

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 114	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>L/S/B</u> F M L	Permanent #: 20	03-122085-106

Gender: Male Female. Age: 57 Years

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

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

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

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease? <u>HBP</u>	✗	✓	
4. Liver Disease ?	✓	③SRH 1/7.15.03	
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>See below</u>	✗	✓	

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

③SRH 1/7.15.03

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>Toprol ③SRH 1/7.17.03</u>		✓	

Comments: Tropfol - Blood Pressure 100mg 1x/day
Climara - .05mg - HRT Patch

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

Interviewer's Signature: San E. Harris Date: 07 / 15 / 03
mm dd yy

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

HTR Study No.: 03-122085-106
Page No.: IV-326

Visit Code	Date	Subject Initials	Subject Screen #: <u>114</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>L/S/B</u> f m l	Permanent #: <u>20</u>	03-122085-106

INCLUSION CRITERIA

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

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <u>Hyst.</u> <input checked="" type="checkbox"/> Surgically Sterile, year <u>1990</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: SRH / 7.15.03

Investigator's Signature: _____

Ann R. Brady

Date: 08/10/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date <u>24</u>	Subject Initials	Subject Screen #: <u>114</u>	Study #
Test Period	<u>07/23/03</u> mm dd yy	<u>L/S/B</u> F M L	Permanent #: <u>20</u>	03-122085-106

CSRH/7.24.03

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: Susan L. Harris Date: 07 / 24 / 03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/24/03</u> mm dd yy	<u>L/S/B</u> F. M L	<u>114</u> Permanent #: <u>20</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>122</u>	<u>17</u>	TNTC	<u>131</u>	<u>18</u>
TNTC	<u>146</u>	<u>16</u>	TNTC	<u>158</u>	<u>17</u>
CFU/mL <u>1.3x10⁷</u> Counted by: <u>AS 17.28.03</u>			CFU/mL <u>1.4x10⁷</u> Counted by: <u>AS 17.28.03</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>79</u>	<u>9</u>	TNTC	TNTC	<u>141</u>	<u>14</u>	TNTC	TNTC	<u>108</u>	<u>5</u>
TNTC	TNTC	<u>58</u>	<u>10</u>	TNTC	TNTC			TNTC	TNTC		
TNTC				TNTC				TNTC			
CFU/mL <u>6.8x10⁴</u> Counted by: <u>AS 17.28.03</u>						CFU/mL <u>1.2x10⁵</u> Counted by: <u>AS 17.28.03</u>					

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>61</u>	<u>11</u>	TNTC	TNTC	<u>58</u>	<u>6</u>	TNTC	TNTC	<u>57</u>	<u>11</u>
TNTC	TNTC	<u>77</u>	<u>6</u>	TNTC	TNTC			TNTC	TNTC		
TNTC				TNTC				TNTC			
CFU/mL <u>6.9x10⁴</u> Counted by: <u>AS 17.28.03</u>						CFU/mL <u>5.8x10⁴</u> Counted by: <u>AS 17.28.03</u>					

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

Calculations Verified by: TG 17.29.03

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

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

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

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>07/29/03</u> mm dd yy	<u>L/S/B</u> F M L	<u>114</u> Permanent #: <u>20</u>	03-122085-106

Date Subject Entered the Study: <u>07/15/03</u> mm dd yy	Follow-Up Visit Date: <u>07/29/03</u> mm dd yy
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Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?

YES NO If yes, complete below:

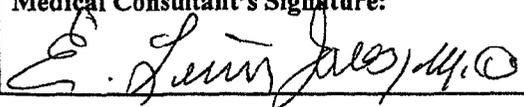
Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)

Comments:

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

YES NO If yes, complete below

Comments:

Medical Consultant's Signature: 	Date <u>7/29/03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>213</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>M/E/C</u> F M L	Permanent #: <u>21</u>	03-122085-106

Gender: Male Female. Age: 63 Years

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

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

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

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

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

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

Comments:

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

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

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

HTR Study No.: 03-122085-106
Page No.: IV - 331

Visit Code	Date	Subject Initials	Subject Screen #: <u>213</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>M/E/C</u> f m l	Permanent #: <u>21</u>	03-122085-106

INCLUSION CRITERIA

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

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input checked="" type="checkbox"/> Post-menopausal, year <u>1995</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: _____

Ann R. Brady

Date: 08/10/03
mm dd yy

Data Collection Form 3
INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: 213	Study #
Test Period	<u>07/29/03</u> mm dd yy	<u>M/E/C</u> F M L	Permanent #: 21	03-122085-106

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

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

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

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

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

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

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

Describe condition: _____

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

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

Medication taken (Complete below) Hospitalized Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

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

Comments:

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

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

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/29/03</u> mm dd yy	<u>M, E, C</u> F M L	<u>213</u>	
		Permanent #:	03-122085-106
		<u>21</u>	

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>256</u> ^Δ	<u>22</u>	TNTC	<u>171</u>	<u>12</u>
TNTC	<u>235</u>	<u>23</u>	TNTC	<u>161</u>	<u>12</u>
CFU/mL <u>2.4 × 10⁷</u> Counted by: <u>TG 17-31-03</u>			CFU/mL <u>1.7 × 10⁷</u> Counted by: <u>TG 17-31-03</u>		

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

LEFT HAND				WASH 1		RIGHT HAND	
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>61</u>	<u>4</u>	TNTC	TNTC	<u>43</u>	<u>4</u>
TNTC	TNTC	<u>53</u>	<u>10</u>	TNTC	TNTC	<u>44</u>	<u>2</u>
TNTC				TNTC			
CFU/mL <u>5.7 × 10⁴</u> Counted by: <u>TG 17-31-03</u>				CFU/mL <u>4.4 × 10⁴</u> Counted by: <u>TG 17-31-03</u>			

LEFT HAND				WASH 11		RIGHT HAND	
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
<u>162</u>	<u>76</u>	<u>7</u>	<u>0</u>	<u>144</u>	<u>85</u>	<u>11</u>	<u>0</u>
[Ⓢ] <u>251</u>	<u>71</u>	<u>10</u>	<u>0</u>	<u>168</u>	<u>91</u>	<u>9</u>	<u>0</u>
<u>145</u>				<u>119</u>			
CFU/mL <u>6.8 × 10³</u> Counted by: <u>EAS 17-31-03</u>				CFU/mL <u>7.3 × 10³</u> Counted by: <u>EAS 17-31-03</u>			

[Ⓢ] Did not estimate due to countability of the plate 7-31-03

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

Calculations Verified by: EAS / 8-1-03

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

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

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

Visit Code	Date	Subject Initials	Subject Screen #: 213	Study #
Follow-up Visit	08/04/03 mm dd yy	M/E/C F M L	Permanent #: 21	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: Dwell on hands.

Medical Consultant's Signature: <i>E. Lynn Jones, MD</i>	Date 8/4/03 mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 131	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>A/D/B</u> F M L	Permanent #: 22	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>23</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. <u>poison ivy</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: Lo-Ogestral - 1xday - 28day - Birth ControlBased on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: <u>Susan R. Harris</u>	Date: <u>07/15/03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-336

Visit Code	Date	Subject Initials	Subject Screen #: <u>131</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>A/D/B</u> f m l	Permanent #: <u>22</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>7/24/03 gk</u>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

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

Reasons for disqualification: _____ Interviewer's Initials/Date: SRH / 7-15-03

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

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: 131	Study #
Test Period	07/24/03 mm dd yy	A/D/B F M L	Permanent #: 22	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: Susan L. Harris Date: 07 / 24 / 03
 mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/24/03</u> mm dd yy	<u>A/D/B</u> F. M. L	<u>131</u> Permanent #: <u>22</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>17</u>	TNTC	<u>147</u>	<u>15</u>
TNTC	<u>172</u>	<u>20</u>	TNTC	<u>146</u>	<u>19</u>
CFU/mL <u>1.6 x 10⁷</u> Counted by: <u>JNB 07-28-03</u>			CFU/mL <u>1.5 x 10⁷</u> Counted by: <u>JNB/07-28-03</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>102</u>	<u>17</u>	TNTC	TNTC	<u>106</u>	<u>15</u>	TNTC	TNTC	<u>137</u>	<u>25</u>
TNTC	TNTC	<u>130</u>	<u>9</u>	TNTC	TNTC	<u>137</u>	<u>25</u>	TNTC	TNTC	<u>137</u>	<u>25</u>
TNTC				TNTC				TNTC			
CFU/mL <u>1.2 x 10⁵</u> Counted by: <u>JNB 07-28-03</u>						CFU/mL <u>1.6 x 10⁵</u> Counted by: <u>JNB 07-28-03</u>					

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>97</u>	<u>19</u>	TNTC	TNTC	<u>100</u>	<u>21</u>	TNTC	TNTC	<u>120</u>	<u>12</u>
TNTC	TNTC	<u>164</u>	<u>19</u>	TNTC	TNTC	<u>120</u>	<u>12</u>	TNTC	TNTC	<u>120</u>	<u>12</u>
TNTC				TNTC				TNTC			
CFU/mL <u>1.3 x 10⁵</u> Counted by: <u>JNB 07-28-03</u>						CFU/mL <u>1.1 x 10⁵</u> Counted by: <u>JNB 07-28-03</u>					

Calculations by: JNB 07-29-03 Raw data reviewed by AMB 08-1-03

Calculations Verified by: Tu 07-29-03

*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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FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>07/29/03</u> mm dd yy	<u>AID/B</u> F M L	<u>131</u> Permanent #: <u>22</u>	03-122085-106

Date Subject Entered the Study: <u>07/15/03</u> mm dd yy	Follow-Up Visit Date: <u>07/29/03</u> mm dd yy
<p>Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?</p> <p><input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, complete below:</p> <p>Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)</p> <hr/> <hr/> <hr/> <p>Comments:</p> <hr/> <hr/> <hr/>	
<p>Has the subject had any health related issues since the treatment procedure?</p> <p><input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, complete below</p> <p>Comments:</p> <hr/> <hr/> <hr/>	

Medical Consultant's Signature: <i>C. J. ...</i>	Date <u>7/29/03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 110	Study #
Subject Qualification	07/15/03 mm dd yy	B/E/F F M L	Permanent #: 23	03-122085-106

Gender: Male Female Age: 49 Years

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

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

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

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

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

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

Comments:

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

Interviewer's Signature: Jamie Busemeyer Date: 07.15.03
mm dd yy

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

HTR Study No.: 03-122085-106
Page No.: IV-341

Visit Code	Date	Subject Initials	Subject Screen #: <u>110</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>B/E/F</u> f m l	Permanent #: <u>23</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 07-15-03

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

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>110</u>	Study #
Test Period	<u>07/23/03</u> mm dd yy	<u>B/E/F</u> F M L	Permanent #: <u>23</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>Susan R. Harris</u>	Date: <u>07 / 23 / 03</u> mm dd yy
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HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/23/03</u> mm dd yy	<u>B, E, F</u> F. M. L.	<u>110</u> Permanent #: <u>23</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>103</u>	13	TNTC	<u>76</u>	10
TNTC	<u>132</u>	13	TNTC	<u>101</u>	8
CFU/mL <u>1.2 x 10⁷</u> Counted by: <u>JNB 107-25-03</u>			CFU/mL <u>8.8 x 10⁶</u> Counted by: <u>JNB 107-25-03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	TNTC	<u>33</u>	TNTC	TNTC	TNTC	<u>29</u>	TNTC	TNTC	TNTC	<u>24</u>
TNTC	TNTC	TNTC	<u>31</u>	TNTC	TNTC	TNTC		TNTC	TNTC	TNTC	
TNTC				TNTC				TNTC			
CFU/mL <u>3.2 x 10⁵</u> Counted by: <u>JNB 107-25-03</u>				CFU/mL <u>2.6 x 10⁵</u> Counted by: <u>JNB 07-25-03</u>							

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>220</u>	<u>21</u>	TNTC	TNTC	<u>134</u>	<u>13</u>	TNTC	TNTC	<u>122</u>	<u>11</u>
TNTC	TNTC	<u>184</u>	18	TNTC	TNTC			TNTC	TNTC		
TNTC				TNTC				TNTC			
CFU/mL <u>2.0 x 10⁵</u> Counted by: <u>ARB 17-25-03</u>				CFU/mL <u>1.3 x 10⁵</u> Counted by: <u>ARB 17-25-03</u>							

Calculations by: TR 17-26-03 Raw data reviewed by SAS / 8-1-03

Calculations Verified by: JNB 107-29-03

*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: 	Date: <u>8 11 03</u> mm dd yy
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FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>07/28/03</u> mm dd yy	<u>B/E/F</u> F M L	<u>110</u> Permanent #: <u>23</u>	03-122085-106

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

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

YES NO If yes, complete below:

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

Comments:

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

YES NO If yes, complete below

Comments:

Medical Consultant's Signature: <i>E. Linn Jones, MD</i>	Date <u>7/28/03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 215	Study #
Subject Qualification	07/21/03 mm dd yy	G/A/H F M L	Permanent #: 24	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:	✓		

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 Buseneyer Date: 07 / 21 / 03
mm dd yy

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

HTR Study No.: 03-122085-106
Page No.: IV-346

Visit Code	Date	Subject Initials	Subject Screen #: <u>215</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>G/A/H</u> f m l	Permanent #: <u>24</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: Ann P. Brady Date: 08/10/08
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>215</u>	Study #
Test Period	<u>07/29/03</u> mm dd yy	<u>G/A/H</u> F M L	Permanent #: <u>24</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 Bachudis Date: 07, 29, 03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/29/03</u> mm dd yy	<u>G/A/H</u> F. M L	<u>215</u> Permanent #: <u>24</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>260</u> ^Δ	<u>20</u>	TNTC	<u>238</u>	<u>13</u>
TNTC	<u>256</u> ^Δ	<u>30</u>	TNTC	<u>186</u>	<u>25</u>
CFU/mL <u>2.5 × 10⁷</u> Counted by: <u>TL 17-31-03</u>			CFU/mL <u>2.0 × 10⁷</u> Counted by: <u>TL 17-31-03</u>		

Δ Not estimated due to constability of the plate. TL 7-31-03

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>126</u>	<u>15</u>	TNTC	TNTC	<u>124</u>	<u>19</u>	TNTC	TNTC	<u>132</u>	<u>15</u>
TNTC	TNTC	<u>136</u>	<u>27</u>	TNTC	TNTC	<u>132</u>	<u>15</u>	TNTC	TNTC	<u>132</u>	<u>15</u>
TNTC				TNTC				TNTC			
CFU/mL <u>1.7 × 10⁵</u> Counted by: <u>JNB 107-31-03</u>						CFU/mL <u>1.3 × 10⁵</u> Counted by: <u>JNB 107-31-03</u>					

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	<u>143</u>	<u>19</u>	<u>2</u>	TNTC	<u>111</u>	<u>9</u>	<u>2</u>	TNTC	<u>117</u>	<u>15</u>	<u>2</u>
TNTC	<u>130</u>	<u>12</u>	<u>3</u>	TNTC	<u>117</u>	<u>15</u>	<u>2</u>	TNTC	<u>117</u>	<u>15</u>	<u>2</u>
TNTC				TNTC				TNTC			
CFU/mL <u>1.4 × 10⁴</u> Counted by: <u>SAS 17-31-03</u>						CFU/mL <u>1.1 × 10⁴</u> Counted by: <u>SAS 17-31-03</u>					

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

Calculations Verified by: SAS 18-1-03

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

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>Ann P. Brady</u>	Date: <u>08/10/03</u> mm dd yy
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Data Collection Form 5A

Subject Initials GAH Subject # 24

Study No. 03-122085-106
Page No. IV-349

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Pink areas	8-10-03	8-11-03	N	1			4*	E. J. [Signature] 8-21-03
Entry Date	Comment/Note: * Probably due to test organism - E. J. G. - 8-21-03							Initials
8-4-03	Two pink areas on backs of hands							E. J. G.
8/11/03	Hands clear no medications used							gh

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

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

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

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

¹Serious Adverse Event/Experience

FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>08, 04, 03</u> mm dd yy	<u>GIAIH</u> F M L	<u>215</u> Permanent #: <u>24</u>	03-122085-106

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

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

YES NO If yes, complete below:

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

Two pink areas on backs of hands
Onset 8-1-03

Comments:

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

YES NO If yes, complete below

Comments:

Medical Consultant's Signature: <u>E. Linn, MD, PhD</u>	Date <u>8, 4, 03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 234	Study #
Subject Qualification	07/21/03 mm dd yy	K, C, B F M L	Permanent #: 25	03-122085-106

Gender: Male Female . Age: 18 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: Stacy E Bacherding

Date: 07/21/03

mm dd yy

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

HTR Study No.: 03-122085-106
Page No.: IV - 352

Visit Code	Date	Subject Initials	Subject Screen #: <u>234</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>K, C, B</u> f m l	Permanent #: <u>25</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: SPB, 7/21/03

Investigator's Signature: _____

Ann R. Brady

Date: 08/10/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: 234	Study #
Test Period	<u>07/29/03</u> mm dd yy	<u>K, C, B</u> F M L	Permanent #: <u>25</u>	03-122085-106

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

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

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

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

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

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

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

Describe condition: _____

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

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

Medication taken (Complete below) Hospitalized Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

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

Comments:

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

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/29/03</u> mm dd yy	<u>K/C/B</u> F M L	<u>234</u> Permanent #: <u>25</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>144</u>	<u>21</u>	TNTC	<u>208</u>	<u>24</u>
TNTC	<u>188</u>	<u>15</u>	TNTC	<u>201</u>	<u>16</u>
CFU/mL <u>1.7x10⁷</u> Counted by: <u>TA 17-31-03</u>			CFU/mL <u>2.0x10⁷</u> Counted by: <u>TA 17-31-03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>81</u>	<u>13</u>	TNTC	TNTC	<u>62</u>	<u>8</u>	TNTC	TNTC	<u>80</u>	<u>3</u>
TNTC	TNTC	<u>107</u>	<u>10</u>	TNTC	TNTC	<u>80</u>	<u>3</u>	TNTC	TNTC	<u>80</u>	<u>3</u>
TNTC				TNTC				TNTC			
CFU/mL <u>9.4x10⁴</u> Counted by: <u>SAS 17-31-03</u>				CFU/mL <u>7.1x10⁴</u> Counted by: <u>SAS 17-31-03</u>				CFU/mL <u>7.1x10⁴</u> Counted by: <u>SAS 17-31-03</u>			

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	<u>159</u>	<u>13</u>	<u>1</u>	TNTC	<u>104</u>	<u>12</u>	<u>1</u>	TNTC	<u>104</u>	<u>12</u>	<u>1</u>
TNTC	<u>133</u>	<u>27</u>	<u>0</u>	TNTC	<u>77</u>	<u>13</u>	<u>0</u>	TNTC	<u>77</u>	<u>13</u>	<u>0</u>
TNTC				TNTC				TNTC			
CFU/mL <u>1.7x10⁴</u> Counted by: <u>SAS 17-31-03</u>				CFU/mL <u>9.0x10⁸</u> Counted by: <u>SAS 17-31-03</u>				CFU/mL <u>9.0x10⁸</u> Counted by: <u>SAS 17-31-03</u>			

Calculations by: JNB 08-01-03 Raw data reviewed by SRH 18-6-03

Calculations Verified by: SAS 8-1-03

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

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

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

Visit Code	Date	Subject Initials	Subject Screen #: 234	Study #
Follow-up Visit	08, 04, 03 mm dd yy	K, C, B F M L	Permanent #: 25	03-122085-106

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

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

YES NO If yes, complete below:

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

Comments:

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

YES NO If yes, complete below

Comments:

Medical Consultant's Signature: <i>C. Steven Jones, M.D.</i>	Date 8, 4, 03 mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>233</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>JIEB</u> F M L	Permanent #: <u>26</u>	03-122085-106

Gender: Male Female Age: 54 Years

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

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

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

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

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

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ? <u>NORVASC 100/25 1x day</u>		✓	
4. Insulin ?	✓		
5. Other ?	✓		

Comments:

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

Interviewer's Signature: Betty M. Conover

Date: 07/21/03
mm dd yy

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

HTR Study No.: 03-122085-106
Page No.: IV-351

Visit Code	Date	Subject Initials	Subject Screen #: <u>233</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>J, E, D</u> f m l	Permanent #: <u>26</u>	03-122085-106

INCLUSION CRITERIA

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

EXCLUSION CRITERIA

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

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

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

Investigator's Signature: <u>Ann R. Brady</u>	Date: <u>08/10/03</u> mm dd yy
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Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: 233	Study #
Test Period	07/29/03 mm dd yy	J, E, B F M L	Permanent #: 26	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. Barchard

Date:

07, 29, 03
mm dd yy

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

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/29/03</u> mm dd yy	<u>J/E/B</u> F M L	<u>233</u> Permanent #: <u>26</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>318</u> ^Δ	<u>21</u>	TNTC	<u>219</u>	<u>14</u>
TNTC	<u>244</u>	<u>24</u>	TNTC	<u>234</u>	<u>31</u>
CFU/mL <u>2.8 × 10⁷</u> Counted by: <u>TG 17-31-03</u>			CFU/mL <u>2.2 × 10⁷</u> Counted by: <u>TG 17-31-03</u>		

Δ could not estimate due to uneven distribution. TG 7-31
① TG 7-31-03

LEFT HAND				WASH 1		RIGHT HAND	
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>176</u>	<u>17</u>	TNTC	TNTC	<u>237</u>	<u>26</u>
TNTC	TNTC	<u>164</u>	<u>31</u>	TNTC	TNTC	<u>279</u> ^Δ	<u>15</u>
TNTC				TNTC			
CFU/mL <u>2.0 × 10⁹</u> Counted by: <u>TG 17-31-03</u>				CFU/mL <u>2.3 × 10⁵</u> Counted by: <u>TG 17-31-03</u>			

LEFT HAND				WASH 11		RIGHT HAND	
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	<u>202</u>	<u>24</u>	<u>4</u>	TNTC	<u>168</u>	<u>44</u>	<u>4</u>
TNTC	<u>197</u>	<u>22</u>	<u>0</u>	TNTC	<u>237</u>	<u>26</u>	<u>1</u>
TNTC				TNTC			
CFU/mL <u>2.0 × 10⁴</u> Counted by: <u>TG 17-31-03</u>				CFU/mL <u>2.8 × 10⁴</u> Counted by: <u>TG 17-31-03</u>			

Calculations by: JNB 08-01-03 Raw data reviewed by SLH 18-6-03

Calculations Verified by: SAS 18-1-03

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

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

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

Visit Code	Date	Subject Initials	Subject Screen #: 233	Study #
Follow-up Visit	08/04/03 mm dd yy	J E B F M L	Permanent #: 26	03-122085-106

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

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

YES NO If yes, complete below:

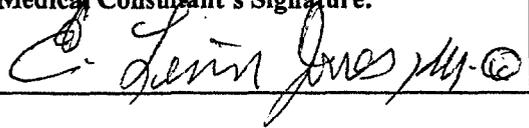
Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)

Comments:

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

YES NO If yes, complete below

Comments:

Medical Consultant's Signature: 	Date 8/4/03 mm dd yy
--	----------------------------

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 230	Study #
Subject Qualification	07/21/03 mm dd yy	WISH F M L	Permanent #: 27	03-122085-106

Gender: <input checked="" type="checkbox"/> Male <input type="checkbox"/> Female	Age: <u>47</u> Years
--	----------------------

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

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

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

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

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

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

Comments:

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

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

HTR Study No.: 03-122085-106
Page No.: IV-362

Visit Code	Date	Subject Initials	Subject Screen #: <u>230</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>W/S/H</u> f m l	Permanent #: <u>27</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"/>	<u>07-21-03</u>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<u>27</u>	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 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 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: BC 107-21-03

Investigator's Signature:

Ann L. Brady

Date: 08/10/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: 230	Study #
Test Period	<u>07/29/03</u> mm dd yy	<u>W/S/H</u> F M L	Permanent #: 27	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. Barchard Date: 07/29/03
mm dd yy

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

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/29/03</u> mm dd yy	<u>W/S/H</u> F. M L	<u>230</u> Permanent #: <u>27</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>213</u>	<u>13</u>	TNTC	<u>207</u>	<u>24</u>
TNTC	<u>284</u> ^Δ	<u>21</u>	TNTC	<u>254</u> ^Δ	<u>12</u>
CFU/mL <u>2.5 × 10⁷</u> Counted by: <u>TG 17-31-03</u>			CFU/mL <u>2.3 × 10⁷</u> Counted by: <u>TG 17-31-03</u>		

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

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>171</u>	<u>10</u>	TNTC	TNTC	<u>33</u>	<u>5</u>	TNTC	TNTC	<u>91</u>	<u>8</u>
TNTC	TNTC	<u>182</u>	<u>18</u>	TNTC	TNTC			TNTC	TNTC		
TNTC				TNTC				TNTC			
CFU/mL <u>1.8 × 10⁵</u> Counted by: <u>TG 17-31-03</u>						CFU/mL <u>8.2 × 10⁴</u> Counted by: <u>TG 17-31-03</u>					

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	** 10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
<u>224</u>	<u>65</u>	<u>26</u>	<u>1</u>	<u>308</u> ^Δ	<u>308</u> ^{LA}	<u>12</u>	<u>1</u>	<u>308</u> ^{LA}	<u>12</u>	<u>11</u>	<u>2</u>
<u>197</u>	<u>100</u>	<u>26</u>	<u>2</u>	<u>241</u>	<u>LA</u>			<u>LA</u>			
<u>213</u>				<u>262</u> ^Δ							
CFU/mL <u>7.6 × 10³</u> Counted by: <u>TG 17-31-03</u>						CFU/mL <u>8.1 × 10³</u> Counted by: <u>TG 17-31-03</u>					

LA = Lab Accident; gross contamination; inhibition of marker organism seen; unable to count plate. TG 7-31-03
** Not used in calculation. JNB 08-01

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

Calculations Verified by: SLH 18-6-03

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

Visit Code	Date	Subject Initials	Subject Screen #: <u>230</u>	Study #
Follow-up Visit	<u>08.04.03</u> mm dd yy	<u>W.S.H</u> F M L	Permanent #: <u>27</u>	03-122085-106

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

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

YES NO If yes, complete below:

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

Comments:

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

YES NO If yes, complete below

Comments:

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

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>175</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>D/B/C</u> F M L	Permanent #: <u>28</u>	03-122085-106

Gender: Male Female . Age: 37 Years

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

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

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

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

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

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

Comments:

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

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

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

HTR Study No.: 03-122085-106
Page No.: IV-367

Visit Code	Date	Subject Initials	Subject Screen #: <u>175</u>	Study #
Subject Qualification	<u>07.21.03</u> mm dd yy	<u>D.B.C</u> f m l	Permanent #: <u>28</u>	03-122085-106

INCLUSION CRITERIA

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

EXCLUSION CRITERIA

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

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

Reasons for disqualification: _____

Interviewer's Initials/Date: JNB 07.21.03

Investigator's Signature: _____

Ann R. Brady

Date: 08.10.03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>175</u>	Study #
Test Period	<u>07/24/03</u> mm dd yy	<u>D/B/C</u> F M L	Permanent #: <u>NA</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: extra subject, returned to lab on 7/29/03

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. Warden Date: 07/28/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>175</u>	Study #
Test Period	<u>07/29/03</u> mm dd yy	<u>D/B/C</u> F M L	Permanent #: <u>28</u>	03-122085-106

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

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

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

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

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

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

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

Describe condition: _____

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

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

Additional Comments: _____

CONCOMITANT MEDICATION

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

Comments: _____

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

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/29/03</u> mm dd yy	<u>D. BC</u> F. M L	<u>175</u>	
		Permanent #:	03-122085-106
		<u>28</u>	

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>181</u>	<u>25</u>	TNTC	<u>306^Δ</u>	<u>10</u>
TNTC	<u>194</u>	<u>23</u>	TNTC	<u>157</u>	<u>24</u>
CFU/mL <u>2.1x10⁷</u> Counted by: <u>TG 17-31-03</u>			CFU/mL <u>2.3x10⁷</u> Counted by: <u>TG 17-31-03</u>		

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

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>43</u>	<u>5</u>	TNTC	TNTC	<u>25</u>	<u>4</u>	TNTC	TNTC	<u>32</u>	<u>1</u>
TNTC	TNTC	<u>56</u>	<u>7</u>	TNTC	TNTC			TNTC	TNTC		
TNTC				TNTC				TNTC			
CFU/mL <u>5.0x10⁴</u> Counted by: <u>JNB 107-31-03</u>				CFU/mL <u>2.8x10⁴</u> Counted by: <u>JNB 107-31-03</u>							

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
<u>211</u>	<u>75</u>	<u>9</u>	<u>0</u>	TNTC	<u>105</u>	<u>11</u>	<u>1</u>	TNTC	<u>105</u>	<u>5</u>	<u>2</u>
<u>216</u>	<u>86</u>	<u>4</u>	<u>0</u>	TNTC				TNTC			
<u>196</u>				TNTC				TNTC			
CFU/mL <u>7.4x10³</u> Counted by: <u>TG 17-31-03</u>				CFU/mL <u>1.0x10⁴</u> Counted by: <u>TG 17-31-03</u>							

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

Calculations Verified by: DS 8-1-03

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

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

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

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>08.04.03</u> mm dd yy	<u>D, B, C</u> F M L	<u>175</u> Permanent #: <u>28</u>	03-122085-106

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

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

YES NO If yes, complete below:

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

Comments:

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

YES NO If yes, complete below

Comments:

Medical Consultant's Signature: <i>E. Levin Jones, MD</i>	Date <u>8.4.03</u> mm dd yy
--	-----------------------------------

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 126	Study #
Subject Qualification	07/15/03 mm dd yy	A/K/G F M L	Permanent #: 29	03-122085-106

Gender: Male Female. Age: 22 Years

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

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

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

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

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

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

Comments:

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

Interviewer's Signature: Stacey C Bacheiding Date: 07/15/03
mm dd yy

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

HTR Study No.: 03-122085-106
Page No.: IV-373

Visit Code	Date	Subject Initials	Subject Screen #: <u>126</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>A/K/G</u> f m l	Permanent #: <u>29</u>	03-122085-106

INCLUSION CRITERIA

Check one

YES	NO	Subject:
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input 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 ...

YES	NO	N/A	Subject:
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input 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>7/23/03 gln</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, 7/15/03

Investigator's Signature: Ann R. Brady

Date: 08/10/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>126</u>	Study #
Test Period	<u>07/23/03</u> mm dd yy	<u>AIKIG</u> F M L	Permanent #: <u>29</u>	03-122085-106

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

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

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

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

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

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

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

Describe condition: _____

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

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

Additional Comments: _____

CONCOMITANT MEDICATION

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

Comments:

Interviewer's Signature: Betty M. Conover Date: 07 / 23 / 03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/23/03</u> mm dd yy	<u>A/K/G</u> F. M L	<u>126</u> Permanent #: <u>29</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>123</u>	<u>17</u>	TNTC	<u>102</u>	<u>9</u>
TNTC	<u>214</u>	<u>14</u>	TNTC	<u>105</u>	<u>5</u>
CFU/mL <u>1.7 x 10⁷</u> Counted by: <u>JNB /07.25.03</u>			CFU/mL <u>1.0 x 10⁷</u> Counted by: <u>JNB /07.25.03</u>		

LEFT HAND				WASH 1		RIGHT HAND	
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>98</u>	<u>11</u>	TNTC	TNTC	<u>175</u>	<u>13</u>
TNTC	TNTC	<u>80</u>	<u>12</u>	TNTC	TNTC	<u>163</u>	<u>24</u>
TNTC				TNTC			
CFU/mL <u>8.9 x 10⁴</u> Counted by: <u>JNB /07.25.03</u>				CFU/mL <u>1.7 x 10⁵</u> Counted by: <u>JNB /07.25.03</u>			

LEFT HAND				WASH 11		RIGHT HAND	
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>124</u>	<u>16</u>	TNTC	TNTC	<u>116</u>	<u>12</u>
TNTC	TNTC	<u>159</u>	<u>17</u>	TNTC	TNTC	<u>114</u>	<u>19</u>
TNTC				TNTC			
CFU/mL <u>1.4 x 10⁵</u> Counted by: <u>JNB /07.25.03</u>				CFU/mL <u>1.2 x 10⁵</u> Counted by: <u>JNB /07.25.03</u>			

Calculations by: JNB /07.26.03 Raw data reviewed by AKG / 8.1.03

Calculations Verified by: JNB /07.29.03

*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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Subject Initials AKG Subject # 29

Study No. 03-122085-106

Page No. IV-376

ADVERSE EVENTS

E. J. ...

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
<i>red bumps</i>	<i>7/23/03</i>	<i>8/21/03</i>	<i>N</i>	<i>1</i>	<i>1</i>	<i>5</i>	<i>4*</i>	<i>[Signature] 8-21-03</i>
Entry Date	Comment/Note: <i>Probably due to test organism.</i>							Initials
<i>7/25/03</i>	<i>red bumps on right and left hands and wrists.</i>							<i>gn</i>
<i>8/21/03</i>	<i>subject contacted on 8.5.03, 8.7.03 and 8.11.03 without response</i>							<i>gn</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

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
5 = Test to follow up

FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	07/28/03 mm dd yy	A.K.G. F M L	126 Permanent #: 29	03-122085-106

Date Subject Entered the Study: 07/15/03 mm dd yy	Follow-Up Visit Date: 07/28/03 mm dd yy
---	---

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

YES NO If yes, complete below:

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

Two red papules on fore arm

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: 7/28/03 mm dd yy
--	------------------------------

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>219</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>G I K I L</u> F M L	Permanent #: <u>30</u>	03-122085-106

Gender: Male Female Age: 64 Years

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

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	<input checked="" type="checkbox"/>		
2. Eczema ?	<input checked="" type="checkbox"/>		
3. Skin Cancer ?	<input checked="" type="checkbox"/>		
4. Skin Allergies ? Please specify:	<input checked="" type="checkbox"/>		
5. Hives ?	<input checked="" type="checkbox"/>		

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

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

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

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	<input checked="" type="checkbox"/>		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	<input checked="" type="checkbox"/>		
3. Heart Medication ?	<input checked="" type="checkbox"/>		
4. Insulin ?	<input checked="" type="checkbox"/>		
5. Other ?	<input checked="" type="checkbox"/>		

Comments:

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

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

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

HTR Study No.: 03-122085-106
Page No.: IV-319

Visit Code	Date	Subject Initials	Subject Screen #: <u>219</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>G/K/L</u> f m i	Permanent #: <u>30</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: _____

Ann R. Brady

Date: 08/10/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: 219	Study #
Test Period	07/29/03 mm dd yy	G / K / L F M L	Permanent #: 30	03-122085-106

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

If no, please indicate condition: _____

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

If no, please explain: _____

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

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

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

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

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

Describe condition: _____

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

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

Medication taken (Complete below) Hospitalized Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

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

Comments:

Interviewer's Signature:

Stacy E. Bacherdig

Date:

07 / 29 / 03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/29/03</u> mm dd yy	<u>G, K, L</u> F. M L	<u>219</u> Permanent #: <u>30</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>216</u>	<u>38</u>	TNTC	<u>212</u>	<u>24</u>
TNTC	<u>194</u>	<u>26</u>	TNTC	<u>257</u> ⓈⓉ	<u>33</u>
CFU/mL <u>2.6x10⁷</u> Counted by: <u>JNB /07-31-03</u>			CFU/mL <u>2.6x10⁷</u> Counted by: <u>JNB /07-31-03</u>		

LEFT HAND				WASH 1		RIGHT HAND	
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>56</u>	<u>13</u>	TNTC	TNTC	<u>74</u>	<u>16</u>
TNTC	TNTC	<u>49</u>	<u>3</u>	TNTC	TNTC	<u>84</u>	<u>7</u>
TNTC				TNTC			
CFU/mL <u>5.3x10⁴</u> Counted by: <u>JNB /07-31-03</u>				CFU/mL <u>7.9x10⁴</u> Counted by: <u>JNB /07-31-03</u>			

LEFT HAND				WASH 11		RIGHT HAND	
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>38</u>	<u>2</u>	TNTC	<u>142</u>	<u>21</u>	<u>1</u>
TNTC	TNTC	<u>70</u>	<u>2</u>	TNTC	<u>199</u>	<u>23</u>	<u>2</u>
TNTC				TNTC			
CFU/mL <u>5.4x10⁴</u> Counted by: <u>TU /17-31-03</u>				CFU/mL <u>1.7x10⁴</u> Counted by: <u>TU /17-31-03</u>			

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

Calculations Verified by: SAS /8-1-03

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

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

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

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

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	08/04/03 mm dd yy	G.K.L. F M L	219 Permanent #: 30	03-122085-106

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

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

YES NO If yes, complete below:

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

Comments:

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

YES NO If yes, complete below

Comments:

Medical Consultant's Signature: <i>E. Lynn Jones, MD</i>	Date: 8/4/03 mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 209	Study #
Subject Qualification	07/21/03 mm dd yy	E/M/M F M L	Permanent #: 31	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>60</u> Years
--	----------------------

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

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

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

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

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

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ? <u>Zocor 20mg 1x day high cholesterol</u>		✓	

Comments:

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

Interviewer's Signature: <u>Jami Basemaya</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-384

Visit Code	Date	Subject Initials	Subject Screen #: <u>209</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>E/M/M</u> f m l	Permanent #: <u>31</u>	03-122085-106

INCLUSION CRITERIA

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

EXCLUSION CRITERIA

Check one...			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input checked="" type="checkbox"/> Post-menopausal, year <u>1989</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: _____

Ann R. Burt

Date: 08/10/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>209</u>	Study #
Test Period	<u>07/29/03</u> mm dd yy	<u>E/M/M</u> F M L	Permanent #: <u>31</u>	03-122085-106

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

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

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

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

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

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

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

Describe condition: _____

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

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

Medication taken (Complete below) Hospitalized Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

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

Comments:

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

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/29/03</u> mm dd yy	<u>E/M/M</u> F. M L	<u>209</u> Permanent #: <u>31</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>218</u>	<u>27</u>	TNTC	<u>150</u>	<u>25</u>
TNTC	<u>226</u>	<u>17</u>	TNTC	<u>179</u>	<u>19</u>
CFU/mL <u>2.2 x 10⁷</u> Counted by: <u>JNB 107-31-03</u>			CFU/mL <u>1.9 x 10⁷</u> Counted by: <u>JNB 107-31-03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>34</u>	<u>3</u>	TNTC	TNTC	<u>40</u>	<u>9</u>	TNTC	TNTC	<u>31</u>	<u>7</u>
TNTC	TNTC	<u>46</u>	<u>3</u>	TNTC	TNTC	<u>31</u>	<u>7</u>	TNTC	TNTC	<u>31</u>	<u>7</u>
TNTC				TNTC				TNTC			
CFU/mL <u>4.0 x 10⁴</u> Counted by: <u>JNB 107-31-03</u>						CFU/mL <u>3.6 x 10⁴</u> Counted by: <u>JNB 107-31-03</u>					

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
<u>145</u>	<u>67</u>	<u>3</u>	<u>1</u>	<u>181</u>	<u>92</u>	<u>6</u>	<u>1</u>	<u>178</u>	<u>65</u>	<u>12</u>	<u>0</u>
<u>178</u>	<u>42</u>	<u>7</u>	<u>1</u>	<u>199</u>	<u>65</u>	<u>12</u>	<u>0</u>	<u>134</u>			
<u>134</u>				<u>168</u>							
CFU/mL <u>5.2 x 10³</u> Counted by: <u>JNB 107-31-03</u>						CFU/mL <u>7.1 x 10³</u> Counted by: <u>JNB 107-31-03</u>					

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

Calculations Verified by: SAS 8-1-03

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

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>Ann R. Brady</u>	Date: <u>08 / 10 / 03</u> mm dd yy
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Data Collection Form 5A

Subject Initials E. M. M. Subject # 31

Study No. 03-122085-106

Page No. IV-387

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date	
Macules	8/1/03	8/12/03	H	1	4(i)	1	4(2)	<i>[Signature]</i> 8/21/03	
Entry Date	Comment/Note: <i>Used Non-Rx Neosporin (2) Due to lost organism.</i>								Initials
8-4-03	<i>Seven red macules on the backs of the hands</i>								<i>[Signature]</i> 8-21-03
8/12/03	<i>Hands clear - neosporin used on bumps from 8/4/03 to 8/10/03 1 to 2 times a day.</i>								<i>[Signature]</i> 8-21-03

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

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

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

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

¹Serious Adverse Event/Experience

FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	08, 04, 03 mm dd yy	E, M, M F M L	209 Permanent #: 31	03-122085-106

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

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

YES NO If yes, complete below:

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

Seven red macules on the backs of the hands.

Comments:

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

YES NO If yes, complete below

Comments:

Medical Consultant's Signature: C. Levin Jones, M.D.	Date 8, 4, 03 mm dd yy
---	------------------------------

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 141	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>C/S/H</u> F M L	Permanent #: 32	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? <u>hbp-controlled</u>		✓	
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify: <u>cholesterol, arthritis</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 ? <u>Maxido 25mg 1xday</u>		✓	
4. Insulin ?	✓		
5. Other ? <u>Cipitor 20mg 1xday (cholesterol)</u>		✓	

Comments: Centrum multi-vitamin 1xday
Tylenol when needed (for arthritis)
added as per SPAN WFO 7/15/03 gn

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

Interviewer's Signature: Stacey E. Beckending Date: 07/15/03
mm dd yy

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

HTR Study No.: 03-122085-106
Page No.: IV - 390

Visit Code	Date	Subject Initials	Subject Screen #: <u>141</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>C/S/H</u> f m l	Permanent #: <u>32</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>1974</u> <input type="checkbox"/> Post-menopausal, year <u>1992</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: SOB, 7/15/03

Investigator's Signature: _____

Ann R. Brady

Date: 08/10/03
mm dd yy

Data Collection Form 3
INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>141</u>	Study #
Test Period	<u>07/24/03</u> mm dd yy	<u>C/J/H</u> F M L	Permanent #: <u>32</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>Susan L. Harris</u>	Date: <u>07/24/03</u> mm dd yy
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HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/24/03</u> mm dd yy	<u>C/J/H</u> F M L	<u>141</u> Permanent #: <u>32</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>142</u>	<u>19</u>	TNTC	<u>180</u>	<u>24</u>
TNTC	<u>183</u>	<u>23</u>	TNTC	<u>145</u>	<u>13</u>
CFU/mL <u>1.6x10⁷</u> Counted by: <u>JNB 107-28-03</u>			CFU/mL <u>1.6x10⁷</u> Counted by: <u>JNB 107-28-03</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>127</u>	<u>8</u>	TNTC	TNTC	<u>103</u>	<u>8</u>	TNTC	TNTC	<u>101</u>	<u>12</u>
TNTC	TNTC	<u>108</u>	<u>22</u>	TNTC	TNTC			TNTC	TNTC		
TNTC				TNTC				TNTC			
CFU/mL <u>1.2x10⁵</u> Counted by: <u>JNB 107-28-03</u>						CFU/mL <u>1.0x10⁵</u> Counted by: <u>JNB 107-28-03</u>					

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>88</u>	<u>20</u>	TNTC	TNTC	<u>106</u>	<u>24</u>	TNTC	TNTC	<u>192</u>	<u>23</u>
TNTC	TNTC	<u>129</u>	<u>13</u>	TNTC	TNTC			TNTC	TNTC		
TNTC				TNTC				TNTC			
CFU/mL <u>1.1x10⁵</u> Counted by: <u>JNB 107-28-03</u>						CFU/mL <u>1.5x10⁵</u> Counted by: <u>JNB 107-28-03</u>					

Calculations by: JNB 107-29-03 Raw data reviewed by: QUB 10-1-03

Calculations Verified by: TL 17-29-03

*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	07/29/03 mm dd yy	C J H F M L	141 Permanent #: 32	03-122085-106

Date Subject Entered the Study: 07/15/03 mm dd yy	Follow-Up Visit Date: 07/29/03 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. Levin Jones, MD</i>	Date 7/29/03 mm dd yy
--	-----------------------------

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>270</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>R J G</u> F M L	Permanent #: <u>33</u>	03-122085-106

Gender: Male Female. Age: 36 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>Sulfa drugs</u>		✓	
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

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

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

Comments:

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

Interviewer's Signature: Jenni Busemeyer Date: 07, 21, 03
mm dd yy

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

HTR Study No.: 03-122085-106
Page No.: IV-395

Visit Code	Date	Subject Initials	Subject Screen #: <u>270</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>R, J, G</u> f m l	Permanent #: <u>33</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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - B-HCG Test Results: <input checked="" type="checkbox"/> negative <input type="checkbox"/> positive <u>7/30/03</u>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

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

Reasons for disqualification: _____ Interviewer's Initials/Date: JNB 07-21-03

Investigator's Signature: _____

Ann P. Budy

Date: 08/10/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>270</u>	Study #
Test Period	<u>07/30/03</u> mm dd yy	<u>R/J/G</u> F M L	Permanent #: <u>33</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. Warden Date: 07/30/03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/30/03</u> mm dd yy	<u>R/J/G</u> F. M L	<u>270</u> Permanent #: <u>33</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>186</u>	<u>18</u>	TNTC	<u>222</u>	<u>11</u>
TNTC	<u>207</u>	<u>28</u>	TNTC	<u>193</u>	<u>18</u>
CFU/mL <u>2.1x10⁷</u> Counted by: <u>RS</u> / 8-1-03			CFU/mL <u>2.1x10⁷</u> Counted by: <u>RS</u> / 8-1-03		

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>80</u>	<u>6</u>	TNTC	TNTC	<u>109</u>	<u>10</u>	TNTC	TNTC	<u>99</u>	<u>4</u>
TNTC	TNTC	<u>87</u>	<u>5</u>	TNTC	TNTC	<u>99</u>	<u>4</u>	TNTC	TNTC	<u>99</u>	<u>4</u>
TNTC	TNTC			TNTC	TNTC			TNTC	TNTC		
CFU/mL <u>8.4x10⁴</u> Counted by: <u>RS</u> / 8-1-03				CFU/mL <u>1.0x10⁵</u> Counted by: <u>RS</u> / 8-1-03				CFU/mL <u>1.0x10⁵</u> Counted by: <u>RS</u> / 8-1-03			

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
<u>149</u>	<u>66</u>	<u>8</u>	<u>1</u>	<u>217</u>	<u>57</u>	<u>5</u>	<u>0</u>	<u>217</u>	<u>57</u>	<u>5</u>	<u>0</u>
<u>173</u>	<u>79</u>	<u>6</u>	<u>0</u>	<u>200</u>	<u>92</u>	<u>15</u>	<u>0</u>	<u>200</u>	<u>92</u>	<u>15</u>	<u>0</u>
<u>165</u>				<u>171</u>				<u>171</u>			
CFU/mL <u>6.5x10³</u> Counted by: <u>RS</u> / 8-1-03				CFU/mL <u>6.9x10³</u> Counted by: <u>RS</u> / 8-1-03				CFU/mL <u>6.9x10³</u> Counted by: <u>RS</u> / 8-1-03			

③AS 8.1.03

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

Calculations Verified by: JNB / 08.01.03

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

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

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

Visit Code	Date	Subject Initials	Subject Screen #: 270	Study #
Follow-up Visit	08 04 03 mm dd yy	R, J, G F M L	Permanent #: 33	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. Levin, MD</i>	Date 8, 4, 03 mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>197</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>WIAIA</u> F M L	Permanent #: <u>34</u>	03-122085-106

Gender: <input checked="" type="checkbox"/> Male <input type="checkbox"/> Female	Age: <u>48</u> Years
--	----------------------

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

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

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

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify: <u>OCD</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>Zoloft 150mg 1x day for Obsessive-Compulsive</u> <u>Meatyl 20mg 1x day for Irritable Bowel</u> <u>Pepcid (OTC) 1x day for Re-Flux</u>		✓	
Comments:			

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

Interviewer's Signature: <u>Maury M. Waxman</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-400

Visit Code	Date	Subject Initials	Subject Screen #: <u>197</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>WIAIA</u> f m l	Permanent #: <u>34</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: MMW 17-21-03

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

Data Collection Form 3
INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>197</u>	Study #
Test Period	<u>07/30/03</u> mm dd yy	<u>W/A/A</u> F M L	Permanent #: <u>34</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. Warkentin Date: 07 / 30 / 03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/30/03</u> mm dd yy	<u>W/A/A</u> F. M L	<u>197</u> Permanent #: <u>34</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>191</u>	<u>16</u>	TNTC	<u>174</u>	<u>22</u>
TNTC	<u>192</u>	<u>24</u>	TNTC	<u>171</u>	<u>14</u>
CFU/mL <u>1.9 × 10⁷</u> Counted by: <u>SP / 8/1/03</u>			CFU/mL <u>1.7 × 10⁷</u> Counted by: <u>SP / 8/1/03</u>		

LEFT HAND				WASH 1		RIGHT HAND	
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>120</u>	<u>3</u>	TNTC	TNTC	<u>94</u>	<u>12</u>
TNTC	TNTC	<u>94</u>	<u>13</u>	TNTC	TNTC	<u>91</u>	<u>17</u>
TNTC				TNTC			
CFU/mL <u>1.1 × 10⁵</u> Counted by: <u>SP / 8/1/03</u>				CFU/mL <u>9.2 × 10⁴</u> Counted by: <u>SP / 8/1/03</u>			

LEFT HAND				WASH 11		RIGHT HAND	
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>30</u>	<u>7</u>	TNTC	TNTC	<u>37</u>	<u>8</u>
TNTC	TNTC	<u>44</u>	<u>4</u>	TNTC	TNTC	<u>40</u>	<u>2</u>
TNTC				TNTC			
CFU/mL <u>3.7 × 10⁴</u> Counted by: <u>PS / 8-1-03</u>				CFU/mL <u>3.8 × 10⁴</u> Counted by: <u>PS / 8-1-03</u>			

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

Calculations Verified by: AS / 8-1-03

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

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>Ann P. Brady</u>	Date: <u>08/10/03</u> mm dd yy
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Data Collection Form 5A

Subject Initials W.A.A. Subject # 34

Study No. 03-122085-106
Page No. IV-403

ADVERSE EVENTS

E.L.J.

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
<i>Macules</i>	<i>7-30-03</i>	<i>8/14/03</i>	<i>N</i>	<i>1</i>	<i>1</i>	<i>4</i>	<i>4*</i>	<i>E.L.J. 8-21-03</i>
Entry Date	Comment/Note: <i>* Probably due to test organism E.L.J. 8-21-03</i>							
<i>8-4-03</i>	<i>Seven red macules on the backs of the hands</i>							
<i>8/14/03</i>	<i>Hands clear no medications used</i>							

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

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

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

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

¹Serious Adverse Event/Experience

FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #: <u>197</u>	Study #
Follow-up Visit	<u>08, 04, 03</u> mm dd yy	<u>W, A, A</u> F M L	Permanent #: <u>34</u>	03-122085-106

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

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

YES NO If yes, complete below:

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

Seven red macules on backs of hands.
Onset 7-30-03 C.L.G.

Comments: _____

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

YES NO If yes, complete below

Comments: _____

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

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
			<u>116</u>	
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>M, T, P</u> F M L	Permanent #: <u>35</u>	03-122085-106

Gender: Male Female. Age: 46 Years

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

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

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

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

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 Busmeyer Date: 07/15/03
mm dd yy

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

HTR Study No.: 03-122085-106
Page No.: IV-406

Visit Code	Date	Subject Initials	Subject Screen #: <u>116</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>MITIP</u> f m l	Permanent #: <u>35</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 107-15-03

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

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>116</u>	Study #
Test Period	<u>07/23/03</u> mm dd yy	<u>M I T I P</u> F M L	Permanent #: <u>35</u>	03-122085-106

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

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

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

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

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

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

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

Describe condition: _____

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

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

Additional Comments: _____

CONCOMITANT MEDICATION

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

Comments:

Interviewer's Signature: Betty M. Conover Date: 07 / 23 / 03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

3.6.03 gnu

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/23/03</u>	<u>MTP</u>	<u>116270</u>	
mm dd yy	F. M L	Permanent #:	03-122085-106
		<u>35</u>	

3 errors 3.6.03 gnu

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>160</u>	<u>25</u>	TNTC	<u>191</u>	<u>24</u>
TNTC	<u>205</u>	<u>23</u>	TNTC	<u>180</u>	<u>17</u>
CFU/mL <u>2.1 x 10⁷</u> Counted by: <u>JNB / 07-25-03</u>			CFU/mL <u>1.8 x 10⁷</u> Counted by: <u>JNB / 07-25-03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	TNTC	<u>69</u>	TNTC	TNTC	TNTC	<u>87</u>	TNTC	TNTC	TNTC	<u>110</u>
TNTC	TNTC	TNTC	<u>51</u>	TNTC	TNTC	TNTC		TNTC	TNTC	TNTC	
TNTC				TNTC				TNTC			
CFU/mL <u>6.0 x 10⁵</u> Counted by: <u>JNB / 07-25-03</u>						CFU/mL <u>9.8 x 10⁵</u> Counted by: <u>JNB / 07-25-03</u>					

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	TNTC	<u>40</u>	TNTC	TNTC	<u>239</u>	<u>32</u>	TNTC	TNTC	<u>200</u>	<u>20</u>
TNTC	TNTC	TNTC	<u>28</u>	TNTC	TNTC			TNTC	TNTC		
TNTC				TNTC				TNTC			
CFU/mL <u>3.4 x 10⁵</u> Counted by: <u>QNB / 7.25.03</u>						CFU/mL <u>4.3</u> Counted by: <u>QNB / 7.25.03</u>					

2.3 2.4 x 10⁵
 (2) TG 7.26.03

Calculations by: TG 17.26.03 Raw data reviewed by SAS / 8-1-03

Calculations Verified by: JNB 107.29.03

*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>G. Smith</u>	Date: <u>9 / 11 / 03</u> mm dd yy
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Data Collection Form 5A

Subject Initials MTP Subject # 35

Study No. 03-122085-106

Page No. IV-410 409

(3) 8.11.03 gr

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date	
red bumps	7/23/03	7/23/03	N	1			4*	<i>[Signature]</i> 8-24-03	
Entry Date	Comment/Note: * Probably due to test organism E.L.9.								Initials
7/25/03	red bumps on both forearms								gr
7/23/03	Squand's clear. no medications used								gr

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

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

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

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

¹Serious Adverse Event/Experience

FOLLOW-UP VISIT

@ 8.11.03
gr

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	07/28/03 mm dd yy	M/T/P F M L	110 Permanent #: 35	03-122085-106

Date Subject Entered the Study: 07/15/03 mm dd yy	Follow-Up Visit Date: 07/28/03 mm dd yy
---	---

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

YES NO If yes, complete below:

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

Comments:

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

YES NO If yes, complete below

Comments:

Medical Consultant's Signature: E. Lynn Jones, MD	Date: 7/28/03 mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 120	Study #
Subject Qualification	07/15/03 mm dd yy	L/S/S F M L	Permanent #: 36	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>45</u> Years
--	----------------------

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

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

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

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

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

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

Comments:

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

Interviewer's Signature: <u>Jami Busemeyer</u>	Date: <u>07, 15, 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 - 412

Visit Code	Date	Subject Initials	Subject Screen #: <u>120</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>L/S/S</u> f m l	Permanent #: <u>36</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>1986</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

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

Reasons for disqualification: _____ Interviewer's Initials/Date: JNB, 07-15-03

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

Data Collection Form 3
INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>120</u>	Study #
Test Period	<u>07/23/03</u> mm dd yy	<u>L/S/S</u> F M L	Permanent #: <u>36</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: Sam R. Harris Date: 07 / 23 / 03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/23/03</u> mm dd yy	<u>L/S/S</u> F. M L	<u>120</u>	
		Permanent #:	03-122085-106
		<u>36</u>	

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>215</u>	<u>15</u>	TNTC	<u>158</u>	<u>13</u>
TNTC	<u>791</u>	<u>25</u>	TNTC	<u>138</u>	<u>21</u>
CFU/mL <u>2.0 x 10⁷</u> Counted by: <u>JNB 107.25.03</u>			CFU/mL <u>1.5 x 10⁷</u> Counted by: <u>JNB 107.25.03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	TNTC	<u>50</u>	TNTC	TNTC	TNTC	<u>62</u>	TNTC	TNTC	TNTC	<u>41</u>
TNTC	TNTC	TNTC	<u>50</u>	TNTC	TNTC	TNTC	<u>41</u>	TNTC	TNTC	TNTC	<u>41</u>
TNTC				TNTC				TNTC			
CFU/mL <u>5.0 x 10⁵</u> Counted by: <u>JNB 107.25.03</u>				CFU/mL <u>5.2 x 10⁵</u> Counted by: <u>JNB 107.25.03</u>				CFU/mL <u>5.2 x 10⁵</u> Counted by: <u>JNB 107.25.03</u>			

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	TNTC	<u>28</u>	TNTC	TNTC	TNTC	<u>49</u>	TNTC	TNTC	TNTC	<u>54</u>
TNTC	TNTC	TNTC	<u>26</u>	TNTC	TNTC	TNTC	<u>54</u>	TNTC	TNTC	TNTC	<u>54</u>
TNTC				TNTC				TNTC			
CFU/mL <u>2.7 x 10⁵</u> Counted by: <u>ARS 17.25.03</u>				CFU/mL <u>5.2 x 10⁵</u> Counted by: <u>ARS 17.25.03</u>				CFU/mL <u>5.2 x 10⁵</u> Counted by: <u>ARS 17.25.03</u>			

Calculations by: TG 17.26.03 Raw data reviewed by SAS 18-1-03

Calculations Verified by: JNB 107.29.03

*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 #:	Study #
Follow-up Visit	<u>07/28/03</u> mm dd yy	<u>L/S/S</u> F M L	<u>120</u> Permanent #: <u>36</u>	03-122085-106

Date Subject Entered the Study: <u>07/15/03</u> mm dd yy	Follow-Up Visit Date: <u>07/28/03</u> mm dd yy
<p>Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?</p> <p><input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, complete below:</p> <p>Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)</p> <hr/> <hr/> <hr/>	
<p>Comments:</p> <hr/> <hr/> <hr/>	
<p>Has the subject had any health related issues since the treatment procedure?</p> <p><input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, complete below</p> <p>Comments:</p> <hr/> <hr/> <hr/>	

Medical Consultant's Signature: <i>E. Levin JMD</i>	Date <u>7/28/03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 140	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>M/L/P</u> F M L	Permanent #: 37	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>50</u> Years
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Does the subject have any of the following at the treatment sites?

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

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

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

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

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

Comments:

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

Interviewer's Signature: <u>Susan R. Harris</u>	Date: <u>07/15/03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-417

Visit Code	Date	Subject Initials	Subject Screen #: <u>140</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>M/LP</u> f m l	Permanent #: <u>37</u>	03-122085-106

INCLUSION CRITERIA

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

EXCLUSION CRITERIA

Check one ...			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input checked="" type="checkbox"/> Post-menopausal, year <u>2001</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: SAH / 7.15.03

Investigator's Signature: Ann R. Brady

Date: 08/10/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>140</u>	Study #
Test Period	<u>07/24/03</u> mm dd yy	<u>M/L/P</u> F M L	Permanent #: <u>37</u>	03-122085-106

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

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

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

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

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

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

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

Describe condition: _____

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

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

Medication taken (Complete below) Hospitalized Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

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

Comments:

Interviewer's Signature: Betty M. Conover Date: 07/24/03
 mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/24/03</u> mm dd yy	<u>M/L/P</u> F. M L	<u>140</u>	
		Permanent #:	03-122085-106
		<u>37</u>	

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>211</u>	<u>16</u>	TNTC	<u>161</u>	<u>18</u>
TNTC	<u>173</u>	<u>21</u>	TNTC	<u>503</u>	<u>14</u>
CFU/mL <u>9x10⁷</u> Counted by: <u>RS / 7.28.03</u>			CFU/mL <u>1.8x10⁷</u> Counted by: <u>RS / 7.28.03</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>91</u>	<u>12</u>	TNTC	TNTC	<u>169</u>	<u>32</u>	TNTC	TNTC	<u>165</u>	<u>25</u>
TNTC	TNTC	<u>90</u>	<u>16</u>	TNTC	TNTC			TNTC	TNTC		
TNTC				TNTC				TNTC			
CFU/mL <u>9.0x10⁴</u> Counted by: <u>JNB / 07.28.03</u>				CFU/mL <u>2.3x10⁵</u> Counted by: <u>JNB / 07.28.03</u>							

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>128</u>	<u>17</u>	TNTC	TNTC	<u>111</u>	<u>14</u>	TNTC	TNTC	<u>139</u>	<u>21</u>
TNTC	TNTC	<u>87</u>	<u>10</u>	TNTC	TNTC			TNTC	TNTC		
TNTC				TNTC				TNTC			
CFU/mL <u>1.1x10⁵</u> Counted by: <u>JNB / 07.28.03</u>				CFU/mL <u>1.2x10⁵</u> Counted by: <u>JNB / 07.28.03</u>							

Calculations by: JNB / 07.29.03 Raw data reviewed by ARB / 18.1.03

Calculations Verified by: TG / 17.29.03

*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>S. Sully</u>	Date: <u>9 / 16 / 03</u> mm dd yy
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Data Collection Form 5A

Subject Initials MLP Subject # 37

Study No. 03-122085-106

Page No. IV-420

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
<i>Popules</i>	<i>7-25-03</i>	<i>8/13/03</i>	<i>N</i>	<i>1</i>	<i>4(1)</i>	<i>1</i>	<i>4(2)</i>	<i>[Signature]</i>
Entry Date	Comment/Note: <i>1) Used Non-Rx Neosporin 2) Due to test progression</i>							
<i>7/29/03</i>	<i>Three popules on wrists</i>							
<i>8/13/03</i>	<i>Used neosporin occasionally - hands & wrists clear, forearms & wrist clear</i>							
	<i>neosporin used from 7/29/03 - 8/13/03 as needed</i>							

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

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

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

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

¹Serious Adverse Event/Experience

FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #: 140	Study #
Follow-up Visit	07/29/03 mm dd yy	M, L, P F M L	Permanent #: 37	03-122085-106

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

Three papules on wrists.
Onset 7-25-03

Comments: _____

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

YES NO If yes, complete below

Comments: _____

Medical Consultant's Signature:	Date ____/____/____ mm dd yy
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DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 209	Study #
Subject Qualification	07/21/03 mm dd yy	BIGIR F M L	Permanent #: 38	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>56</u> Years
--	----------------------

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

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

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

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

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

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ? <u>Progesterone @ two times per day 7/21/03</u>		✓	

Comments:

Premarin 0.9 mg / 0.425mg 1x day
 Provera 0.425mg 1st 10 days of the month (HRT)

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

Interviewer's Signature:

Stacey E. Bacherdig

Date:

07/21/03
mm dd yy

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

HTR Study No.: 03-122085-106
Page No.: IV-423

Visit Code	Date	Subject Initials	Subject Screen #: <u>269</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>B, G, R</u> f m l	Permanent #: <u>38</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>1970</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: SAB, 7/21/03

Investigator's Signature: Ann R. Brady

Date: 08/10/03
mm dd yy

Data Collection Form 3
INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>269</u>	Study #
Test Period	<u>07/30/03</u> mm dd yy	<u>B / G / R</u> F M L	Permanent #: <u>38</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. Warden</u>	Date: <u>07 / 30 / 03</u> mm dd yy
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HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/30/03</u> mm dd yy	<u>B/G/R</u> F. M L	<u>269</u> Permanent #: <u>38</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>77</u>	11	TNTC	<u>100</u>	13
TNTC	<u>114*</u>	5	TNTC	<u>84</u>	9
CFU/mL <u>9.6 x 10⁶</u> Counted by: <u>SP / 8/1/03</u>			CFU/mL <u>9.2 x 10⁶</u> Counted by: <u>SP / 8/1/03</u>		

~~Unlabelled plate~~ © SAS 8-1-03

LEFT HAND				WASH 1		RIGHT HAND	
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>150</u>	8	TNTC	TNTC	<u>126</u>	16
TNTC	TNTC	<u>160</u>	20	TNTC	TNTC	<u>95</u>	16
CFU/mL <u>1.6 x 10⁵</u> Counted by: <u>SP / 8/1/03</u>				CFU/mL <u>1.1 x 10⁵</u> Counted by: <u>SP / 8/1/03</u>			

LEFT HAND				WASH 11		RIGHT HAND	
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	<u>223</u>	<u>17</u>	3	TNTC	TNTC	<u>113</u>	15
TNTC	<u>161</u>	<u>26</u>	0	TNTC	TNTC	<u>89</u>	16
TNTC				TNTC			
CFU/mL <u>2.0 x 10⁴</u> Counted by: <u>PS / 8-1-03</u>				CFU/mL <u>1.0 x 10⁵</u> Counted by: <u>PS / 8-1-03</u>			

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

Calculations Verified by: SAS / 8-1-03

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

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>Ann R. Brady</u>	Date: <u>08 / 10 / 03</u> mm dd yy
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Data Collection Form 5A

Subject Initials BGR Subject # 38

Study No. 03-122085-106

Page No. IV-426

ADVERSE EVENTS

Ed J. ...

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
red bumps w/ swelling	8/1/03	8/21/03	N	1	1	5	4*	<i>Ed J. ...</i> 8-21-03
Entry Date	Comment/Note: * Probably due to test organism.							Initials
8/1/03	red bumps with swelling on left hand							gn

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
see above for events & dates								8/21/03 gn
Entry Date	Comment/Note:							Initials
8-4-03	Four red moles on the backs of the hands							<i>Ed J. ...</i>
8/21/03	Subject contacted on 8.7.03 and 8.11.03 without response							gn

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
5 = Test to follow up

FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #: <u>269</u>	Study #
Follow-up Visit	<u>08, 04, 03</u> mm dd yy	<u>B, G, R</u> F M L	Permanent #: <u>38</u>	03-122085-106

Date Subject Entered the Study:

07, 21, 03

mm dd yy

Follow-Up Visit Date:

08, 04, 03

mm dd yy

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

YES NO If yes, complete below:

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

Four red macules on backs of hands

Comments:

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

YES NO If yes, complete below

Comments: Nausea 8-3-04

Medical Consultant's Signature:

E. Levin Jones, MD

Date

8, 4, 03
mm dd yy