CleanTech® Summary of Clinical Studies

This summary contains a subset of our over 50 conducted clinical laboratory studies that are most recent and relevant to our current product offerings. The studies prove CleanTech®'s ability to remove more than 99.9% of harmful pathogens from the hands and footwear, wash more effectively and consistently than a manual wash, and remove the risk of cross-contamination. Studies and results included in this summary prove that:

- CleanTech® Automated Handwashing Stations have at least a mean reduction of 99.9% of pathogens including E. coli, Coronavirus, and Feline Calicivirus (surrogate for Norovirus), after a 12 second automated hand wash and rinse cycle.
- CleanTech® results in greater pathogen reduction than a manual hand wash.
- Regardless of the pathogen, CleanTech® does not cross contaminate from one user to the next.
- CleanTech® enhancements, both the wetted boot dip and low-moisture footwear sanitizing pan, remove more than 99.9% of harmful pathogens such as Salmonella enterica and Listeria monocytogenes from footwear during the CleanTech® 12 second automated hand wash cycle.

To provide the most accurate and unbiased results, all of the studies performed and outlined in this summary were executed in partnership with an independent GLP-certified laboratory. Standards defined by both FDA (Food and Drug Administration) and ASTM International (American Society for Testing and Materials) were leveraged to perform these studies.

History of Efficacy Testing:

Since 1988, Meritech has performed over 50 clinical laboratory studies to test the efficacy of CleanTech® Automatic Handwashing and Footwear Sanitizing Stations. We have continued to test, improve, and re-test CleanTech® in order to definitively prove that our innovative technology is providing the perfect hand wash and footwear sanitization—every time. CleanTech® was developed to overcome the variability of manual hygiene and to take the guesswork out of whether an effective hygiene event has occurred. By standardizing and quality-controlling the handwashing and footwear sanitizing process, you can gain peace of mind that every employee and guest in your facility has clean hands and, if applicable, sanitized footwear.

More important than what we do is why we do it. We believe that in order to truly create a healthier and safer world, we must redefine human hygiene to make it vastly more effective. We have developed CleanTech® to redefine the handwashing process and deliver the "perfect hand wash" every time. We understand that in redefining that process, thorough testing of the technology is a necessary aspect in adopting this new method.

CleanTech® Handwashing Stations Efficacy

CleanTech® Fully Automated Handwashing Stations are proven to remove more than 99.9% of harmful pathogens in 12 seconds. This conclusion was yielded as a result of a series of individual studies challenging CleanTech® against a variety of commonly transmitted and harmful pathogens. While it is not feasible to test every harmful pathogen a human could potentially encounter, we are confident that the selection of pathogens we have tested provides an accurate view of how our technology would behave against all pathogens.

Methodology:

Studies were performed following the methodology specified by the FDA 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 Glove Juice Method is one of the most common procedures for testing efficacy of handwashing products. This method involves the test subject first applying harmful pathogens to the surface of the hands. The subject dons sterile gloves, and a solution is added to the gloves. This solution is then tested in order to measure the concentration of pathogens present on the surface of the skin. Next, the test subject washes their hands, and performs the same steps to don sanitized gloves and fill with the sampling solution. The post wash concentration is then compared to the first sample in order to quantitatively measure pathogen reduction. Results are measured in log reduction. Log reduction stands for a 10-fold (one decimal) or 90% reduction in numbers of live bacteria. Another way to look at it is: 1-Log Reduction would reduce the number of bacteria 90%, 2-Log represents 99% reduction, and so on.

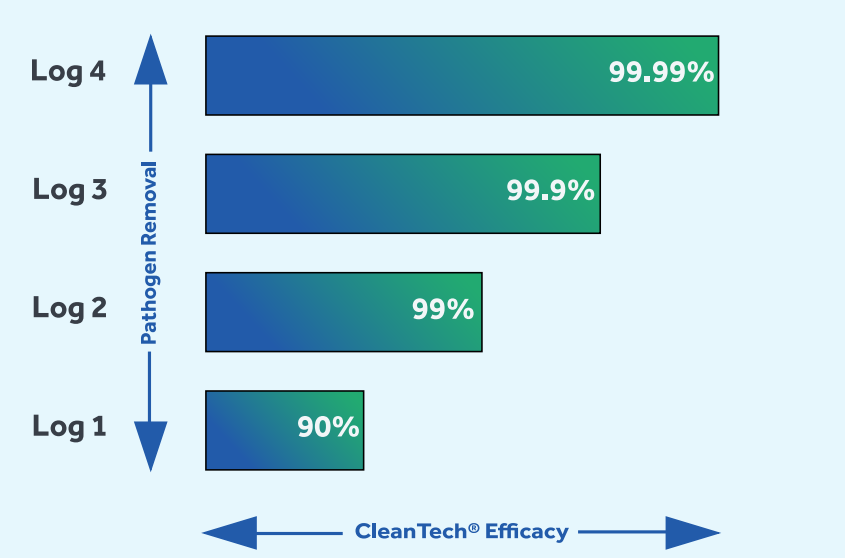

FIGURE 1 *A chart displaying the relationship between Log10 reduction representing the removal of the pathogen in question and the percentage removed representing the effectivness of CleanTech®.*

Proving Effective Pathogen Removal

Pathogen Specific Testing:

When testing CleanTech® it is important to consider the type of pathogen you intend to measure. The human hand contains a variety of bacteria. The vast majority of these are harmless, resident bacteria, that is always on the hands and does not cause illness or infection. However, some bacteria on the hands is not harmless. These are the transient bacteria, which are not normal on the hand and can cause illness or even death. CleanTech® is designed to remove transient bacteria.

When counting the bacteria reduction on the hands due to handwashing, it is important to be as accurate as possible in measuring the transient bacteria reduction. If you simply count all bacteria removed from the hands, you will be counting mainly the harmless bacteria and you will not have a true measure of the pathogen reduction. A total plate count of all bacteria, as compared to a pathogen specific count, will render an inaccurate measure of the efficacy of the handwashing method.

Determination of immediate virucidal efficacy of the CleanTech® ELF Fully Automated Handwashing Station using UltraPure (5ml) against Feline Calicivirus (surrogate for Norovirus) in 12 Seconds.
This study evaluated the performance of the CleanTech® ELF's 12-second cycle using 5ml UltraPure hand hygiene solution against Feline Calicivirus surrogate for Norovirus as the marker organism. The transient microorganism reduction by CleanTech® 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.

Determination of immediate microorganism efficacy of the CleanTech® ELF Fully Automated Handwashing Station using UltraPure (5ml) against E. coli in 12 Seconds.
This study evaluated the performance of the CleanTech® ELF's 12-second cycle using 5ml UltraPure hand hygiene solution against E. coli as the marker organism. The transient microorganism reduction by CleanTech® 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.

Determination of immediate virucidal efficacy of the CleanTech® 500EZ Automated Handwashing Station using UltraPure (5ml) against Coronavirus in 12 Seconds.
This study evaluated the performance of the CleanTech® 500EZ 12-second cycle using 5ml UltraPure hand hygiene solution against Coronavirus as the marker organism. The transient microorganism reduction by CleanTech® was measured at a statistical summary of the mean $\log_{10}$ of 3.00, which equated to an average reduction of 99.9% removal of the Coronavirus. Some results in the study were substantially higher and having a higher $\log_{10}$ of up to 3.25, which equates to a reduction of 99.94% removal of the organism.

Resident Pathogens

Resident pathogens are microorganisms that are always present on or in a person to help prevent infection from transient pathogens.

Transient Pathogens

Transient pathogens are unable to remain in the body for extended periods of time due to the body's immune system eliminating microbes over time, physical or chemical changes within the body that discourage microbe growth, and difficulty competing with established resident microbes.

Results and Analysis

Each of the studies performed resulted in at least a mean reduction of 99.9% of the pathogen in question. We have tested against both transient and resident pathogens, bacterias, and viruses. The results of the studies referenced clearly show how CleanTech® Automated Handwashing Stations effectively remove more than 99.9% of pathogens from the hand in a 12-second automated hand wash and rinse cycle.

Proving Efficacy Over Manual Hand Wash

Evaluation of Microorganism Reduction with a CleanTech® ELF Fully Automated Handwashing Station vs. manual washing using a non-antimicrobial detergent lotion solution against Serratia Marcescens in 15 seconds.
This study evaluated the performance of the CleanTech® ELF Automated Handwashing station set for a total cycle length of 15 seconds using 5ml 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 CleanTech® 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 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.

Results and Analysis

The study shows that CleanTech® results in greater pathogen reduction than a manual hand wash. Additionally, it is noteworthy that the manual hand wash 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® 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. Why 15 seconds? This study was conducted in partnership with Kimberly Clark, a company focused on providing supplies to the healthcare industry. Based on hygiene standards for healthcare, we tested against a 15 second hand wash. Why wasn't UltraPure used? We wanted to prove the efficacy of the mechanics of the CleanTech® hand wash outside of the chemistry; we proved that when you use the incorrect chemical solution, the pathogen reduction (while better than a manually conducted hand wash) is not as significant or effective as when used with UltraPure hand hygiene solution.

Proving Elimination of Cross-Contamination Risk

Determination if the CleanTech® ELF Fully Automated Handwashing Station against E. coli in 12 Seconds could cross contaminate a hand of another user.

This study evaluated the performance of the CleanTech® ELF Automated Handwashing Station set for a total cycle length of 12 seconds using 5ml antimicrobial hand soap 2% against E. coli as the marker organism and if the system could cross contaminate from one person inoculated with E. coli to another sterile user.

Results and Analysis

It was determined that 0.00 colony-forming unit/ml (CFU's) was transferred from the E. coli inoculated hands to the sterile hands of another user. This information establishes that the **CleanTech® Fully Automated Handwashing Station is not cross contaminating users**. Regardless of the pathogens, this study shows there was no cross-contamination risk of that same pathogen being transferred to the next user.

CleanTech® Footwear Enhancements Efficacy

CleanTech® Footwear Sanitizing Pans are proven to remove more than 99.9% of harmful pathogens in 12 seconds. This conclusion was yielded as a result of a series of individual studies challenging two solutions used in CleanTech® sanitizing pans against a variety of frequently transmitted and harmful pathogens. While it is not feasible to test every harmful pathogen a human could potentially encounter, we are confident that the selection of pathogens we have tested against provides an accurate view of how our technology and solutions would behave against commonly known pathogens.

Methodology:

The purpose of this study is to evaluate the effectiveness of two footwear sanitizing solutions when challenged with two organisms, *Salmonella enterica* (ATCC #13076) and *Listeria monocytogenes* (ATCC #19112). Utilizing the CleanTech® 2000S Boot Dip and Sole Clean Systems.

Prior to these studies there was no standard methodology established for studying the efficacy of footwear sanitization methods. Meritech, in partnership with a 3rd party FDA-certified lab, developed this footwear sanitizing efficacy testing methodology based on existing ASTM standard test methods. The contamination procedure is based on a modification of the test procedure described in ASTM E2784-10 *Standard Test Method for Evaluation of the Effectiveness of Handwash Formulations Using the Paper Towel.* To establish a baseline, 60ml of the pathogen was applied to a paper towel, the test subject then stood on the contaminated paper towel for 5 seconds, then the footwear dried for 1 minute before using the glove juice method to recover the pathogen and test concentration. To measure the impact of the CleanTech® Footwear Sanitizing Pans, the test subject followed the same contamination and drying procedure before the subject disinfected the footwear using the product. After using the product the footwear dried for 5 minutes before using the glove juice method to recover the pathogen and test for concentration. The baseline pathogen counts were compared to the post-footwear sanitizing event pathogen counts to measure overall pathogen reduction.

Proving Effective Pathogen Removal with Footwear Sanitizing Methods Suitable for Wet Production Environments

Determination of immediate virucidal efficacy of the CleanTech® Wetted Sanitizing Boot Dip with SelfClean against Salmonella enterica in 12 Seconds.

This study evaluated the performance of Meritech's CleanTech® Wetted Sanitizing Boot Dip set for a total length of 12 seconds using 1,000 ppm of SelfClean footwear solution against Salmonella enterica as the marker organism. The transient microorganism reduction by CleanTech® was measured at a statistical summary of the mean $\log_{10}$ of 3.35, which equated to a reduction of 99.95% removal of the pathogen, with some results having a higher $\log_{10}$ of up to 3.71, which equates to a reduction of 99.98% removal of the pathogen.

Proving Effective Pathogen Removal with Footwear Sanitizing Methods Suitable for Low-Moisture Environments

Determination of immediate virucidal efficacy of the CleanTech® SoleClean Footwear Sanitizing Pan with Sanifect D2 against Salmonella enterica in 12 Seconds.

This study evaluated the performance of the CleanTech® SoleClean Footwear Sanitizing Pan set for a total length of 12 seconds using Sanifect D2 surface sanitizer against Salmonella enterica as the marker organism. The transient microorganism reduction by CleanTech® was measured at a statistical summary of the mean $\log_{10}$ of 4.24, which equated to a reduction of 99.994% removal of the pathogen, with some results having a higher $\log_{10}$ of up to 4.53, which equates to a reduction of 99.997% removal of the pathogen.

Determination of immediate virucidal efficacy of the CleanTech® SoleClean Footwear Sanitizing Pan with Sanifect D2 against Listeria monocytogenes in 12 Seconds.

This study evaluated the performance of the CleanTech® SoleClean Footwear Sanitizing Pan set for a total length of 12 seconds using Sanifect D2 surface sanitizer against Listeria Monocytogenes as the marker organism. The transient microorganism reduction by CleanTech® was measured at a statistical summary of the mean $\log_{10}$ of 4.24, which equated to a reduction of 99.994% removal of the pathogen, with some results having a higher $\log_{10}$ of up to 4.57, which equates to a reduction of 99.998% removal of the pathogen.

Interested in learning more?

Our team of hygiene experts is ready to help

Results and Analysis

Each of the studies performed resulted in at least a mean reduction of 99.9% of the pathogen in question. Certain studies resulted in as much as 99.998% pathogen reduction. Both sanitizing solutions effectively removed the pathogens challenged. The results of the studies referenced clearly show how **CleanTech® Footwear Sanitizing Technology effectively removes more than 99.9% of pathogens from footwear in 12 seconds.**

Conclusion

CleanTech® combines the best of chemistry and engineering to deliver the perfect hand wash every time. These studies validate that our revolutionary technology provides consistently effective hand and footwear hygiene events. With each product yielding significant and consistent results it can be said with great confidence that CleanTech® Fully Automated Hygiene Technology removes more than 99.9% of harmful pathogens in just 12 seconds. Additionally, our technology is faster and more effective than a manual hand hygiene event while eliminating the risk of human error and variability in the hygiene process.

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