

# **COMPARISON VALIDATION OF THE CINTAS INDUSTRIAL CLEANING PROCESS OF CLEANROOM GARMENTS VERSUS THE CINTAS CLEANROOM CLEANING PROCESS OF CLEANROOM GARMENTS USED IN FOOD PROCESSING INDUSTRIES**

## **I. Purpose**

This trial is one component of the complete validation of the industrial cleaning process of Cleanroom garments for food processing companies and services provided by Cintas Corporation. The purpose of this trial is to compare the final viable (microbial) bioburden of Cleanroom laundering of Cleanroom garments used in the food processing industry with the final viable (microbial) bioburden of industrial laundering of Cleanroom garments used in the food processing industry.

Cleanroom laundering of Cleanroom garments is typically performed for reusable garments used in all contamination controlled manufacturing in such industries as aerospace, semiconductor, microelectronics, disc drive, medical device, pharmaceutical and now food processing.

The Cleanroom laundering process at Cintas Cleanroom Resources is fully validated. Documented evidence of validation is available for review at the facility.

## **II. Background**

Each Cintas Cleanroom Resources facility has validated their Cleanroom processing cycles. Each facility adheres to Cintas Corporate policies, Cleanroom Division policies and procedures, the Cleanroom Division Quality Manual, and location-specific standard operating procedures. All of these documents are available for review at each facility.

The “six-log microbial reduction industrial wash process” used in Cintas industrial locations is validated for non-cleanroom garments used in food processing industries. This process is known to be deleterious to the physical properties of many Cleanroom fabrics and components. Over the years, Cintas has tested and validated the fabrics and components of the Cleanroom garments to determine the most durable, Cleanroom compatible, gamma compatible Cleanroom garment system. Over time, the fabric and components will degrade.

The purpose of this trial was to compare the final microbial bioburden of the Cleanroom garments laundered in each process.

## **III. Scope**

The scope of this validation was to determine the final microbial bioburden of Cleanroom laundered Cleanroom garments versus industrial laundered Cleanroom garments used in a typical food processing manufacturing scenario.

NOTE: This trial does not evaluate the two processes for garment integrity over the life of the garment.

#### IV. Procedure

##### A. Specifications

NOTE: The following specifications are based on historical device bioburden results for Cleanroom garments at Cintas Cleanroom Resources.

1. < 47 CFU (colony forming units)/garment.

##### B. Materials

Five Integrity-1800 coveralls processed at Cintas Loc# 342, Normal, IL.  
Five Integrity-1800 coveralls processed at Cintas Loc# 236, Greenville, SC.

Tryptic Soy Agar (TSA) with Lecithin and Polysorbate 80 (Tween 80), Rodac™ plates, Catalog # P3500, Lot# 46106-1, Expiration date: July 14, 2004. Supplied by PML Microbiologicals, 27120 SW 95<sup>th</sup> Avenue, Wilsonville, OR 97070, (800) 547-0659.

##### C. Methods

1. Integrity 1800 coveralls were Cleanroom processed per the validated Cleanroom laundering process at Cintas Cleanroom Resources, Greenville, SC.
2. Integrity 1800 coveralls were industrially processed per the “six-log microbial reduction” wash formula at Cintas, Normal, IL.
3. The Integrity 1800 coveralls processed at Greenville, SC were individually packaged in Cleanroom compatible, gamma compatible antistatic Cleanroom bags inside the ISO Class 3 cleanroom.
4. The Integrity 1800 coveralls processed at Normal, IL were placed in a plastic bag and shipped to the Greenville, SC facility for microbial testing.

5. Five Integrity 1800 coveralls from each laundering process were selected for surface microbial testing.
6. The surface microbial testing method selected is routinely used in the FDA regulated industries for medical devices and pharmaceutical manufacturing for personnel monitoring for presence of aerobic bacteria, molds and yeasts.
7. The front and back surfaces of each coverall were tested by placing the Rodac™ plate firmly on the fabric surface. The plates were incubated for aerobic bacteria for three days at 32° C +/- 2° C and an additional two more days for molds and yeasts at room temperature per Cintas SOP-11, "Monitoring Cleanrooms for Microbial Content".
8. The results for each coverall were recorded. Refer to Table 1.

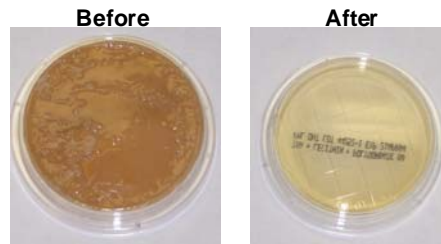
D. Attachments

1. Table 1. Surface Microbial data. Specification: < 47 CFU (colony forming units) per garment.

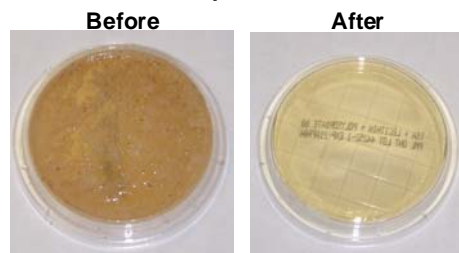
I-1800 Coverall	1	2	3	4	5	Average Bioburden
Cleanroom Processed	0	0	0	0	1	0.2 CFU
Industrial Processed	1	0	3	0	0	0.8 CFU

2. Table 2. Pictorial results of above data.

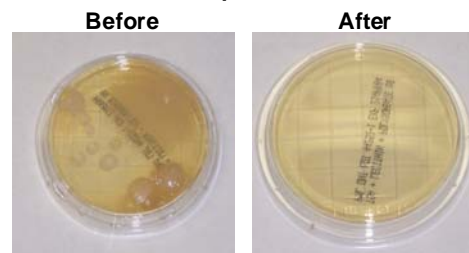
Sample 1



Sample 2



Sample 3



V. Discussion of Results

- A. The results of the Cleanroom processed garments provide documented evidence that the Cleanroom laundering process produces garments that are free of food pathogenic bacteria, molds and yeasts.
- B. The results of the industrial processed garments provide documented evidence that the industrial laundering process produces garments that are free of food pathogenic bacteria, molds and yeasts.
- C. The historical device bioburden average for Cleanroom processed garments at Greenville, SC was (2001=17.6 CFU, 2002=8.6 CFU, 2003=11.6 CFU) well below the maximum level of < 47 CFU required for gamma sterilization of the Cleanroom garments.
- D. The aesthetic evaluation of the coveralls washed in both wash formulas was unremarkable.
- E. The microbiological test data indicates both wash formulas remove pathogenic food microorganisms.

VI. Conclusions

- A. All bacteria cultured were typical airborne contaminants. No molds or yeasts were cultured.
- B. The major barrier properties to fluids, pore size and repellency of the fabric after industrial processing using the “six-log microbial reduction” wash process should be evaluated over the life of the garment.
- C. The conclusion is that these coveralls are processed using comparable cycles.

## VII. Summary

Testing was performed at Cintas Cleanroom Resources in Greenville, SC, to compare the Cintas validated “6 log microbe reducing” industrial wash process with the existing Cleanroom wash process for the Cleanroom garments used in the Mt. Pleasant, Iowa food processing plant. Each garment from both the Cleanroom and the industrial process was tested using a Rodac™ contact plate on the fabric surface of both the front and the back of the garment. Test results showed that the wash process of the industrial facility yielded comparable results to the Cleanroom wash process for removal of microbial organisms. This would indicate that the Cintas industrial wash process is suitable for removal of microbial bioburden at the same level as the current Cleanroom wash process.