MERITECH
TECHNOLOGY FOR INFECTION CONTROL

Clinical Bulletin

Independent Laboratory Studies Summary

Conducted by:
BioScience Laboratories

The testing methods are based on the methodology specified by the Food and Drug Administration Tentative Final Monograph (TFM) for *Effectiveness Testing of an Antiseptic Handwash or Health-Care Personnel Handwash* (FR59:116, 17 June 94, pp. 31448-31450) and ASTM E 1174 *Standard Test method for Evaluation of the Effectiveness of Healthcare Personnel Handwash Formulations.*

Revised 1/20/17

Determination of Immediate Virucidal Efficacy of the CleanTech® IC/ELF Automated Handwashing system using Ultra-Pure 2% (5 ml) against Feline Calicivirus (surrogate for Norovirus) in 12 Seconds – The purpose of this study was to determine the immediate antiviral efficacy of the Meritech handwashing system, using one cleaning agent, when challenged with Feline Calicivirus (FCV) strain F-9, a surrogate for Human Norovirus. This study evaluated the performance of Meritech's automated hand cleansing system set for a total cycle length of 12 seconds using 5 ml Ultra-Pure 2% antimicrobial agent against Feline Calicivirus surrogate for **Norovirus** as the marker organism. The transient microorganism reduction by Meritech's automated system was measured at a statistical summary of the mean $\log_{10}$ of **4.17**, which equated to a reduction of **99.993%** removal of the virus, with some results having a higher $\log_{10}$ of up to **4.25**, which equates to a reduction of **99.994%** removal of the virus.

This study evaluated the antiviral efficacy of one test system when challenged with FCV strain F-9 (ATCC #VR-782). A sufficient number of human subjects were recruited to ensure that at least three human volunteers were evaluated in this study. Each test subject had a known volume of FCV placed on a site demarcated on each fingerpad and allowed to dry. The contaminated sites then were exposed to the cleaning agent using the test system. Log_{10} reductions in the virus titer following treatment with the test materials were compared to a baseline recovery value. Neutralization and Cytotoxicity Controls were performed concurrently with the test. All plating of viral elution's post-product exposure were performed in four replicates. This study met the following five criteria that constitute a valid evaluation: 1) a greater than 4.00 mean $\log_{10}$ infectivity titer value was recovered from the Baseline Control from all three subjects; 2) cells in the Negative Control wells were viable and attached to the bottom of the well; 3) the medium was free of contamination in all wells of the plates; 4) cytotoxicity of the Cleaning Agent (Cytotoxicity Control) did not affect cell morphology in the dilutions of the test necessary to demonstrating the reduction of the virus; and 5) the Cleaning Agent was neutralized immediately after exposure and did not affect virus infectivity.

For the Meritech CleanTech® IC/ELF Test System using the Cleaning Agent Ultra-Pure 2% (Alkyl dimethyl benzyl ammonium chloride and Alkyl dimethyl ethyl benzyl ammonium chloride [Lot Number UL13-243]), the viral titers recovered after product application 1 were reduced significantly from baseline populations. The Test System using the Cleaning Agent produced a mean $\log_{10}$ reduction of 4.17.

The methodology for this evaluation was based on the Standard Test Method for Determining the Virus-Eliminating Effectiveness of Hygienic Handwash and Handrub Agents Using the Fingerpads of Adults, ASTM E1838-10.

Determination of Immediate Microorganism Efficacy of the CleanTech® IC/ELF Automated Handwashing system using Ultra-Pure 2% (5ml) against E-Coli in 12 Seconds – This study evaluated the performance of Meritech's ELF automated hand cleansing system set for a total cycle length of 12 seconds using 5 ml Ultra-Pure 2% antimicrobial agent against E-Coli as the marker organism. The transient microorganism reduction by Meritech's automated system was measured at a statistical summary of the mean $\log_{10}$ of **3.00**, which equated to a reduction of **99.9%** removal of the E-Coli. Some results in the study were substantially higher and having a higher $\log_{10}$ of up to **3.45**, which equates to a reduction of **99.96%** removal of the organism.

The results indicated on the first wash a mean $\log_{10}$ of 3.08 or a 99.92%, the fifth wash with a mean $\log_{10}$ of 2.97 or a 99.89%, and the tenth wash with a mean $\log_{10}$ of 2.95 or a 99.89%. The testing methods are based on the methodology specified by the Food and Drug Administration Tentative Final Monograph (TFM) for *Effectiveness Testing of an Antiseptic Handwash or Health-Care Personnel Handwash* (FR59:116, 17 June 94, pp. 31448-31450) and ASTM E 1174 *Standard Test method for Evaluation of the Effectiveness of Healthcare Personnel Handwash Formulations.*

The purpose of this study was to determine the antimicrobial efficacy of the Meritech Handwashing System using one cleaning agent. The indicator microorganism used for challenge was *Escherichia coli* (ATCC #11229). Three subjects were used in testing over the course of 10 consecutive product applications. The antimicrobial efficacy was determined from microbial samples taken after product applications 1, 5, and 10. No statistical analysis was performed on the results of the study; rather, mean $\log_{10}$ and percent reductions from baseline were calculated.

Determination of Immediate Microorganism Efficacy of the CleanTech® IC/ELF Automated Handwashing system using CHG 2% (5ml) against E-Coli in 12 Seconds – This study evaluated the performance of Meritech's ELF automated hand cleansing system set for a total cycle length of 12 seconds using 5 ml CHG 2% antimicrobial agent against E-Coli as the marker organism. The transient microorganism reduction by Meritech's automated system was measured at a statistical summary of the mean $\log_{10}$ of **3.06** after 10 washes, which equated to a reduction of **99.91%** removal of the E-Coli. Some results in the study were substantially higher and having a higher $\log_{10}$ of up to **3.54**, which equates to a reduction of **99.97%** removal of the organism.

The results indicated on the first wash a mean $\log_{10}$ of 2.67 or a 99.79%, the fifth wash with a mean $\log_{10}$ of 2.66 or a 99.78%, and the tenth wash with a mean $\log_{10}$ of 3.06 or a 99.91%. The testing methods are based on the methodology specified by the Food and Drug Administration Tentative Final Monograph (TFM) for *Effectiveness Testing of an Antiseptic Handwash or Health-Care Personnel Handwash* (FR59:116, 17 June 94, pp. 31448-31450) and ASTM E 1174 *Standard Test method for Evaluation of the Effectiveness of Healthcare Personnel Handwash Formulations.*

The purpose of this study was to determine the antimicrobial efficacy of the Meritech Handwashing System using one cleaning agent. The indicator microorganism used for challenge was *Escherichia coli* (ATCC #11229). Three subjects were used in testing over the course of 10 consecutive product applications. The antimicrobial efficacy was determined from microbial samples taken after product applications 1, 5, and 10. No statistical analysis was performed on the results of the study; rather, mean $\log_{10}$ and percent reductions from baseline were calculated.

Determination of Immediate Microorganism Efficacy of the CleanTech® IC/ELF Automated Handwashing system using Ultra-Pure 2% (5ml) against E-Coli in 12 Seconds – This study evaluated the performance of Meritech's ELF automated hand cleansing system set for a total cycle length of 12 seconds using 5 ml Ultra-Pure 2% antimicrobial agent against E-Coli as the marker organism. The transient microorganism reduction by Meritech's automated system was measured at a statistical summary of the mean $\log_{10}$ of **2.66** after 1 wash, which equated to a reduction of **99.8%** removal of the E-Coli. Some results in the study were substantially higher and having a higher $\log_{10}$ of up to **4.09**, which equates to a reduction of **99.997%** removal of the organism.

The results indicated on the first wash a mean $\log_{10}$ of 2.66 or a 99.8%, the fifth wash with a mean $\log_{10}$ of 2.43 or a 99.6%, and the tenth wash with a mean $\log_{10}$ of 2.45 or a 99.6%. The testing methods are based on the methodology specified by the Food and Drug Administration Tentative Final Monograph (TFM) for *Effectiveness Testing of an Antiseptic Handwash or Health-Care Personnel Handwash* (FR59:116, 17 June 94, pp. 31448-31450) and ASTM E 1174 *Standard Test method for Evaluation of the Effectiveness of Healthcare Personnel Handwash Formulations.*

The purpose of this study was to determine the antimicrobial efficacy of the Meritech Handwashing System using one cleaning agent. The indicator microorganism used for challenge was *Escherichia coli* (ATCC #11229). Fifteen subjects were used in testing over the course of 10 consecutive product applications. The antimicrobial efficacy was determined from microbial samples taken after product applications 1, 5, and 10. No statistical analysis was performed on the results of the study; rather, mean $\log_{10}$ and percent reductions from baseline were calculated.

Determination of Microorganism Reduction with Antimicrobial / Detergent hand soap (5 ml) and a CleanTech® IC/ELF Automated Handwashing system against E-Coli in 12 Seconds – This study evaluated the performance of Meritech's ELF automated hand cleansing system set for a total cycle length of 12 seconds using 5 ml antimicrobial / detergent agent against E-Coli as the marker organism. The transient microorganism reduction by Meritech's automated system was measured at a statistical summary of the mean $\log_{10}$ of **2.35**, which equated to a reduction of **99.55%** removal of the E-Coli, with some results having a higher $\log_{10}$ of up to **3.11**, which equates to a reduction of **99.92%** removal of the organism.

The testing methods are based on the methodology specified by the Food and Drug Administration Tentative Final Monograph (TFM) for *Effectiveness Testing of an Antiseptic Handwash or Health-Care Personnel Handwash* (FR59:116, 17 June 94, pp. 31448-31450) and ASTM E 1174 *Standard Test method for Evaluation of the Effectiveness of Healthcare Personnel Handwash Formulations.*

Determination, Comparison, and Evaluation of Microorganism Reduction with Nine different Handwash configurations using several Antimicrobial handwash solutions and a CleanTech 2000S system against Serratia Marcescens in 10 seconds – This study evaluated the performance of Meritech's CleanTech 2000S automated hand cleansing system set for a total cycle length of 10 seconds using several Antimicrobial test solutions both in 5 ml & 10 ml antimicrobial agent against Serratia Marcescens as the marker organism.

The transient microorganism reduction by Meritech's automated system using Antimicrobial / Detergent hand soap was measured at a statistical summary of the mean $\log_{10}$ of **3.19 – 3.47**, which equated to a reduction of **99.94% - 99.97%** removal of the Serratia Marcescens, with some results having a higher $\log_{10}$ of up to **3.72**, which equates to a reduction of **99.98%** removal of the organism.

The testing methods are based on the methodology specified by the Food and Drug Administration Tentative Final Monograph (TFM) for *Effectiveness Testing of an Antiseptic Handwash or Health-Care Personnel Handwash* (FR59:116, 17 June 94, pp. 31448-31450) and ASTM E 1174 *Standard Test method for Evaluation of the Effectiveness of Healthcare Personnel Handwash Formulations.*

Determination, Comparison, and Evaluation of Microorganism Reduction with a CleanTech IC/ELF system vs. manual washing using a non-antimicrobial detergent lotion solution against Serratia Marcescens in 15 seconds – This study evaluated the performance of Meritech's CleanTech IC/ELF automated hand cleansing system set for a total cycle length of 15 seconds using 5 ml of Detergent Hand Soap (non-antimicrobial)against Serratia Marcescens as the marker organism and compared to the Personnel Healthcare Handwash Procedure.

The transient microorganism reduction by Meritech's automated system using Detergent Hand Soap was measured at a statistical summary of the mean $\log_{10}$ of **1.57**, which equates to a reduction of **97.31%** removal of the Serratia Marcescens. The transient microorganism m reduction by manual washing using Detergent Hand Soap (non-antimicrobial) was measured at a statistical summary of the mean $\log_{10}$ of **1.45**, which equates to a reduction of **96.45%** removal of the Serratia Marcescens.

Though both methods tested were statistically equivalent it is noteworthy that the manual handwash method is described in the report as a 30 second wash, the entire process requires 60 seconds when inclusive of the wash and rinse steps. According to the ASTM standard, the manual wash and rinse procedure is conducted by washing in a vigorous manner for 30 seconds over all surfaces of the hands and lower third of the forearms. This is then followed by a 30 second rinse under tap water. Considering this detail, the Meritech CleanTech IC/ELF accomplished equivalent removal of bacteria from the hands using one 15 second total wash and rinse cycle compared to a 60 second manual wash and rinse process.

The testing methods are based on the methodology specified by the Food and Drug Administration Tentative Final Monograph (TFM) for *Effectiveness Testing of an Antiseptic Handwash or Health-Care Personnel Handwash* (FR59:116, 17 June 94, pp. 31448-31450) and ASTM E 1174 *Standard Test method for Evaluation of the Effectiveness of Healthcare Personnel Handwash Formulations.*

Determination of Microorganism Reduction with a CleanTech® IC/ELF Automated Handwashing system against E-Coli in 12 Seconds – This study evaluated the performance of Meritech's ELF automated hand cleansing system set for a total cycle length of 12 seconds using 5 ml Chlorhexidine Gluconate 2% (CHG) antimicrobial agent against E-Coli as the marker organism. The transient microorganism reduction by Meritech's automated system was measured at a statistical summary of the mean $\log_{10}$ of **3.49**, which equated to a reduction of **99.97%** removal of the E-Coli, with some results having a higher $\log_{10}$ of up to **4.54**, which equates to a reduction of **99.997%** removal of the organism.

The results indicated on the first wash a mean $\log_{10}$ of 2.45 or a 99.65%, the fifth wash with a mean $\log_{10}$ of 2.84 or a 99.85%, and the tenth wash with a mean $\log_{10}$ of 3.49 or a 99.97%. With 1st, 5th, and 10th washes being evaluated and meeting the FDA criteria for a Health-Care Personnel Handwash. The testing methods are based on the methodology specified by the Food and Drug Administration Tentative Final Monograph (TFM) for *Effectiveness Testing of an Antiseptic Handwash or Health-Care Personnel Handwash* (FR59:116, 17 June 94, pp. 31448-31450) and ASTM E 1174 *Standard Test method for Evaluation of the Effectiveness of Healthcare Personnel Handwash Formulations.*

Determination of Immediate Virucidal Efficacy of the CleanTech® IC/ELF Automated Handwashing system against Feline Calicivirus (surrogate for Norovirus) in 15 Seconds – The purpose of this study was to determine the immediate antiviral efficacy of the Meritech CleanTech® IC/ELF handwashing system. This study evaluated the performance of Meritech's automated hand cleansing system set for a total cycle length of 15 seconds using 5 ml Chlorhexidine Gluconate 2% (CHG) antimicrobial agent against Feline Calicivirus surrogate for **Norovirus** as the marker organism. The transient microorganism reduction by Meritech's automated system was measured at a statistical summary of the mean $\log_{10}$ of **3.97**, which equated to a reduction of **99.99%** removal of the virus, with some results having a higher $\log_{10}$ of up to **4.25**, which equates to a reduction of **99.994%** removal of the virus.

The subjects' use of the CleanTech® IC/ELF system and towel-dry removed the Feline Calicivirus strain (surrogate to Norovirus) to the lower detection limit of the test in seven (7) of the nine (9) samples: thereby, demonstrating a greater than **4.00 $\log_{10}$** reduction **(99.99% Virucidal efficacy)** in seven (7) of the nine (9) samples. The other two (2) samples were a **3.75 $\log_{10}$** reduction which equated to a reduction of **99.98%** Virucidal efficacy. Reductions in the virus titer were the result of mechanical removal by the CleanTech® IC/ELF system and the towel-dry. The towel-dry was included in the testing to simulate normal and clinical use of the system. Chlorhexidine Gluconate is effective against viruses with a

lipid outer envelope, but in not significantly active against non-enveloped viruses such as Feline Calicivirus. Nevertheless, the detergents in the cleaning agent (Chlorhexidine Gluconate soap) may have assisted in the removal of the virus form the skin.

The methodology for this evaluation was based on the *Standard Test method for Determining the Virus-Eliminating Effectiveness of Liquid Hygienic Handwash and Handrub Agents Using the Fingerpads of Adult Volunteers*, ASTM E 1838.02.

Determination if the CleanTech® IC/ELF Automated Handwashing system against E-Coli in 12 Seconds could Cross Contaminate a Hand of Another User – This study evaluated the performance of Meritech's ELF automated hand cleansing system set for a total cycle length of 12 seconds using 5 ml Chlorhexidine Gluconate 2% (CHG) antimicrobial agent against E-Coli as the marker organism and if the system could cross contaminate from one person inoculated with E-Coli to anther sterile user. **It was determined that 0.00 CFU/mL was transferred from the E-Coli inoculated hands to the sterile hands of another user and that this system is not cross contaminating users.**

Determination of Microorganism Reduction with Chlorhexidine Gluconate 2% (5 ml) and a CleanTech® IC/ELF Automated Handwashing system against E-Coli in 15 Seconds. – This study evaluated the performance of Meritech's ELF automated hand cleansing system set for a total cycle length of 15 seconds using 5 ml Chlorhexidine Gluconate 2% (CHG) antimicrobial agent against E-Coli as the marker organism. The transient microorganism reduction by Meritech's automated system was measured at a statistical summary of the mean $\log_{10}$ of **3.37**, which equated to a reduction of **99.96%** removal of the E-Coli, with some results having a higher $\log_{10}$ of up to **4.54**, which equates to a reduction of **99.997%** removal of the organism.

The results indicated on the first wash a mean $\log_{10}$ of 2.64 or a 99.77%, the fifth wash with a mean $\log_{10}$ of 2.86 or a 99.86%, and the tenth wash with a mean $\log_{10}$ of 3.37 or a 99.96%. With 1st, 5th, and 10th washes being evaluated and meeting the FDA criteria for a Health-Care Personnel Handwash. The testing methods are based on the methodology specified by the Food and Drug Administration Tentative Final Monograph (TFM) for *Effectiveness Testing of an Antiseptic Handwash or Health-Care Personnel Handwash* (FR59:116, 17 June 94, pp. 31448-31450) and ASTM E 1174 *Standard Test method for Evaluation of the Effectiveness of Healthcare Personnel Handwash Formulations.*

Determination of Microorganism Reduction with Chlorhexidine Gluconate 4% (5 ml) and a CleanTech® IC/ELF Automated Handwashing system against E-Coli in 15 Seconds. – This study evaluated the performance of Meritech's ELF automated hand cleansing system set for a total cycle length of 15 seconds using 5 ml Chlorhexidine Gluconate 4% (CHG) antimicrobial agent against E-Coli as the marker organism. The transient microorganism reduction by Meritech's automated system was measured at a statistical summary of the mean $\log_{10}$ of **3.33**, which equated to a reduction of **99.95%** removal of the E-Coli, with some results having a higher $\log_{10}$ of up to **4.63**, which equates to a reduction of **99.998%** removal of the organism.

The results indicated on the first wash a mean $\log_{10}$ of 2.58 or a 99.74%, the fifth wash with a mean $\log_{10}$ of 2.97 or a 99.89%, and the tenth wash with a mean $\log_{10}$ of 3.33 or a 99.95%. With 1st, 5th, and 10th washes being evaluated and meeting the FDA criteria for a Health-Care Personnel Handwash. The testing methods are based on the methodology specified by the Food and Drug Administration Tentative Final Monograph (TFM) for *Effectiveness Testing of an Antiseptic Handwash or Health-Care Personnel Handwash* (FR59:116, 17 June 94, pp. 31448-31450) and ASTM E 1174 *Standard Test method for Evaluation of the Effectiveness of Healthcare Personnel Handwash Formulations.*

Determination of Microorganism Reduction with Chlorhexidine Gluconate 2% (5 ml) and a CleanTech® IC/ELF Automated Handwashing system against Staphylococcus Aureus in 15 Seconds. – This study evaluated the performance of Meritech's ELF automated hand cleansing system set for a total cycle length of 15 seconds using 5 ml Chlorhexidine Gluconate 2% (CHG) antimicrobial agent against Staphylococcus Aureus as the marker organism. The transient microorganism reduction by Meritech's automated system was measured at a statistical summary of the mean $\log_{10}$ of **2.73**, which equated to a reduction of **99.81%** removal of the Staph, with some results having a higher $\log_{10}$ of up to **3.40**, which equates to a reduction of **99.96%** removal of the organism. The increasing efficacy over time due to CHG's persistence was substantiated; furthermore, a mean $\log_{10}$ reduction of **1.06,** or **91.29%, was demonstrated one hour post handwashing after re-contaminating the hands.**

The testing methods are based on the methodology specified by the Food and Drug Administration Tentative Final Monograph (TFM) for *Effectiveness Testing of an Antiseptic Handwash or Health-Care Personnel Handwash* (FR59:116,

17 June 94, pp. 31448-31450) and ASTM E 1174 *Standard Test method for Evaluation of the Effectiveness of Healthcare Personnel Handwash Formulations.*

Comparison of an Automated Handwash to a Manual Handwash – This study evaluated the performance of Meritech's automated hand cleansing system to a manual handwash using Serratia Marcescens as a marker organism, and a 4% Chlorhexidine Gluconate (CHG) antimicrobial agent. The transient microorganism $\log_{10}$ reduction by Meritech's automated system was measured at 3.80, which equated to a reduction of *99.95%*. The results clearly substantiate the persistent effect (increasing efficacy over time) of CHG.

Healthcare Personnel Formulation Evaluation – This test was designed to study the immediate antimicrobial effectiveness of transient microorganism removal during Meritech's wash cycle using Serratia Marcescens as a marker organism. The results showed a reduction of 99.3% after just one wash.

Comparison of a Manual Handwash to an Automated System **–** This study compared Meritech's automated hand cleansing system to a 30-second manual handwash using Chlorhexidine Gluconate (CHG). The results from both the manual and the automated hand cleansing system demonstrated a statistically equivalent 99.9% reduction in transient microorganisms. The persistence of CHG was demonstrated with increasing reductions with repeated hand washes.

Determination of Microorganism Reduction with Chlorhexidine Gluconate – This study was designed to test the efficacy of Chlorhexidine Gluconate (CHG) on transient microorganisms during a standard automated wash using one of Meritech's systems. The transient microorganism reduction was measured at 99.88%.

Two Phase Handwash Evaluation Using Two Different Concentrations of CHG **–** The purpose of this study was to determine and rate the antimicrobial efficacy of several handwash configurations using CHG 2% and CHG 4%, testing against Serratia Marcescens as the marker organism. The results show that CHG 4% clearly outperformed CHG 2%, with CHG 4% resulting in a 3.64 log reduction, equating to a percent reduction of 99.93%. CHG's persistence was clearly evident once again.

Determination, Comparison, and Evaluation of Antimicrobial Efficacy of Nine Handwash Configurations **–** This test was designed to study the efficacy of nine different handwash configurations in Meritech's automated hand cleansing system using Serratia Marcescens as a marker organism. The percent pathogen reductions ranged from a low of 99.41% to a high of 99.98%. The increasing efficacy over time due to CHG's persistence was substantiated.

Antimicrobial Efficacy Determination – This study evaluated the efficacy of five different handwash configurations. The results showed Meritech's CleanTech system provided a 99.15% reduction in transient microorganisms.

"All five product configurations demonstrated statistically significant $\log_{10}$ reductions in bacterial populations. The manual wash and the standard CleanTech wash with CHG were statistically equivalent in de germing effectiveness."

Pilot Determination of Handwash Configurations – The study was designed to test the efficacy of the Meritech automated hand cleansing system. Results show that E. coli was reduced by 99.17% after just one wash.