



UniFirst Garment Service for Healthcare and Product Protection Process

Workwear Solutions for Healthcare Industry Safety

A laboratory study to measure the effectiveness of UniFirst's specialized garment service as a pathogen reduction method in the laundering and processing of healthcare industry work garments.

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Healthcare Safety Background

Contamination control is one of the major challenges the healthcare industry faces today, and organizations of all types and sizes are actively seeking solutions. The risk of healthcare-associated infections (HAIs) increases each year, with antibiotic-resistant organisms, such as MRSA, on the rise. Each year, nearly 2 million Americans develop some form of a healthcare-acquired infection, most due to an antibiotic-resistant organism. While there may not be one comprehensive solution, there are many different strategies that can be implemented as preventive measures. Preventive measures are critical to help reduce contamination and risk of infection. Improved attention toward hygiene practices, especially hand cleaning and sanitizing, is one of the major steps that have been implemented within the healthcare industry to help combat contamination threats. Another important preventive measure is ensuring the cleanliness of all reusable apparel worn by healthcare industry workers. Items such as lab coats and scrubs are exposed to contamination on a daily basis and need to be hygienically laundered and processed in order to help reduce contamination levels within healthcare environments.

Reducing HAIs not only helps improve the overall patient outcomes of a healthcare facility, but it also has a positive impact on the bottom line. According to the Centers for Disease Control and Prevention (CDC), HAIs cost the healthcare industry approximately \$45 billion annually¹. In addition, legislation such as the American Recovery and Reinvestment Act of 2009 and the Patient Protection and Affordable Care Act of 2010 incorporate funding incentives for reduced HAIs and financial penalties for facilities reporting high HAIs.

The presence of diseases contaminating organisms in healthcare environments is a main contributor to HAIs that may cause longer hospital stays and higher costs affecting patients and insurers alike. The CDC and healthcare institutions are cognizant of this fact, and track and periodically report on HAIs. The following are the results of a large surveillance study conducted for HAI's from 2006–2007².

Overall, 463 hospitals reported one (1) or more HAIs: 412 (89%) were general acute care hospitals, and 309 (67%) had 200–1,000 beds. Some patients acquired more than one (1) organism, as there were 28,502 HAIs reported among 25,384 patients. The 10 most common pathogens (accounting for 84% of any HAIs) were coagulase-negative staphylococci (15%), *Staphylococcus aureus* (15%), *Enterococcus* species (12%), *Candida* species (11%), *Escherichia coli* (10%), *Pseudomonas aeruginosa* (8%), *Klebsiella pneumoniae* (6%), *Enterobacter* species (5%), *Acinetobacter baumannii* (3%), and *Klebsiella oxytoca* (2%). The pooled mean proportion of pathogenic isolates resistant to antimicrobial agents varied significantly across types of HAI for some pathogen-antimicrobial combinations. As many as 16% of all HAIs were associated with the following multidrug-resistant pathogens: methicillin-resistant *S. aureus* (8% of HAIs), vancomycin-resistant *Enterococcus faecium* (4%), carbapenem-resistant *P. aeruginosa* (2%), extended-spectrum cephalosporin-resistant *K. pneumoniae* (1%), extended-spectrum cephalosporin-resistant *E. coli* (0.5%), and carbapenem-resistant *A. baumannii*, *K. pneumoniae*, *K. oxytoca*, and *E. coli* (0.5%). Nationwide, the majority of units reported no HAIs due to these antimicrobial-resistant pathogens.

The rationale for the organisms that have been chosen for this study is based on the prevalence and types of organisms most commonly associated with these HAIs. The organisms have been categorized based on bacteriological characteristics and the laboratory's ability to safely handle and work with the specified organisms.

¹ *The Direct Medical Costs of Healthcare Associated Infections in U.S. Hospitals and the Benefits of Prevention*. Division of Healthcare Quality Promotion, Centers for Disease Control. R. Douglas Scott II, March 2009.

² *Antimicrobial-Resistant Pathogens Associated With Healthcare-Associated Infections: Annual Summary of Data Reported to the National Healthcare Safety Network at the Centers for Disease Control and Prevention, 2006–2007*. Infection Control and Hospital Epidemiology November 2008, vol. 29, no. 11

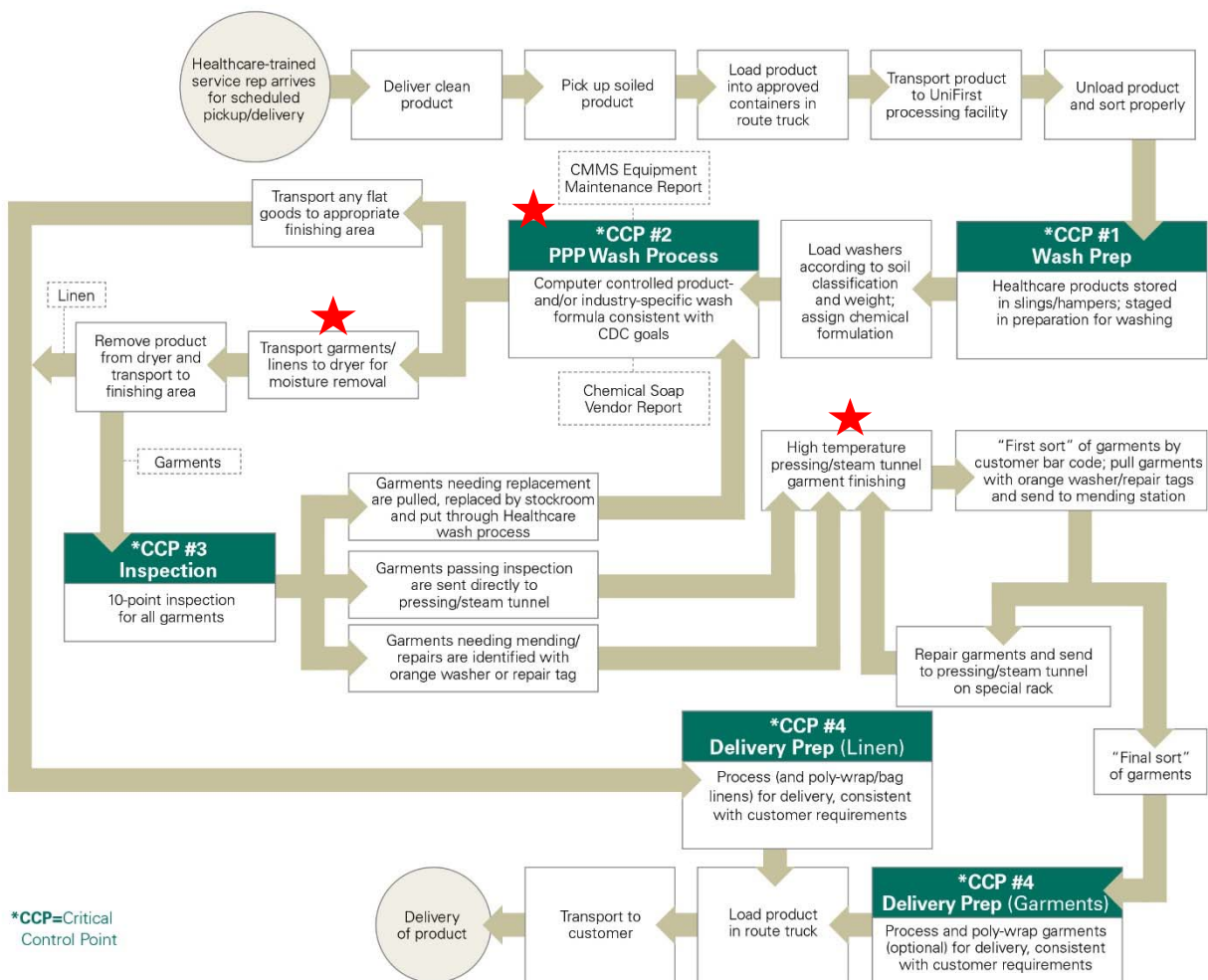
UniFirst Garment Service for Healthcare

In order to effectively minimize potential contamination, work garments worn by healthcare employees need to be specially maintained, processed, and managed. To address these needs, UniFirst Corporation, a uniform service and supply company operating throughout the U.S. and Canada, developed its specialized UniFirst Garment Service for Healthcare, specifically designed to reduce potential bacterial contaminants that could be associated with soiled healthcare employee workwear.

UniFirst Garment Service for Healthcare includes a portal-to-portal process, called the Product Protection Process (PPP), designed to minimize cross-contamination risks on delivered goods from uniforms and other work apparel. The UniFirst PPP begins at customer facilities where all soiled garments are collected and sorted following Universal Precautions. Garments are then further segregated upon arrival at the UniFirst processing plant (also following Universal Precautions), then laundered to meet healthcare safety specifications, steamed and/or pressed, and poly-bagged (optional) for delivery. All processing follows defined UniFirst healthcare garment Standard Operating Procedures (SOPs), which address the Critical Control Points (CCPs) and processing steps associated with contamination risks. In the end, UniFirst consistently delivers hygienically clean garments to its healthcare industry customers on a regular schedule.

This proprietary healthcare uniform program was developed following healthcare laundering guidelines set forth by the CDC (*Guidelines for Environmental Infection Control*, 2003), OSHA's guidelines for handling biologically contaminated laundry (*Bloodborne Pathogens Standard*, 1910.1030), and *Universal Precautions for Preventing Transmission of Bloodborne Infections*. UniFirst Garment Service for Healthcare has been instituted in UniFirst servicing plants, and UniFirst personnel involved receive detailed training on the unique safety requirements of these types of accounts. The detailed steps in UniFirst's process are identified in the following flow chart.

UniFirst Product Protection Process (PPP)



The UniFirst Product Protection Process has three (3) primary stages (annotated by ★) where microbial contamination is eliminated as indicated with stars in the flow chart above.

1. Specialized healthcare wash cycle
2. Dryer cycle
3. Steam tunnel finishing/garment pressing cycle

The optional poly-wrap stage is an additional preventive measure to help protect cleaned garments from exposure to environmental contaminants after processing, throughout the delivery process, and prior to being worn. Once the garments have gone through the full PPP, they are packaged and loaded onto a delivery vehicle and transported to the UniFirst customer.

Garment laundering service begins with the delivery of hygienically clean garments and the pickup of soiled ones from the customer facility. Soiled garments are brought to the transport vehicle and loaded into segregated plastic liners. Soiled items are then transported to a UniFirst processing facility to undergo

the complete Product Protection Process that, in addition to drying, steam tunnel/pressing, and other important steps associated with the process, includes four (4) defined CCPs:

CCP 1 – Soiled garments segregated and stored in slings/hampers; staged in preparation for washing

CCP 2 – Garments undergo UniFirst’s specialized healthcare wash process

CCP 3 – 10-point quality inspection of all garments (with processes to address any flaws that could put health safety at risk; e.g., apparel damage, fabric shedding, loose buttons, etc.)

CCP 4 – Finished garments prepared for redelivery (poly-wrapped, if desired), consistent with customer requirements

UniFirst Garment Service for Healthcare Processing Steps:

1. **Loading the route vehicle for delivery** – Truck loaded with appropriate segregation containers, bags, and hygienically clean garments.
2. **Delivery of clean garments** – Hygienically clean (poly-wrapped, if desired) garments are delivered to designated area at customer site.
3. **Pickup of soiled garments** – Soiled garments are placed in plastic bags and put on route truck in segregated containers/bins.
4. **Return to UniFirst processing facility (plant)** – Soiled garments are transported to a UniFirst industrial laundry plant.
5. **Unloading soiled garments** – Garments are sorted, identified as “healthcare industry-related,” and segregated using designated slings.
6. **Washing and drying** – Slings loaded with identified “healthcare industry-related” soiled garments are brought to wash aisle and hygienically laundered with a specified wash process and cleaning formula. After the wash cycle, items are loaded into dryers for moisture removal and garment conditioning.
7. **Inspection and garment finishing** – All hygienically clean garments undergo 10-point quality inspections; garments passing inspection go through a high temperature steam tunnel or garment press. Garments failing inspection are routed for mending or replacements and go through the complete Product Protection Process again.
8. **First sort** – All garments are segregated and sorted by delivery schedule, customer, and wearer using proprietary bar code scanning technology.
9. **Final delivery of hygienically clean garments** – Finished, sorted garments (optionally poly-wrapped) are segregated and transported from plant to designated site at customer location or UniFirst branch for final customer delivery.

Laboratory Tests

To measure the effectiveness of UniFirst Garment Service for Healthcare, we needed to determine if it is an effective pathogen-reduction methodology in the laundering and processing of healthcare work garments. To scientifically measure this, UniFirst turned to North American Science Associates Inc. (NAMSA) for an objective laboratory study.

NAMSA is a microbiology consulting service and Good Manufacturing Practice (GMP) testing laboratory with expertise in contamination controls for the medical device industry. NAMSA developed and executed formal protocols based on scientific laboratory methods to assess the microbiological contamination controls used by UniFirst in its Garment Service for Healthcare. The study was based on the guidelines set for controlling biocontamination on garments in laundering processes: ISO 14698 *Annex D and E Biocontamination Control of Laundry Services*, a guidance document for cleaning validations of reusable medical devices; AAMI TIR12:2010 *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: a guide for medical device manufacturers*, a guidance document for culturing microbial organisms; ANSI/AAMI/ISO 11737-1:2006/(R)2011 – *Sterilization of healthcare products – Microbiological methods – Part 1: Determination of the population of microorganisms on product* and applicable General Chapters of the United States Pharmacopeia (USP), and FDA healthcare safety guidelines and requirements.

The following is a summary of the studies conducted by NAMSA to evaluate the ability of UniFirst Garment Service for Healthcare to reduce and control microbial contamination during the laundering, processing and delivery, including a poly-wrap bag option, for healthcare industry work garments. Example healthcare garment items include soiled uniforms, soiled scrubs, and laboratory coats. Bacterial cross-contamination from all of these sources is a known cause of concern for both UniFirst and its many healthcare industry customers. This scientific laboratory analysis was commissioned by UniFirst to quantify pathogen reductions within the company's specialized garment service, Product Protection Process, and optional poly-wrap garment protection bag.

Test System Development

In order to correctly assess the microbial reduction power of UniFirst Garment Service for Healthcare and Product Protection Process, the testing needed to be conducted on healthcare industry relevant organisms. *However, wild type organisms are difficult to work with and can be dangerous to laboratory personnel. Therefore, using laboratory controlled organisms of similar types as the wild type is the preferred, safe, and effective method to demonstrate the microbial reduction power of the UniFirst PPP.*

The rationale for the organisms that were chosen for this study was based on the organisms most commonly associated with HAIs. The organisms were categorized based on bacteriological characteristics and the laboratory's ability to safely handle and work with the organisms. See Table 1 for selection of organisms used in this study.

Not only did the appropriate organisms have to be determined, but the garments used in the test had to be selected based on their ability to capture a majority of the related challenges garments could pose to the laundering system. In the end, an 80/20 polyester/cotton poplin blend was chosen because it is one of the most commonly used garments in the healthcare industry.

Table 1

Selected Organism	Organism Classification	Related Organisms	Gram Stain Reaction	Growth Characteristics
<i>Escherichia coli</i>	Enterobacteriaceae	<i>Shigella</i> , <i>Enterobacter</i> , <i>Salmonella</i>	Gram negative bacillus	aerobic
<i>Staphylococcus aureus</i>	Catalase positive organisms	<i>Enterococcus</i> , <i>Listeria</i> (rod shaped)	Gram positive	aerobic
<i>Pseudomonas aeruginosa</i>	Non-enteric, motile organisms	<i>Vibrio</i> , <i>Campylobacter</i>	Gram negative bacillus	aerobic
<i>Candida albicans</i>	Yeast (Saccharomycetes)	<i>Cryptococcus</i>	Gram positive	aerobic

Feasibility Study

A feasibility study was designed to evaluate the viability of populations of various healthcare industry-related and clinically relevant vegetative organisms (*Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Escherichia coli* and *Candida albicans*)³ directly inoculated onto garment swatches that were attached to new, full-size healthcare industry-style garments (Figure 1). This was necessary because vegetative organisms cannot survive for extended periods of time after inoculation on the test articles due to cellular dehydration. The data would demonstrate organism viability for a potential timeline of 12 hours from sample preparation to transportation to UniFirst (where they would be exposed to the garment processing steps), then transportation back to the lab where the test swatches would be cultured for determination of microbial reduction. In order to accurately assess the microbial reduction power of UniFirst Garment Service for Healthcare and the steam tunnel process, it was necessary to make sure these processes were reducing the organisms and not cellular dehydration. The feasibility study determined how long the test organisms inoculated on the swatches were able to survive.



Figure 1

Feasibility Study Results

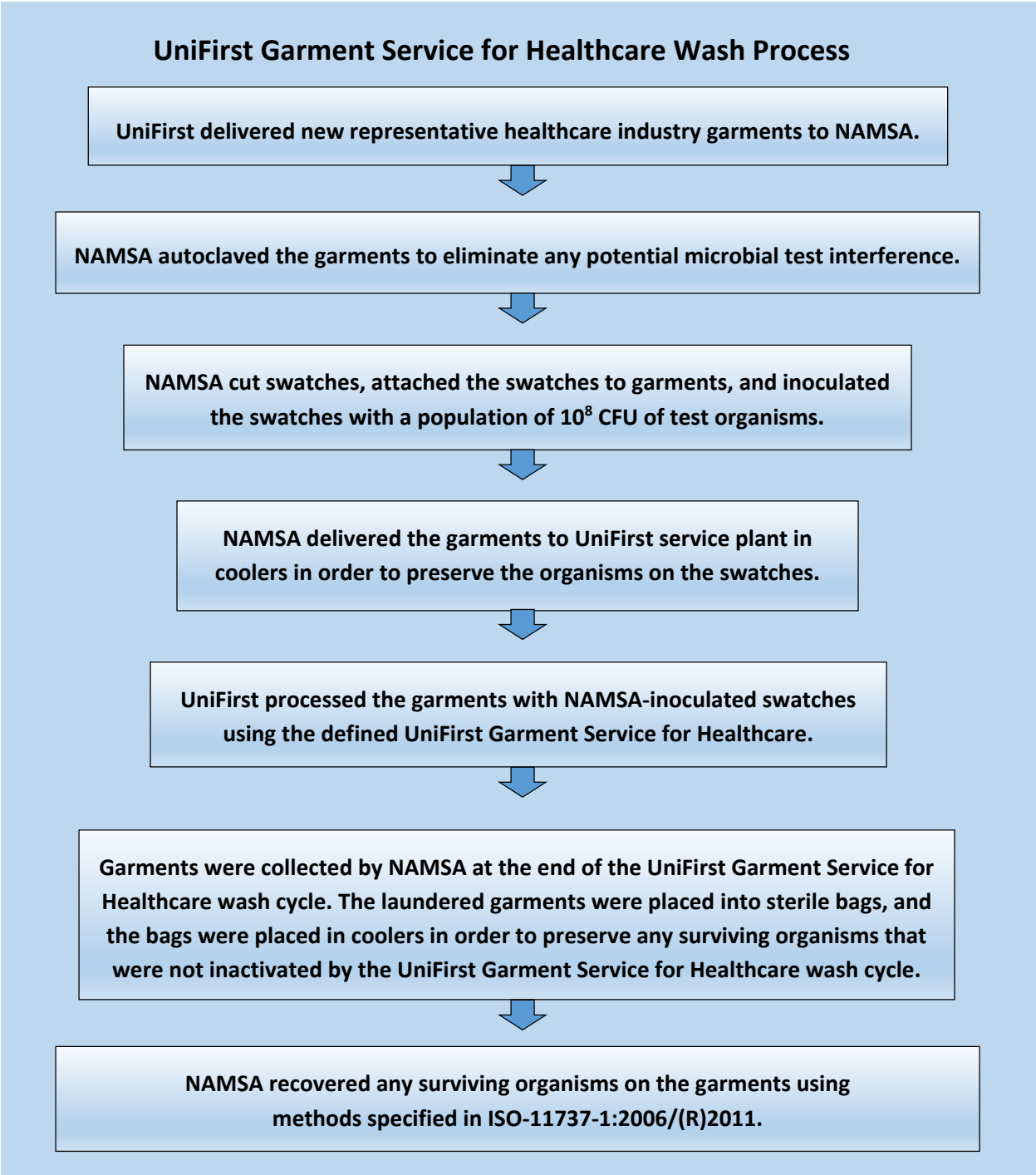
The feasibility study results demonstrated the inoculated garments needed to be kept cool in order to prevent organism die-off; therefore, the inoculated garments would need to be transported in coolers to and from the UniFirst processing facility. The feasibility study results also demonstrated that *Pseudomonas aeruginosa* was not a suitable organism for use in the test, as it did not survive the minimum 12-hour viability challenge time. It also demonstrated that these organisms, if present on garments used in the field, would not survive on garments once they are no longer on their host (i.e., person wearing the garment or the wet processing environment) due to cellular dehydration or die-off.

Taking into account the results of the feasibility study, the actual comprehensive study was designed and conducted as follows.

³ Centers for Disease Control and Prevention; Healthcare-associated Infections (HAIs) <http://www.cdc.gov/HAI/index.html>

UniFirst Testing Strategy

The study was designed with (1) accuracy, (2) precision, (3) selectivity, (4) sensitivity, (5) stability, and (6) reproducibility in mind. The UniFirst Garment Service for Healthcare study is illustrated in the flowcharts below.



UniFirst GMP Study for Steam Tunnel Process

UniFirst delivered a new set of representative healthcare industry garments to NAMSA.



NAMSA autoclaved the garments to eliminate any potential microbial test interference.



NAMSA cut swatches, attached the swatches to garments, and inoculated the swatches with a population of 10^8 CFU of test organisms.



NAMSA delivered the garments to UniFirst service plant in coolers in order to preserve the organisms on the swatches.



UniFirst processed the garments with the NAMSA-inoculated swatches using high temperature steam tunnel exposure.



Garments were collected by NAMSA at the end of the steam tunnel process. The steam-processed garments were placed into sterile bags and the bags were returned to coolers in order to preserve any surviving organisms that were not reduced by the steam tunnel exposure.



NAMSA recovered any contamination on the garments using methods specified in ISO-11737-1:2006/(R)2011.

The microbiological tests conducted were designed to assess the microbial load reduction capabilities of UniFirst Garment Service for Healthcare and Product Protection Process, as well as garment delivery cross-contamination prevention with optional poly-wrap garment bags. The tests conducted represent an exaggerated contamination scenario, as garment samples were inoculated with excessive quantities of bacteria (approximately 100 million organisms). Fabric swatches were used to localize the bacterial inoculation, and to make laboratory sampling as accurate and reproducible as possible. The swatches were cut from extra garments provided, made of the same materials as their host garments, in order to remain consistent with the routine garment materials. Three (3) indicator organisms were chosen to represent the different types of bacterial and fungal pathogens that are common sources of microbial contamination within the healthcare industry and were robust enough to survive the test sample transportation duration. The test organisms were used to challenge the three (3) main stages of the UniFirst PPP where microbial lethality and reduction of cross-contamination takes place:

1. Specialized healthcare garment wash cycle
2. Steam tunnel finishing/garment pressing cycle
3. Optional poly-wrap garment bagging

The test organisms selected to test the efficacy of UniFirst Garment Service for Healthcare and Product Protection Process were:

Escherichia Coli (E. coli) – A common gram-negative intestinal pathogen.

Staphylococcus aureus – A bacteria that is a common contaminant found in healthcare facilities, some strains are known to be antibiotic resistant.

Candida albicans – A clinically relevant yeast that has widespread infection potential.

UniFirst Process Testing

Fabric swatches (16 cm² area, Figure 2) were separately inoculated with the indicator organisms, attached to full garments (matching fabric types), and packed into coolers for transport to UniFirst. Once at UniFirst, the garments were removed from coolers and bags and exposed to each step of the UniFirst Garment Service for Healthcare. Each one of the three (3) processing steps were challenged separately in order to quantify the microbial reduction power of each step. Each step was tested three (3) times with three (3) lab garments. The replicate testing demonstrates consistency and reproducibility. After exposure to each individual processing step, the garments were collected and placed individually into sterile bags and into coolers for transportation back to the laboratory. Positive control garments containing inoculated swatches that were exposed to all the study conditions, with the exception of the microbial reduction steps of UniFirst Garment Service for Healthcare, were transported with the test garments.

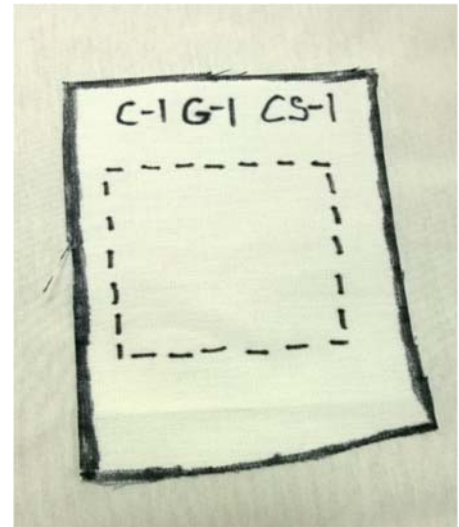


Figure 2

Once all samples were transported back to the NAMSA laboratory, the swatches were removed from the garments and cultured for surviving organisms using a validated organism recovery method.

All methods were validated to demonstrate accuracy, precision, consistency and robustness of the test methods.

UniFirst Process Testing Study Results

The testing process and subsequent lab results demonstrate that UniFirst Garment Service for Healthcare reduces bacterial contamination levels on work garments by >99.9999%.

The results achieved with UniFirst Garment Service for Healthcare utilizing UniFirst's specialized formula detergent shows a 99.9999% reduction of all three critical organisms, when compared to the positive controls. The results achieved using UniFirst Garment Service for Healthcare are shown in Table 2 and Figure 3. The results achieved with the high temperature steam tunnel exposure achieved at least a 99.9999% reduction of all three critical organisms. The results of the steam tunnel process are shown in Table 3 and Figure 4.

Table 2: UniFirst Garment Service for Healthcare Wash Cycle Results

Challenge Organism	Initial Inoculum Challenge Without UniFirst Wash Cycle Process (Positive Controls)	Recovery Counts Post-UniFirst Garment Service for Healthcare Wash Cycle Process	Microbial Percent Reduction of Post-UniFirst Garment Service for Healthcare Wash Cycle Process
<i>Escherichia coli</i>	3.3×10^6	1.0×10^1	>99.9999%
<i>Staphylococcus aureus</i>	9.1×10^7	6.3×10^0	>99.9999%
<i>Candida albicans</i>	1.4×10^8	1.6×10^2	>99.9999%

Figure 3: Inoculated Healthcare Industry Garments Exposed to UniFirst Garment Service for Healthcare Wash Cycle

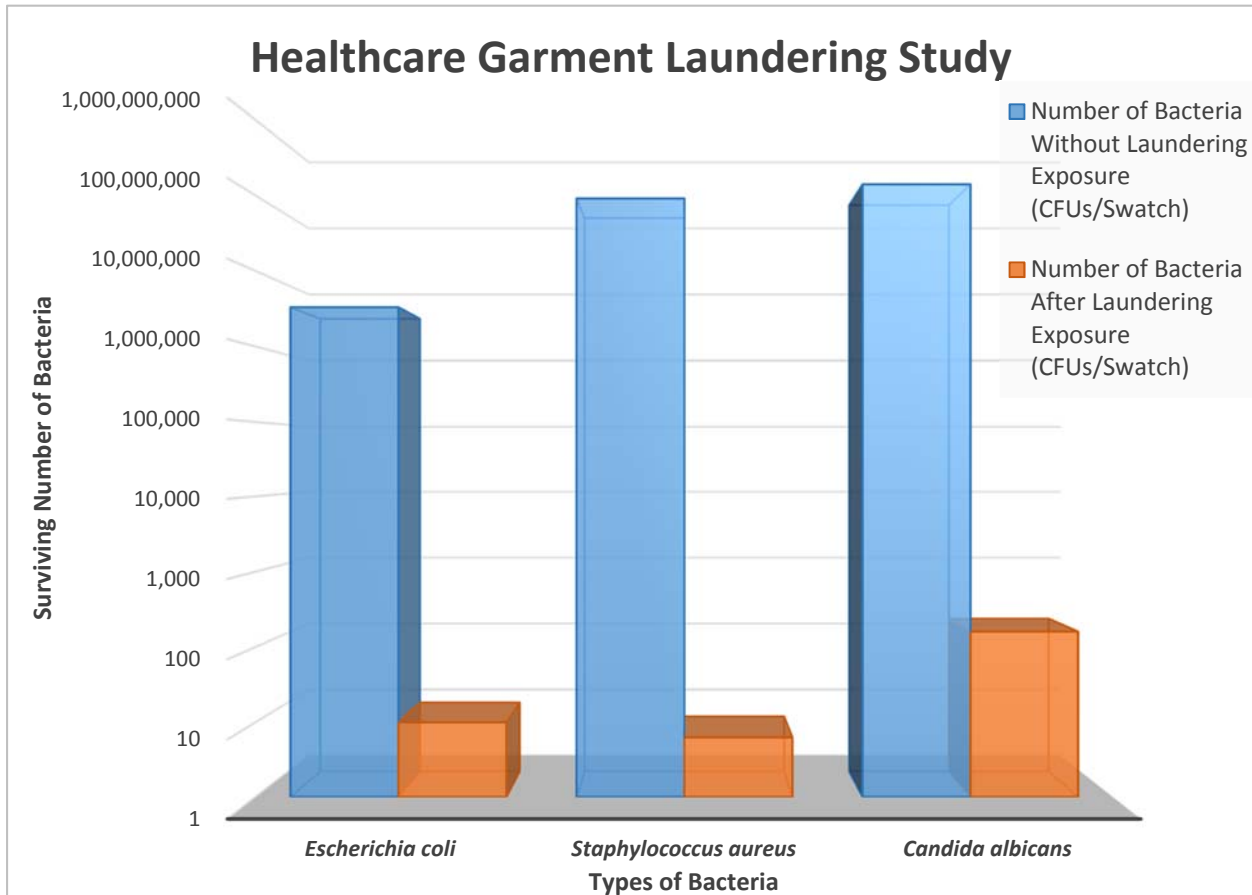
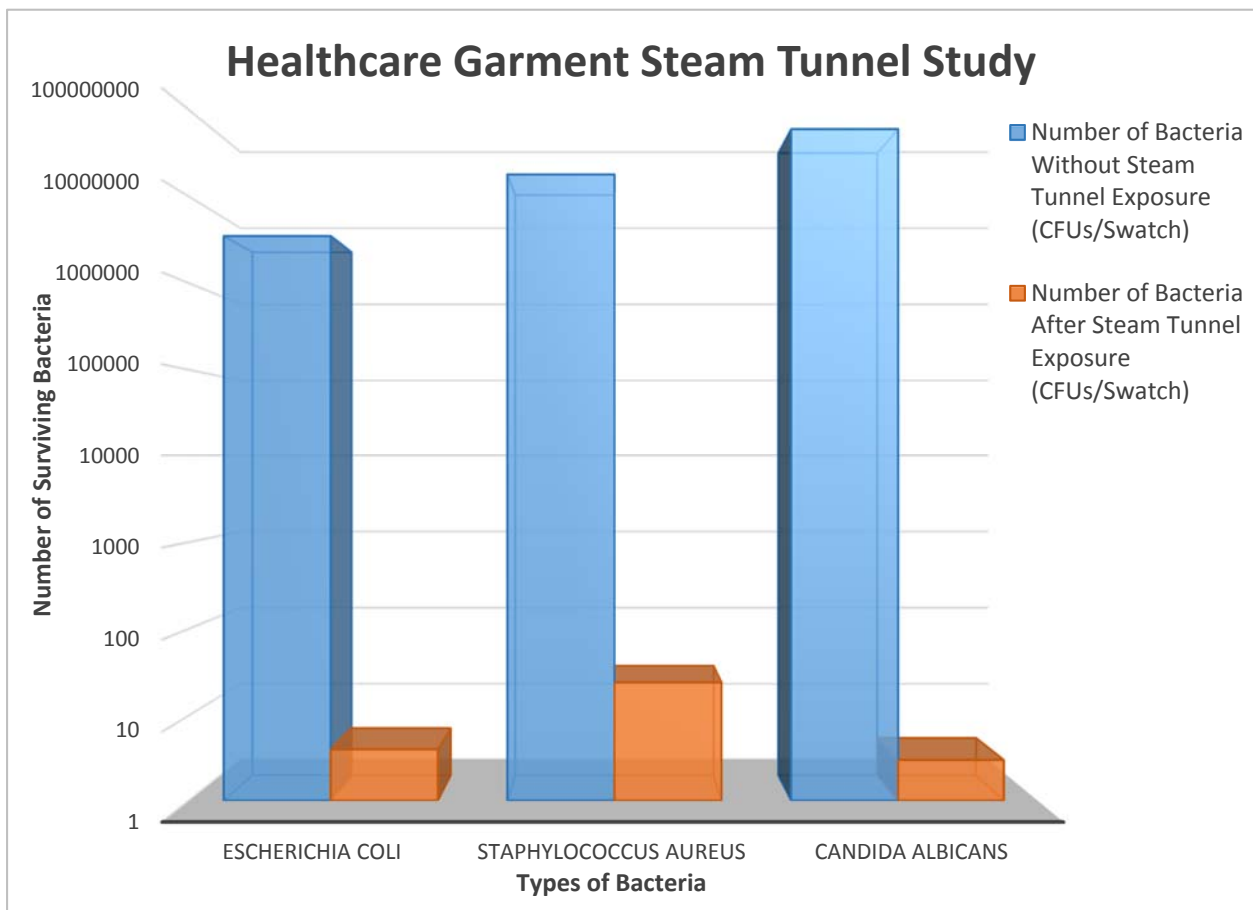


Table 3: UniFirst Garment Service for Healthcare Steam Tunnel Process Results

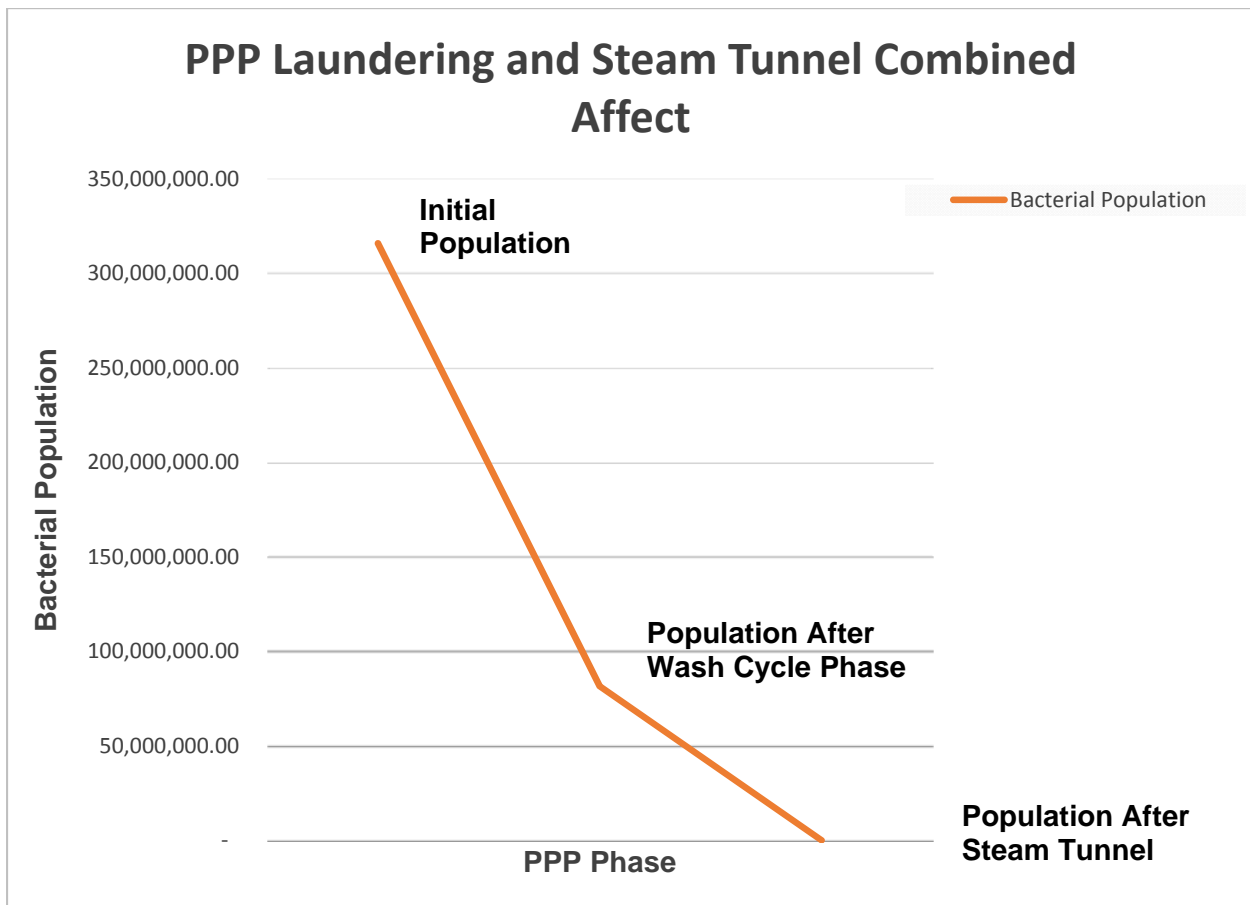
Challenge Organism	Initial Inoculum Challenge Without UniFirst Garment Service for Healthcare Steam Tunnel Process (Positive Controls)	Recovery Counts Post-UniFirst Garment Service for Healthcare Steam Tunnel Process	Microbial Percent Reduction of UniFirst Garment Service for Healthcare Steam Tunnel Process
<i>Escherichia coli</i>	3.5×10^6	4.3×10^0	>99.9999%
<i>Staphylococcus aureus</i>	1.8×10^7	2.4×10^1	>99.9999%
<i>Candida albicans</i>	6.0×10^7	3.0×10^0	>99.9999%

Figure 4: Inoculated Healthcare Industry Garments Exposed to UniFirst Garment Service for Healthcare Steam Tunnel



Each of the laundering and steam tunnel steps in the Product Protection Process demonstrated it is effective in reducing over 100 million organisms per process. UniFirst Garment Service for Healthcare consistently reduces harmful bacteria and yeast levels on soiled healthcare industry garments.

Figure 5: UniFirst Garment Service for Healthcare PPP Wash Cycle and Steam Tunnel Combined Effect



The microbial testing challenged inherent intrinsic parameters of UniFirst Garment Service for Healthcare and steam tunnel processing to demonstrate quantifiable microbial contamination reduction in the specialized wash process and high temperature steam tunnel/garment press finishing. Each critical process has a significant impact on the reduction of bacteria from worn garments. In fact, **Figure 5 demonstrates the combined effect and the clear advantage that UniFirst Garment Service for Healthcare provides.** UniFirst Garment Service for Healthcare provides redundant microbial lethality that results in hygienic cleanliness of soiled garments. This comprehensive study shows UniFirst and its customers the proven methods based on GMP tests that indicate definitive pathogen reduction from garment processing, and highlights the microbicidal effectiveness of UniFirst Garment Service for Healthcare for effectively processing healthcare industry garments.

The study results demonstrate the reduction of microbial contamination in the processing of healthcare industry garments. The microorganisms are reduced in very significant quantities by the laundering and steam tunnel operations as depicted in the CCPs and the entire UniFirst Garment Service for Healthcare and PPP. The microbial lethality of UniFirst Garment Service for Healthcare is exhibited across various types of microorganisms from bacteria to yeasts. The broad spectrum microbial lethality of the specialized service, as demonstrated in this study, indicates that common healthcare contaminants will be effectively eradicated.

In Figure 5, the lethality efficiency of the UniFirst Garment Service for Healthcare wash cycle is further exhibited on the individual challenge organisms. The initial challenge levels were between 3 million and 140 million organisms. The recovery after UniFirst Garment Service for Healthcare was between 6 and 160 CFU. The steam tunnel had a similar effect on the challenge organisms. The population of organisms on garments going into the steam tunnel was between 5 million and 85 million organisms. The population recovered after the steam tunnel process was between 4 and 34 CFU. The combination of the two processes used together effectively eliminated over 300 million organisms. This demonstrates that UniFirst Garment Service for Healthcare effectively eradicates a broad spectrum of bacteria and yeasts that represent the majority of healthcare industry related pathogens.

The charts and graphs of this study depict the overall effectiveness of UniFirst Garment Service for Healthcare in killing microorganisms. It provides a visual assessment of the removal of microorganisms from soiled healthcare garments. These garments are worn in proximity to healthcare activities and patients; therefore, keeping them hygienically clean is an important control point.

Test results demonstrate that soiled/contaminated healthcare industry garments can be laundered, serviced, and returned to customers hygienically clean and virtually pathogen-free as a result of the inherent microbicidal properties of UniFirst Garment Service for Healthcare.

Poly-Wrap Garment Bag Effectiveness Testing and Results

The efficaciousness of the poly-wrap garment protection bags was tested by dividing 20 new healthcare industry garments into two (2) test groups: one (1) group of 10 garments was processed through UniFirst Garment Service for Healthcare then placed in a poly-wrap garment protection bag and transported to the lab for testing; the other group of 10 garments was processed through UniFirst Garment Service for Healthcare and transported to the lab for testing without the use of poly-wrap garment protection bags. Once at the lab, both groups of garments were individually tested for bacterial contamination levels.

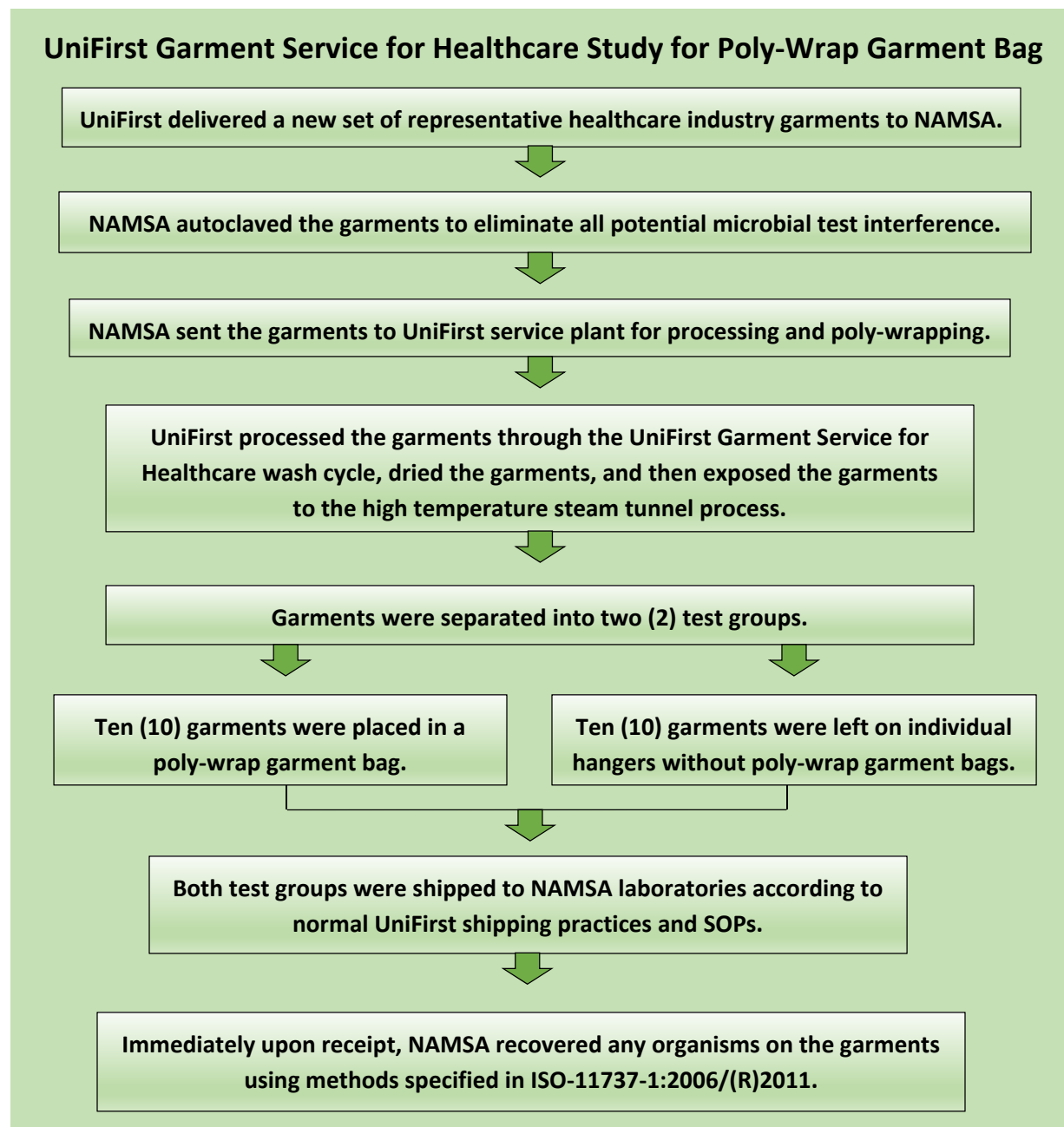
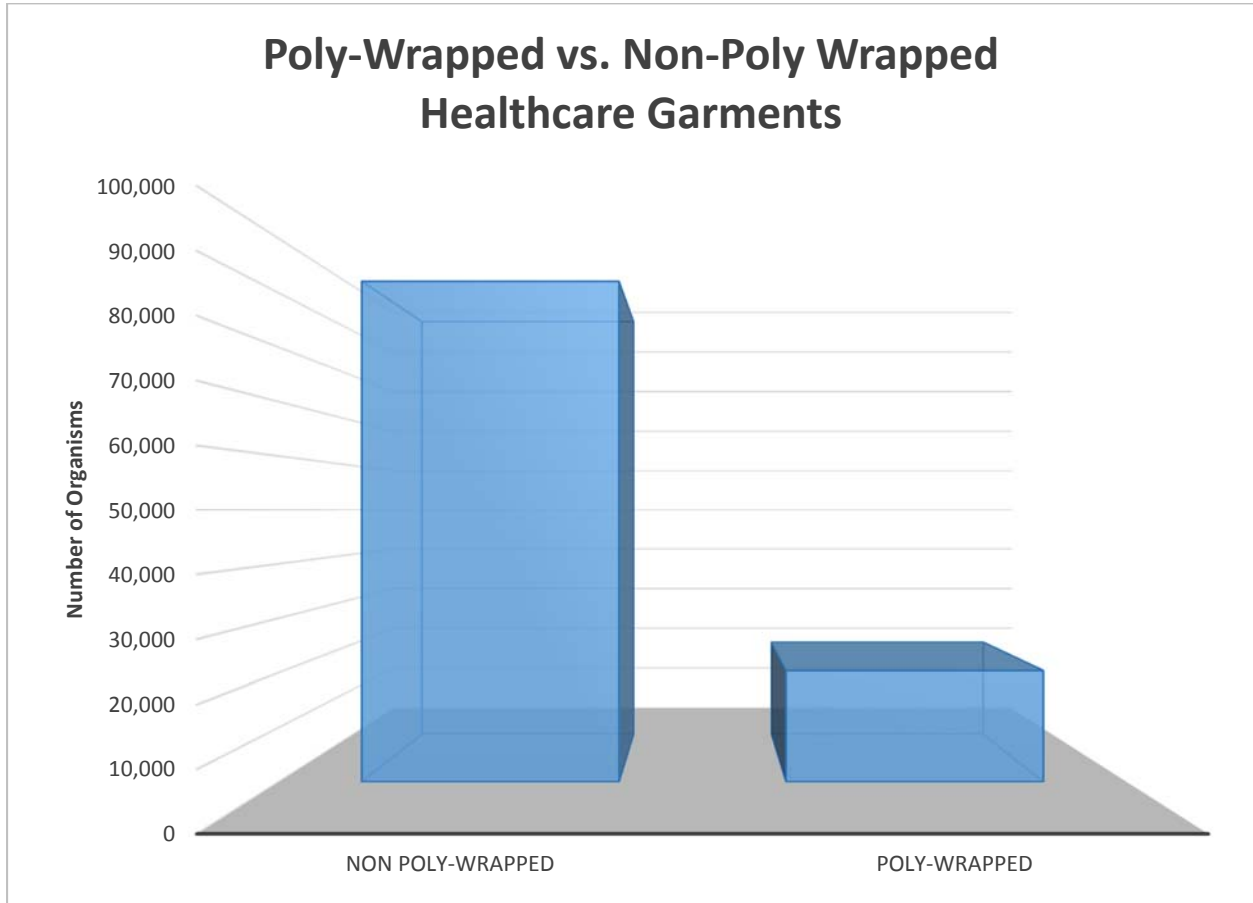


Figure 6: Poly-Wrap Garment Production Bag Effectiveness



The results of the study evaluated the microbial contamination protection potential of the poly-wrap garment protection bag determined that using the poly-wrap garment protection bag resulted in **77.8% fewer microorganisms** than the garments without the poly-wrapped protection. Figure 6 depicts the comparison in the number of organisms recovered on garments that were shipped without garment protection bags (92,080 CFU) versus the number of organisms recovered on garments that were shipped inside of the poly-wrap garment protection bags (20,407 CFU). This study demonstrates a clear advantage by using UniFirst poly-wrap garment protection bags in the transportation process of the cleaned garments.

Conclusions

Laboratory tests indicate that UniFirst Garment Service for Healthcare and Product Protection Process reduces bacterial contamination levels on workwear by >99.9999%.

UniFirst Garment Service for Healthcare is a systematic, preventive approach to controlling potential microbiological hazards associated with healthcare work garments. UniFirst Garment Service for Healthcare works effectively to reduce microbiological contamination to safe levels (reduces microbial contamination levels on workwear by >99.9999%).

This study measured, monitored, and documented the effectiveness of UniFirst Garment Service for Healthcare and demonstrated that it, along with the Product Protection Process, is a consistent pathogen reduction methodology for laundering and processing healthcare-related work garments. It provided proof of effective garment disinfection consistent with the safety goals of those in healthcare industries.

**UniFirst Garment Service for Healthcare is available from UniFirst Corporation:
800.225.3364 / unifirst.com.**

Endnote

The testing and results documented in this paper reflect UniFirst's Standard Operating Procedures (SOPs) in place at the time the study was conducted. Wash formula and processing innovations in the textile services industry may result in UniFirst varying these SOPs. However, any such variations are expected to yield comparable levels of hygienically clean results consistent with CDC and OSHA guidelines and standards.

About NAMSA®

NAMSA is the global medical research organization providing comprehensive services to advise clients and evaluate the safety and efficacy of medical devices, IVDs, and combination products. For nearly 50 years, NAMSA clients have utilized its consulting, testing, and clinical services to bring safe and effective therapies to market.

Definitions

Critical Control Points (CCPs) – Crucial points, steps, or procedures within a process for controlling cross contamination where controls can be applied and contamination can be prevented, eliminated, or reduced to acceptable levels.

FDA – The Food and Drug Administration is an agency of the United States Department of Health and Human Services, a U.S. federal executive department. The FDA is responsible for protecting and promoting public health through the regulation and supervision of healthcare safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceuticals/medications, vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), veterinary products, and cosmetics.

GMP – Good Manufacturing Practices are practices and the systems required to be adapted in pharmaceutical manufacturing, quality control, and quality system covering the manufacture and testing of pharmaceuticals or drugs, including active pharmaceutical ingredients, diagnostics, healthcare, pharmaceutical products, and medical devices. GMPs provide guidance that outlines the aspects of production and testing that can impact the quality of a product.

HAI – Healthcare-associated infections. These are infections that patients get while receiving treatment in healthcare facilities for medical or surgical conditions.

ISO – International Organization for Standardization is an international standard-setting body composed of representatives from various national standards organizations. Founded in 1947, the organization promulgates worldwide proprietary, industrial, and commercial standards.

Microbiology Terminology

- **Bacterium** – Prokaryotic microorganisms typically a few micrometers in length that exhibit two (2) shapes ranging from spheres (cocci) to rods (bacilli). Bacteria are present in most habitats, growing in almost all types of environments. There are typically 40 million bacterial cells in a gram of soil and a million bacterial cells in a milliliter of fresh water. In all, there are approximately five nonillion (5×10^{30}) bacteria on Earth, forming a biomass that exceeds that of all plants and animals.
- **CFU** – A colony forming unit is the microbiological term to quantify a single organism. Study levels for pathogenic challenges were greater than 100 million organisms or CFU.
- **Fungus** – A member of a large group of eukaryotic organisms that includes microorganisms, such as yeasts and molds. These organisms are classified separate from plants, animals, and bacteria.
- **Pathogen** (aka, infectious agent or germ) – A microbe, microorganism such as a bacterium, or fungus that causes disease in its animal or plant host.

Product Protection Process (PPP) – The Product Protection Process is UniFirst’s portal-to-portal servicing procedure specifically designed to prevent cross-contamination threats from being carried on uniforms and other worker garments. PPP begins at the customer’s facility and extends throughout all handling, laundering, and finishing to safely deliver hygienically clean garments on a regular schedule.

UniFirst Garment Service for Healthcare – UniFirst’s specialized garment safety program specifically designed to limit potential bacterial contaminants that could be associated with healthcare employee workwear. The program follows healthcare laundering guidelines set forth by the CDC (*Guidelines for Environmental Infection Control*, 2003), OSHA’s guidelines for handling contaminated laundry (*Bloodborne Pathogens Standard*, 1910.1030), and *Universal Precautions for Preventing Transmission of Bloodborne Infections*.