

MICROBIOTEST PROTOCOL

**USING THE FINGERPADS OF ADULT SUBJECTS TO
INVESTIGATE THE VIRUCIDAL ACTIVITY OF
HANDWASH AND HANDRUB AGENTS**

Data Requirements
Research and Development

Prepared for
US Food and Drug Administration
Center for Drug Evaluation and Research

June 26, 2003

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MICROBIOTEST Protocol: FDA.1.06.26.03

MICRBIOTEST Project Number: _____

OBJECTIVE:

This study is designed to evaluate the activity of a hygienic handwash/handrub agent. This test examines the test agent in the manner in which it will be used. The protocol employs human subjects, and therefore, it requires approval by an Institutional Review Board (IRB) prior to initiation of testing.

SUMMARY OF TEST METHOD:

The test method to be used is a standard of ASTM International (formerly the American Society for Testing and Materials) and carries the designation E1838-02¹. This study will consist of a washout period of at least seven days, followed by a one-day treatment period. The test agent will be evaluated against a control product. At least twelve male or female subjects, 18 to 70 years old, will be used for each test agent. Test and control formulations will be randomized and run concurrently.

During the washout period, subjects must agree to refrain from using topical or systemic antibiotics, medicated lotions and creams, antibacterial soaps, anti-acne drugs, and anti-dandruff shampoos until the study is completed. After the washout period, the subjects will appear at the clinical site to begin a one-day treatment period. During this period, each subject's thumb- and fingerpads will be contaminated with a suspension a challenge virus deemed safe and suitable for such testing (see Appendix).

Appropriate samples collected from the subject's hands and the required controls will be analyzed for the presence of test viruses capable of replicating.

Discussion:

As reported by Hazelton and Gelderblom², over 30,000 different viruses comprising 56 separate families have been identified; 26 of the families contain viruses of vertebrates with 21 of those consisting of viruses that can infect humans.

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1. ASTM Designation E 1838-02, Standard Test Method for Determining the Virus Eliminating Effectiveness of Liquid Hygienic Handwash and Handrub Agents Using the Fingerpads of Adult Volunteers. Approved April 10, 2002. Pub. July 2002.
 2. Hazelton, PR and Gelderblom, HR. Electron microscopy for rapid detection of infectious agents in emergent situations. *Emerg. Infect. Dis.* 2003; 9:294-303.

Although human pathogenic viruses are not members of normal skin microflora, it is well known that human hands can act as vehicles for the transmission of enteric, respiratory, ocular and possibly genital viral infections^{3,4}. According to the World Health Organization (WHO), acute respiratory infections and diarrheal diseases lead to an annual loss of 83 and 73 million years of healthy life, respectively; viral infections alone are estimated to kill nearly 6 million persons per year globally. Additionally, viruses are among the most frequent nosocomial pathogens. In particular, pediatric units and geriatric wards are highly prone to seasonal introductions and dissemination of viral infections (reviewed in Aitken and Jeffries, 2001)⁵. Viruses are discharged from infected hosts in various body secretions and excretions, which can reach susceptible hosts by direct or indirect contact with such contamination^{6,7} particularly when the human infectious viral-dose may be as low as 1-10 infectious units^{8,9,10,11}. The significance of regular and proper hand decontamination in infection control is well recognized. Despite much available evidence of the role of contaminated hands in the spread of viral infections^{12,13}, and the mounting demand from manufacturers to assess the virus-eliminating activity of handwash and handrub agents, no test protocols for the purpose are recognized by the federal regulatory agencies in the U.S.

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3. Ansari SA, Sattar SA, Springthorpe VS, Wells GA, Tostowaryk W. In vivo protocol for testing efficacy of hand-washing agents against viruses and bacteria: experiments with rotavirus and Escherichia coli. *Appl Environ Microbiol* 1989 Dec;55(12):3113-8.
 4. <http://www.cdc.gov/handhygiene/materials.htm>
 5. Aitken, C and Jeffries, D. Nosocomial spread of viral diseases. *Clin. Microbiol. Rev.* 2001; 14: 528-546
 6. Sattar, SA and MK Ijaz. Transmission of viral infections through airborne route. *CRC Critical Reviews in Environmental Control* 17: 89-131, 1987.
 7. Sattar, SA and MK Ijaz. Airborne Viruses. In: *Manual of Environmental Microbiology*. P Wilkes and LD Stenzenbach (eds.) ASM press, Washington, USA, p. 871-883,2002.
 8. Westwood, JCN and Sattar, SA. The minimal infectious dose. In: G Berg et al., eds. *Viruses in Water*. Washington, DC: American Public Health Association. 1976, pp.61-69.
 9. Ijaz, MK, MI Sabara, PJ Frenchick, and LA Babiuk. Assessment of intestinal damage in rotavirus infected newborn mice by D-xylose absorption test. *Journal of Virological Methods* 18: 153-157, 1987.
 10. Ijaz, MK, D Dent, D Haines, and LA Babiuk. Development of a murine model to study the pathogenesis of rotavirus infection. *Experimental and Molecular Pathology* 51:186-204, 1989.
 11. Ward, RL, Bernstein, DI, Knowlton, DR, et al. Prevention of surface-to-human transmission of rotaviruses by treatment with disinfectant spray. *J. Clinical Microbiol.* 29: 1991-1996, 1991.
 12. Sattar SA, Tetro J, Springthorpe VS. Impact of changing societal trends on the spread of infections in American and Canadian homes. *Am J Infect Control* 1999 Dec;27(6):S4-21.
 13. Larson, E. Hygiene of the skin: When is clean too clean? *Emerg. Infect. Dis.* 2001; 7: 225-230.
- Protocol: FDA.1.06.26.03

Although the U.S. Food and Drug Administration's (FDA) Center for Food Safety and Nutrition (CFSAN)^{14,15,16} recognize the significance of viruses being disseminated by food handlers and healthcare workers and the role played by hands, the Tentative Final Monograph (TFM) of FDA does not address the role of viruses¹⁷.

Viruses play a leading role in both morbidity and mortality. More recently there has been an up surge of viral infections due the emergence and or re-emergence these infectious agents^{18, 19, 20}. Infectious viruses have been recovered from naturally contaminated hands. It has been reported that hands of caregivers and food handlers are important vehicles in transmission of many enteric, respiratory, ocular and possibly genital viral infections particularly if genital mucosa is not intact. Proper antiseptic procedure used for decontamination of hands can interrupt such dissemination. Despite this, the efficacies of hygienic handwash and handrub agents are traditionally tested against bacteria alone, which may not predict their activity against viruses²¹. A standardized test protocol, developed by the University of Ottawa's Center for Research on Environmental Microbiology (CREM), is now available to test different types of formulations against a variety of human pathogenic viruses²². This method, which is now an ASTM standard¹, has been used by a number of labs including that of the current Director of the U.S. Centers for Disease Control and Prevention (CDC)²³. Acceptance of this test protocol by the FDA will greatly assist testing labs in meeting the mounting demands.

14. <http://vm.cfsan.fda.gov/~comm/handhyg.html>

15 . U.S. Food and Drug Administration. No Bare Hand Contact. Report of the Nat. Advisory Committee for the Microbiological Criteria for Food. Center for Food Safety and Applied Nutrition. Washington, DC: U.S. FDA, November 199.

16 <http://vm.cfsan.fda.gov/~comm/handhyg.html>

17 . U.S. Food and Drug Administration. Tentative Final Monograph for Health-Care Antiseptic Products. Washington, DC: U.S. FDA, June 1994.

18 . <http://www.cdc.gov/nceh/vsp/outbreak/pdf/outbreakslist.pdf>

19 . <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5215a2.htm>

20 . <http://216.30.131.200/Health+and+Industry/Alerts/CDC-Update,+Monkeypox+outbreak+in+Wisconsin,+Illinois,+and+Indiana+6-9-03.htm>

21 . Ansari SA, Sattar SA, Springthorpe VS, Wells GA, Tostowaryk W. In vivo protocol for testing efficacy of hand-washing agents against viruses and bacteria: experiments with rotavirus and *Escherichia coli*. Appl Environ Microbiol 1989 Dec;55(12):3113-8.

22 . Sattar SA, Ansari SA. The fingerpad protocol to assess hygienic hand antiseptics against viruses. J Virol Methods 2002 May 16;103(2):171-81.

23 . Woolwine, JD and Gerberding, JL. Effect of testing method on apparent activities of antiviral disinfectants and antiseptics. Antimicrob. Agents Chemother. 1995; 39: 921-923.

STUDY POPULATION:

An adequate number of subjects will be enrolled in the study to ensure that at least twelve will be available for the evaluation of each test and control product. Any subject terminating his/her participation prior to completion of the test will be replaced. Subjects participating in the study will be compensated financially. Those willing to participate in the testing will be screened for their eligibility based upon the following inclusion/exclusion criteria.

- A. Subject inclusion criteria: Subjects will be eligible for enrollment if they meet the requirements established for inclusion in bactericidal hand studies.
- B. Subject exclusion criteria: Subjects will not be enrolled in the study if they:
 - 1. Are currently participating in another clinical study;
 - 2. Have participated in any type of wash study within the past (14) days;
 - 3. Have cuts, scratches, or other skin disorders on their hands or wrists;
 - 4. Have soap, detergents, and/or perfume allergies;
 - 5. Have eczema or psoriasis on their hands or wrists;
 - 6. Have used any antibiotic medication within the past 14 days;
 - 7. Are not in good general health.
- C. Other study restrictions:
 - 1. Subjects should not use any personal cleansing products other than those provided.
 - 2. Subjects should avoid hot tubs and swimming in chlorinated pools.
 - 3. Subjects should avoid exposing their hands to harsh cleaning products, such as chlorine or solvents.

STUDY DESIGN AND PROCEDURES:

- A. Materials and Supplies: provided by MICROBIOTEST including but not limited to:
 - 1. Test virus as requested by the sponsor.
 - 2. Host: specific for the virus used.

3. Media and reagents: appropriate for the virus-host system employed.
 - a. Earle's balanced salt solution (EBSS)
 - b. 2x Minimum Essential Media with 2% agarose (CCM)
 - c. 70% ethanol (or depending upon the test virus, any anti-microbial agent known to inactivate the test virus)
 - d. AOAC synthetic hard water, 200 ppm
 - e. EBSS containing neutralizer (EBSS+)
 - f. Minimum essential media Eagle's (MEME) containing fetal bovine serum (FBS) [MEM]

B. Inoculum preparation:

Viral stocks are obtained from reputable sources and are propagated at MICROBIOTEST. They are titered and stored in an ultra-low temperature freezer. Records are maintained that demonstrate the origin of the virus.

Frozen viral stocks will be thawed on the day of the test (freshly prepared viral stocks may be used also). The organic soil concentration will be adjusted to at least 5% for the volume of the viral suspension.

C. Study schedule:

1. Subject qualification and enrollment:

Prospective subjects will be screened for their eligibility to participate in the study. Qualified subjects will be given non-antibacterial soap, shampoo, and antiperspirant/deodorant, rubber gloves, unscented non-medicated lotion. They will be instructed to use the soap, shampoo, antiperspirant/deodorant, lotion, and rubber gloves provided and to follow the written instructions for the entire study period.

2. Washout period:

This period will last seven to fourteen days. Subjects will follow the study instructions and use the non-antibacterial soap, shampoo, deodorant, rubber gloves and unscented non-medicated lotion.

3. Treatment period:

On the day of the treatment period, subjects will come to the test facility. Their hands and wrists will be examined to ensure that they are free of cuts, lesions, and other skin disorders. They will be asked if they have had any illnesses or used any medications in the last seven days. Subjects meeting the study criteria will be eligible to continue in the study and will be randomized.

Before starting the treatment procedures, the subjects will be asked to remove all jewelry and clip their fingernails to 2 mm of free edge. They will be asked to clean under their nails with nail picks that will be provided at the clinical site. Figure 1 of the protocol outlines the main procedures for application and assay on the treatment day.

C. Pre-test handwash procedure:

The subject will wash his/her hands with a non-medicated soap for at least 10 seconds, rinse, and then dry them thoroughly with a clean paper towel. This procedure will reduce variability in the test results by removing accumulated oil and dirt from the hands. About 3-5 mL of 70% (v/v) ethanol will be dispensed in the palm of one of the washed hands and the subject will rub it well over the entire surface of both hands until the alcohol and water have evaporated completely.

D. Thumbpad/fingerpad preparation and inoculation:

The thumbpads and fingerpads will be demarcated by pressing the opening of an empty plastic cryogenic vial to demarcate a target area to receive the challenge virus inoculum.

Ten μL of the virus suspension will be inoculated at the center of each demarcated area ($\geq 10^4$ infectious units/area). Thumbpads will be used to determine the amount of infectious virus placed in each demarcated area (Input Control). Each thumbpad will be contaminated and eluted immediately and decontaminated. The inoculum on each fingerpad will be dried for 20 to 30 min under ambient conditions.

E. Test:

The dried inoculum on selected fingerpads will be exposed to the test agent by placing 1.0 mL of the test agent in a plastic cryovial. The virus-contaminated area on the fingerpad will make a seal over the mouth of the vial and the vial will be inverted to allow the contents to remain in contact with the contaminated area for the designated exposure time while subjecting the vial to a specified number of full inversions. For viscous formulations, the vial will be inverted and its contents will be in contact with the contaminated area for the designated exposure period without additional inversions. The area on the fingerpad will be scraped with the inside rim of the vial to recover as much of the fluid as possible.

If necessary, in order to simulate the post treatment rinsing of hands, the treated area on the fingerpad will be exposed to 1 mL of AOAC hard water, 200 ppm for 5–10 seconds with 10 inversions of the vial. If determinations are to be made after the drying of washed hands, the demarcated area can be dried in air or with a sterile paper towel for a specified time and then the virus recovered by elution.

The mouth of a vial containing 1 mL of EBSS+ will be placed over the treated area to elute the virus. The vial will be inverted 20 times with the treated thumb/fingerpad making a seal over the opening and it will remain in contact for 5-10 seconds. After the last inversion, the vial will be turned upright and the pad of the thumb or finger will be scraped using the inside rim of the vial to recover as much of the fluid as possible.

F. Post-treatment handwash procedure:

After the demarcated area has been sampled, it will be decontaminated by pressing the inoculated area for 2-3 minutes over a gauze square soaked in a 70% ethanol or other antimicrobial known to inactivate the challenge virus. Following the completion of all sampling, the subject will wash his/her hands thoroughly with soap and water and dry them well before leaving the test area.

G. Cell culture:

The eluate collected from the samples will be used for making serial ten-fold dilutions in EBSS.

Selected dilutions will be added to a culture of host cell monolayers (four wells per dilution, per replicate), and incubated for 60–90 minutes at $37\pm 2^{\circ}\text{C}$ with $5\pm 1\%$ CO_2 in air for viral adsorption. After the adsorption period, the fluid will be withdrawn; the monolayers washed with EBSS, and refed with CCM.

The cultures will be incubated for 5-7 days at $37\pm 2^{\circ}\text{C}$ with $5\pm 1\%$ CO_2 in air, Depending on the challenge virus, these parameters may change. Post-incubation, the infectious virions will be detected by the method selected by the Study Director to be most sensitive. Again this will depend on the challenge virus selected.

H. Control:

1. Inoculum control:

Ten μL of the challenge virus will be inoculated onto the thumbpads of each hand. Immediately thereafter, each thumbpad will be eluted and processed as the test.

2. Dried virus control:

After the challenge virus has dried under ambient conditions, two fingerpads will be used to determine the recovery of virus after the drying of the virus inoculum. Each fingerpad sampled will be eluted and processed as the test.

3. Recovery control:

One mL of AOAC synthetic hard water will replace the test agent and the dried virus will be treated as the test. Two fingerpads will be used in this control.

4. Neutralizer effectiveness control:

This control will be performed prior to testing. One mL of the test agent will be neutralized with one mL of EBSS+. Immediately thereafter, an aliquot of the virus will be added to the mixture. A portion of this sample will be used to make serial ten-fold dilutions in EBSS. Selected dilutions will be plated, adsorbed, and incubated as mentioned in the cell culture section of the protocol.

5. Cytotoxicity:

This control will be processed as the neutralizer effectiveness control except that virus will not be added.

6. Cytotoxicity-related viral interference control:

The test agent may or may not be effective against the challenge virus while being toxic to the cells employed to detect its infectivity and may mislead the outcome of the test. To determine possibility of such viral interference by any residual cytotoxic molecules, host cells treated with serially diluted neutralized test agent will be infected with known number of infectious virus. Post-incubation they will be scored and compared with non-treated infected host cells control. This will rule out any possibility of cytotoxicity-related viral interference remaining in the neutralized test agent post-contact time.

7. Cell viability control (CVC):

This control will demonstrate that cells remain viable throughout the course of the assay period. In addition, it will also confirm the sterility of the cell culture media employed throughout the assay period.

I. Calculation:

The infectious virus titer will be determined from the test and appropriate control data using the method of Reed and Muench, Am. J. of Hyg. 1938, 27:493. The test results shall be reported as the reduction of the virus titer due to treatment with test agent expressed as \log_{10} . The sponsor should provide the test product devoid of active to determine the true virucidal activity of the test agent.

SPONSOR PROVIDED STUDY MATERIALS AND SUPPLIES:

The quantity of all treatment products and other study supplies shipped to and returned from the clinical site by the sponsor of the study will be documented.

OTHER STUDY DOCUMENTATION AND REQUIREMENTS:**A. Concomitant medication**

If the subject has used any antibiotic or steroid medication during the washout period, information pertaining to that medication will be recorded appropriately. If the Investigator determines that the use of this medication will affect the results of this study, the subject's participation will be terminated.

B. Adverse reaction reporting

If, while using the test agent, a subject experiences unexpected or unusual clinical symptoms (e.g., rash, irritation), he/she will be examined by the Investigator immediately. The Investigator will determine whether: (a) the adverse event is likely to be associated with product treatment or the study procedures; (b) the reaction warrants termination of participation; and/or (c) treatment is necessary. All information pertaining to the presenting signs, assessment of the relationship of the adverse event to the product treatment, any prescribed treatment, and all the follow-up visits, including final resolution will be documented. The Investigator will notify the Sponsor's representative of occurrence of any of these events.

C. Deviations from the protocol

Any deviation from the protocol not previously agreed to by the Sponsor and Investigator that occurs during the conduct of the study will be documented and the sponsor notified at the earliest possible time.

D. Subject termination and completion

A concerted effort will be made to retain all subjects in the study. If a subject is terminated prior to study completion, the reason for termination will be documented also.

E. Additional information concerning the test:

The proposed experimental start and termination dates; additional information about the test agent; and the type of neutralizers to be used in the test will be addressed in a project sheet issued separately for each study.

ETHICAL AND REGULATOR REQUIREMENTS:**A. Institutional Review Board (IRB) review and approval**

Review by an IRB is required to conduct this study. A copy of the approval letter along with a list of the IRB members acting on this protocol and a statement that the IRB is in compliance with current Good Clinical Practices (GCP) regulations will be provided to the Sponsor.

B. Subject informed consent

Prior to study initiation, all subjects will be informed as to the type of study, the procedures to be followed, the general nature of the product being tested, and any known or anticipated adverse reactions that might result from participation. Each subject must sign the written informed consent before participating in the test period. The informed consent will contain all the basic elements outlined in 21 CFR § 50.25.

C. Study monitoring

The Investigator will permit a representative of the Sponsor to visit during the course of the study. During this visit, the investigator will permit the Sponsor's monitor to inspect all forms and corresponding study subjects' records to verify adherence to the protocol. The Sponsors monitor will also be permitted to review and verify laboratory reports, case report forms, drug/test article supply and inventory records. Any comments/instructions made by the Sponsors monitor will be recorded in the investigator's study file.

D. Protocol revisions and amendments

With the exception of emergency situations, no changes or deviations from this protocol will be permitted. Amendments to the final protocol will be initiated by the Sponsor. If the Investigator deviates from the agreed final protocol, the Sponsor's monitor will be informed of the change by telephone, fax or e-mail as soon as possible.

All amendments will be consecutively numbered, described any changes being made, and the reasons for them. They will be signed and dated by the sponsor and the investigator.

E. Record retention

The Investigator will store all original study records in the archives at MICROBIOTEST, INC., such as but not limited to:

- Final signed protocol,
- Protocol amendments/revisions/clarification,
- Copies of all case report forms,
- Investigators report,
- Correspondence with the IRB and Sponsor,
- Any Investigator-generated or Sponsor-generated study documents
- Source documents.

These files will be made available for inspection upon reasonable request by authorized representatives of the sponsor or the Food and Drug Administration or other appropriate regulatory authority.

PERSONNEL AND TESTING FACILITIES:

A principal investigator will be assigned before initiation of the test. Resumes for all personnel are maintained and are available on request. This study will be conducted at MICROBIOTEST, INC., 105B Carpenter Drive, Sterling, Virginia 20164.

DATA PRESENTATION:

The final report will include the following information in tabular form for the test and appropriate control data:

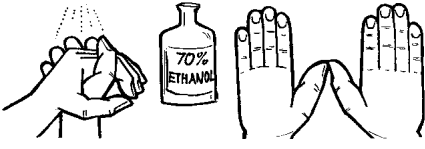

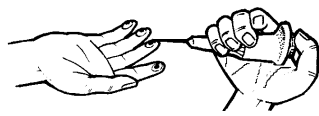

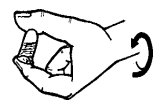
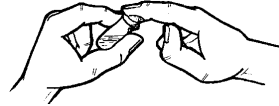
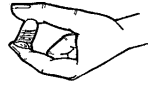
- The initial titer of the test virus after application to the area.
- The average CCID₅₀/mL) recovered from the treated areas for each subject.

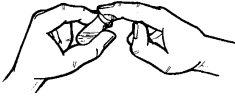


REPORT FORMAT:

MICROBIOTEST employs a standardized report format for each test design. Each final report will provide the following information:

- Sponsor identification.
- Test material identification
- Type of test and project number.
- Dates of study initiation and completion.
- Interpretation of results.
- Conclusion.
- Signature of study director.
- Test results presented in tabular form.
- Methods and evaluation criteria.
- Quality Assurance and Compliance statements.

Figure 1. Procedure for in vivo evaluation of the virus-eliminating activity of handwash and handrub agent using the fingerpad test*

Steps	
(1) The panelist washes hands with non-germicidal soap and tap water and dries them with paper towel. About 3-5 mL of 70%(v/v) ethanol is placed on the hands and they are rubbed together till dry.	 An illustration showing a hand being washed under a spray of water, followed by a bottle of 70% ethanol, and then two hands being rubbed together.
(2) Each digit is pressed against the mouth of an empty cryovial (8 mm inside diameter.) to demarcate the target area.	 An illustration of a hand with a finger being pressed against the mouth of a small vial to mark a spot on the fingerpad.
(3) 10 µL of virus with or without soil load is placed at center of each demarcated area. Inoculum from the two thumbpads is eluted immediately (Step 8 below) to act as 'input' control for virus.	 An illustration of a hand with a small vial being used to apply a drop of liquid to the center of a fingerpad.
(4) Inoculum on fingerpads allowed to become visibly dry (20-25 minutes). Two randomly selected fingerpads are eluted immediately (Step 8) at the end of drying ('baseline' control).	 An illustration of a hand with a small vial being used to elute a spot from a fingerpad.
(5) Dried inoculum on at least two randomly selected fingerpads is exposed to 1 mL of test agent or control fluid in a cryovial for desired contact time, with specified number of full inversions.	 An illustration of a hand with a finger being inserted into a vial to expose a fingerpad to a liquid.
(6) Skin scraped against inside lip of vial to collect as much fluid as possible. For waterless handwash agents or to determine virus elimination after exposure to the product alone, fingerpads can be eluted (Step 8) without further treatment	 An illustration of two hands, one holding a vial and the other using a finger to scrape against the inside lip of the vial.
(7) To simulate post-treatment rinsing of hands, fingerpads are exposed to 1 mL of hard water for 5-10 seconds. Virus can be eluted (Step 8) at this stage or after drying of hands. To determine virus removal after the drying of washed hands, they can be dried in air or with paper or cloth towel for specified time and virus recovered from them.	 An illustration of a hand with a small vial being used to elute a spot from a fingerpad.

<p>(8) To elute virus, the digit is placed on the mouth of a cryovial with 1 mL of eluent and subjected to 20 full inversions; skin is scraped against inside lip of vial to collect as much fluid as possible. The eluates and controls are titrated for virus and \log_{10} reductions calculated.</p>		
<p>(9) The panelist decontaminates the hands by pressing the inoculated areas for 2-3 minutes against a tissue or paper towel soaked in 70% ethanol or depending upon the test virus, any anti-microbial agent known to inactivate the test virus. The panelist then washes hands thoroughly with soap and water and dries them well before leaving the test area.</p>		

- ASTM Designation E 1838-02, Standard Test Method for Determining the Virus Eliminating Effectiveness of Liquid Hygienic Handwash and Handrub Agents Using the Fingerpads of Adult Volunteers. Approved April 10, 2002. Pub. July 2002 and ²⁴

24. Sattar SA, Ansari SA. The fingerpad protocol to assess hygienic hand antiseptics against viruses. J Virol Methods 2002 May 16; 103(2):171-81.

CONSENT FORM FOR PROTOCOL MICROBIOTEST Project XXX-XXX

**THE USE OF FINGERPADS OF ADULT SUBJECTS TO INVESTIGATE THE
VIRUCIDAL ACTIVITY OF HANDWASH AND HANDRUB AGENTS**

To avoid any coercion, the Principal Investigator will not seek volunteers. A member of his staff will ask suitable individuals if they would be willing to take part in the study. The names of only those who are willing will then be given to the Principal Investigator.

Dr. M. Khalid Ijaz, DVM, Ph.D.
Vice President

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And

Affiliate Professor
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George Mason University, Fairfax, VA 22030

INFORMED CONSENT FORM will be provided upon request

APPENDIX III

DERMATOGRAPHIS/DERMATOLOGIC/MEDICAL HISTORY – will be provided upon request