u>27</u>	TNTC	<u>163</u>	<u>19</u>
TNTC	<u>144</u>	<u>21</u>	TNTC	<u>175</u>	<u>17</u>
CFU/mL 1.6 x 10⁷ Counted by: <u>JNB 107-30-03</u> <u>2.0 x 10⁷</u>			CFU/mL 1.7 x 10⁷ Counted by: <u>JNB 107-30-03</u>		

③ Cas 8-1-03

LEFT HAND				WASH 1				RIGHT HAN			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³		10 ⁻¹	10 ⁻²	10 ⁻³	
TNTC	TNTC	<u>63</u>	<u>6</u>	TNTC	TNTC	<u>60</u>		TNTC	TNTC	<u>60</u>	
TNTC	TNTC	<u>43</u>	<u>8</u>	TNTC	TNTC	<u>68</u>		TNTC	TNTC	<u>68</u>	
TNTC				TNTC				TNTC			
CFU/mL <u>5.3 x 10⁴</u> Counted by: <u>JNB 107-30-03</u>				CFU/mL <u>6.4 x 10⁴</u> Counted by: <u>JNB 107-</u>							

LEFT HAND				WASH 11				RIGHT HA			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³		10 ⁻¹	10 ⁻²	10 ⁻³	
<u>179</u>	<u>61</u>	<u>3</u>	<u>0</u>	<u>156</u>	<u>53</u>	<u>10</u>		<u>156</u>	<u>53</u>	<u>10</u>	
<u>173</u>	<u>80</u>	<u>13</u>	<u>1</u>	<u>164</u>	<u>51</u>	<u>10</u>		<u>164</u>	<u>51</u>	<u>10</u>	
<u>137</u>				<u>199</u>				<u>199</u>			
CFU/mL <u>6.3 x 10³</u> Counted by: <u>JNB 107-30-03</u>				CFU/mL <u>5.2 x 10³</u> Counted by: <u>JNB 107-</u>							

Calculations by: TG 17-31-03 Raw data reviewed by SRH 8-6-03

Calculations Verified by: JNB 108-01-03

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

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>9 / 11 / 03</u> mm dd yy
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Data Collection Form 5A

Subject Initials M. F. M. Subject # 89

Study No. 03-122085-1

Page No. IV-701

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigat Signature/Initials
Macules	7-31-03	8/11/03	H	1	1	1	4*	C. Leim
Entry Date	Comment/Note: * Probably due to test organism E. coli							
8-1-03	Five red macules on forearms, 8-2-03							
8/11/03	Hands clear no medications used							

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

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-ship	Investig Signature
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=Unrelate

Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (s)

Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

¹Serious Adverse Event/Experience

FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen # 180	Study #
Follow-up Visit	08/01/03 mm dd yy	M, F, M F M L	Permanent #: 89	03-122085-106

Date Subject Entered the Study: 07/21/03 mm dd yy	Follow-Up Visit Date: 08/01/03 mm dd yy
---	---

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

YES NO If yes, complete below:

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

*Five red macules on forearms.
Onset 7-31-03*

Comments:

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

YES NO If yes, complete below

Comments:

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

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>199</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>G, B, M</u> F M L	Permanent #: <u>90</u>	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. Boekendin Date: 07/21/03
mm dd yy

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

HTR Study No.: 03-12208
Page No.: IV

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>G. B. M</u> f m i	<u>199</u> Permanent #: <u>90</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: SEB, 7/21/03

Investigator's Signature: _____

Date: 07/21/03

3 mm dd yy

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>199</u>	Study #
Test Period	<u>07/28/03</u> mm dd yy	<u>G/B/M</u> F M L	Permanent #: <u>90</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. Wetton Date: 07/28/03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/28/03</u> mm dd yy	<u>G.B.M</u> F. M L	<u>199</u> Permanent #: <u>90</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNFC	<u>238</u>	<u>18</u>	TNFC	TNFC	<u>26</u>
TNFC	<u>175</u>	<u>19</u>	TNFC	TNFC	<u>30</u>
CFU/mL <u>2.1 x 10⁷</u> Counted by: <u>VUH/7-30-03</u>			CFU/mL <u>2.8 x 10⁷</u> Counted by: <u>VUH/7-30-03</u>		

LEFT HAND				WASH 1		RIGHT HAND	
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	
TNFC	TNFC	<u>55</u>	<u>7</u>	TNFC	TNFC	<u>42</u>	
TNFC	TNFC	<u>52</u>	<u>2</u>	TNFC	TNFC	<u>69</u>	
CFU/mL <u>5.4 x 10⁴</u> Counted by: <u>VUH/7-30-03</u>				CFU/mL <u>5.6 x 10⁴</u> Counted by: <u>VUH/7-30-03</u>			

LEFT HAND				WASH 11		RIGHT HAND	
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	
<u>32</u>	<u>12</u>	<u>1</u>	<u>0</u>	<u>63</u>	<u>13</u>	<u>4</u>	
<u>31</u>	<u>13</u>	<u>0</u>	<u>0</u>	<u>77</u>	<u>25</u>	<u>1</u>	
<u>33</u>				<u>73</u>			
CFU/mL <u>9.6 x 10²</u> Counted by: <u>VUH/7-30-03</u>				CFU/mL <u>2.0 x 10³</u> Counted by: <u>VUH/7-30-03</u>			

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

Calculations Verified by: JNB/10-30-03

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

Underlined values are used for calculation of CFU/mL

TNFC - 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	08/01/03 mm dd yy	G, B, M F M L	199 Permanent #: 90	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.)

Comments:

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

YES NO If yes, complete below

Comments:

Medical Consultant's Signature: <i>E. Lewis Jones M.D.</i>	Date: 8/4/03 mm dd yy
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