

STAT EPID Data Report

NSF International Applied Research Center

Report Date: 29-July-2019

Customer Name: Process Cleaning Solutions
Contact: Michael Rochon
Description: ACC and *Clostridium difficile* Analysis of 195 total samples evaluating University Hospital's current Sporicidal Disinfection Procedure and PCS' Cleaning Process
Test Type: Test Only
Job Number: J-00334285, J-00335491, J-00338077
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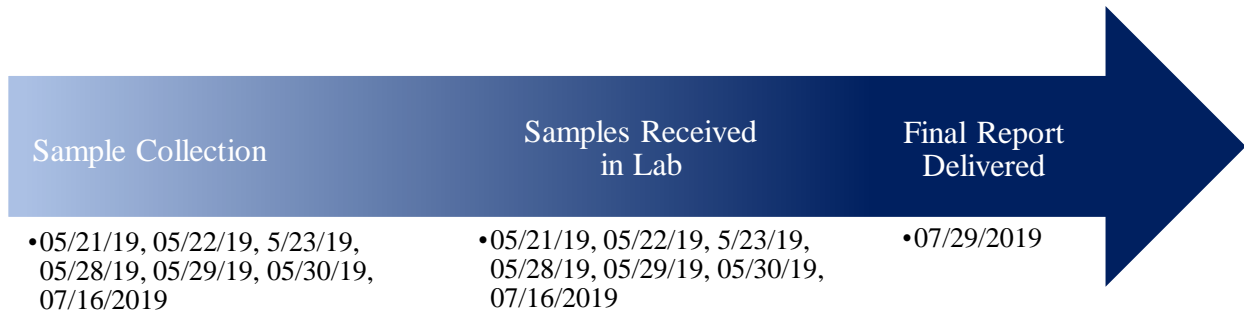
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Report Authorization: _____

Jesse Miller, Director, Applied Research Center

Timeline



Experimental Summary

Sample Collection

- A total of 195 swab samples were collected from a large teaching hospital in Michigan. Samples were collected pre-cleaning and post-cleaning for both the hospital's current sporicidal disinfection process as well as the PCS cleaning process. Sample collection for each of the cleaning processes occurred on different days.
- Seventy-five (75) samples were collected before cleaning.
- Sixty (60) samples were collected post-cleaning with the hospital's current sporicidal disinfection process.
- Sixty (60) samples were collected post-cleaning with the PCS process, which involved the use of ready-to-use disposable wipes pre-charged in a 200-ppm hypochlorite solution with a neutral pH of 8.5-9.5.
- All cleaning was performed by trained hospital environmental services staff. Dry time was not timed by staff or by NSF International. Efficacy for daily cleaning was observed only (discharge cleaning was not considered).
- Rooms were chosen randomly based on availability for cleaning as determined by the environmental services staff. Surfaces sampled include:
 - Top of Toilet Seat
 - Bedside Table
 - Bed Rail: Bed rail samples were taken from the side rail or foot rail depending on patient positioning and availability.
 - Other: When the target surface was not accessible, an alternative surface (i.e. sink, call button, bathroom hand grab bar, and chair arm rest) was selected for sampling.
- After sample collection, all rooms were re-cleaned by staff using their existing sporicidal disinfectant. Sampling was not performed after this reclean.
- All samples were transported in cold conditions to the NSF microbiology lab on the same day of collection.

Methodology

- Samples arrived cold to the microbiology test laboratory.
- All samples were analyzed for total aerobic colony counts (ACC) and for presence/absence of *Clostridium difficile*.
- Upon receipt, each swab was vortexed and plated (dilution factor = 10 for all samples).
- Samples were plated by spread plate method. Triplicate plating of neat only was performed.
- Samples were incubated at 37°C for 48 hours. After 48 hours, colonies were counted, and CFU/sample reported.
- The upper limit of detection is >300 CFU/sample or >30 CFU/cm². The lower limit of detection is <10 CFU/sample or <0.10 CFU/cm².
- *C. difficile* samples were processed using CCMB-TAL media. Samples were incubated at 37°C for 48 hours. Samples were analyzed at 24 and 48 hours.

Statistical Analysis

- CFU/sample were converted to CFU/cm² under the assumption that a surface area of approximately 100cm² was sampled.

Results

Table 1: Results for samples collected on May 21, 2019 before and after application of the sporicidal disinfectant reported in average CFU/cm² and Presence/absence of *C. difficile*.

| Sporicidal Disinfection | | | | | | |
|-------------------------|------------------------|------------------------|-----------------------------|---------------------------------------|-----------------------------|---------------------------------------|
| | | | Before | | After | |
| Date | Room | Item | Average CFU/cm ² | <i>C. difficile</i> Present or Absent | Average CFU/cm ² | <i>C. difficile</i> Present or Absent |
| 5/21/2019 | 5438 | Bedside Table | N/A | N/A | <0.10 | Absent |
| | 5438 | Call Button | N/A | N/A | 0.30 | Absent |
| | 5438 | Bathroom Hand Grab Bar | N/A | N/A | 0.37 | Absent |
| | 5438 | Top Toilet Seat #1 | N/A | N/A | 0.93 | Absent |
| | 5438 | Top Toilet Seat #2 | N/A | N/A | <0.10 | Absent |
| | 5437 | Bathroom Hand Grab Bar | N/A | N/A | 0.20 | Absent |
| | 5437 | Bedside Table | N/A | N/A | 1.83 | Absent |
| | 5437 | Top Toilet Seat #1 | N/A | N/A | 3.27 | Absent |
| | 5437 | Top Toilet Seat #2 | N/A | N/A | >30 | Absent |
| | 5437 | Bed Rail Side | N/A | N/A | >30 | Absent |
| | 5432 | Bedside Table | N/A | N/A | 0.43 | Absent |
| | 5432 | Bed Rail Side | N/A | N/A | 7.30 | Absent |
| | 5432 | Top Toilet Seat #1 | N/A | N/A | 4.90 | Absent |
| | 5432 | Top Toilet Seat #2 | N/A | N/A | 0.23 | Absent |
| | 5432 | Bathroom Hand Grab Bar | N/A | N/A | <0.10 | Absent |
| | 5431 | Bedside Table | N/A | N/A | 1.43 | Absent |
| | 5431 | Bed Rail Side | N/A | N/A | >30 | Absent |
| | 5431 | Top Toilet Seat #1 | N/A | N/A | 0.10 | Absent |
| | 5431 | Top Toilet Seat #2 | N/A | N/A | <0.10 | Absent |
| | 5431 | Bathroom Hand Grab Bar | N/A | N/A | <0.10 | Absent |
| | 5433 | Bedside Table | N/A | N/A | 0.37 | Absent |
| | 5433 | Bed Rail Side | N/A | N/A | 3.00 | Absent |
| | 5433 | Top Toilet Seat #1 | N/A | N/A | <0.10 | Absent |
| | 5433 | Top Toilet Seat #2 | N/A | N/A | <0.10 | Absent |
| | 5433 | Bathroom Hand Grab Bar | N/A | N/A | <0.10 | Absent |
| | 5435 | Chair Arm Rest | N/A | N/A | 0.43 | Absent |
| | 5435 | Top Toilet Seat #1 | N/A | N/A | >30 | Absent |
| | 5435 | Top Toilet Seat #2 | N/A | N/A | >30 | Absent |
| 5435 | Bedside Table | N/A | N/A | 0.97 | Absent | |
| 5435 | Bathroom Hand Grab Bar | N/A | N/A | >30 | Absent | |

Table 2: Results for samples collected on May 22, 2019 before and after application of the sporicidal disinfectant reported in average CFU/cm² and Presence/absence of *C. difficile*.

| Sporicidal Disinfection | | | | | | |
|-------------------------|---------------|-----------------|-----------------------------|---------------------------------------|-----------------------------|---------------------------------------|
| | | | Before | | After | |
| Date | Room | Item | Average CFU/cm ² | <i>C. difficile</i> Present or Absent | Average CFU/cm ² | <i>C. difficile</i> Present or Absent |
| 5/22/2019 | 5430 | Call Button | 0.23 | Absent | <0.10 | Absent |
| | 5430 | Bedside Table | 0.53 | Absent | <0.10 | Absent |
| | 5430 | Top Toilet Seat | 3.77 | Absent | <0.10 | Absent |
| | 5431 | Top Toilet Seat | 30 | Absent | <0.10 | Absent |
| | 5431 | Call Button | 8.13 | Absent | 0.6 | Absent |
| | 5431 | Bed Rail Foot | 1.47 | Absent | <0.10 | Absent |
| | 5435 | Bedside Table | 8.87 | Absent | <0.10 | Absent |
| | 5435 | Bed Rail Foot | 30 | Absent | <0.10 | Absent |
| | 5435 | Top Toilet Seat | 30 | Absent | 16.60 | Absent |
| | 5137 | Top Toilet Seat | 25.50 | Absent | <0.10 | Absent |
| | 5137 | Bedside Table | 8.37 | Absent | <0.10 | Absent |
| | 5137 | Bed Rail Foot | 4.30 | Absent | <0.10 | Absent |
| | 5138 | Top Toilet Seat | 30 | Absent | <0.10 | Absent |
| | 5138 | Bed Rail Foot | 2.93 | Absent | <0.10 | Absent |
| 5138 | Bedside Table | 2.80 | Absent | <0.10 | Absent | |

Table 3: Results for samples collected on May 23, 2019 before and after application of the sporicidal disinfectant reported in average CFU/cm² and Presence/absence of *C. difficile*.

| Sporicidal Disinfection | | | | | | |
|-------------------------|---------------|-----------------|-----------------------------|---------------------------------------|-----------------------------|---------------------------------------|
| | | | Before | | After | |
| Date | Room | Item | Average CFU/cm ² | <i>C. difficile</i> Present or Absent | Average CFU/cm ² | <i>C. difficile</i> Present or Absent |
| 5/23/2019 | 5423 | Top Toilet Seat | 30 | Absent | 0.27 | Absent |
| | 5423 | Bedside Table | 30 | Absent | 7.97 | Absent |
| | 5423 | Bed Rail Foot | 10.90 | Absent | 0.13 | Absent |
| | 5424 | Top Toilet Seat | 0.23 | Absent | <0.10 | Absent |
| | 5424 | Bedside Table | <0.10 | Absent | <0.10 | Absent |
| | 5424 | Bed Rail Foot | 0.77 | Absent | <0.10 | Absent |
| | 5422 | Top Toilet Seat | 30 | Absent | <0.10 | Absent |
| | 5422 | Bedside Table | 0.33 | Absent | 14.70 | Absent |
| | 5422 | Bed Rail Foot | 30 | Absent | <0.10 | Absent |
| | 5129 | Top Toilet Seat | 0.10 | Absent | <0.10 | Absent |
| | 5129 | Bedside Table | 3.23 | Absent | <0.10 | Absent |
| | 5129 | Bed Rail Foot | 0.30 | Absent | <0.10 | Absent |
| | 5132 | Top Toilet Seat | 30 | Absent | >30 | Absent |
| | 5132 | Bedside Table | 30 | Absent | <0.10 | Absent |
| 5132 | Bed Rail Foot | 16.50 | Absent | <0.10 | Absent | |

Table 4: Results for samples collected on May 28, 2019 before and after the PCS cleaning process reported in average CFU/cm² and Presence/absence of *C. difficile*.

| PCS Cleaning Process | | | | | | |
|----------------------|------|-----------------|-----------------------------|---------------------------------------|-----------------------------|---------------------------------------|
| | | | Before | | After | |
| Date | Room | Item | Average CFU/cm ² | <i>C. difficile</i> Present or Absent | Average CFU/cm ² | <i>C. difficile</i> Present or Absent |
| 5/28/2019 | 5422 | Top Toilet Seat | 1.83 | Absent | 0.13 | Absent |
| | 5422 | Bed Rail Foot | 1.07 | Absent | <0.10 | Absent |
| | 5422 | Bedside Table | N/A | Absent | 0.77 | Absent |
| | 5432 | Bedside Table | 12.80 | Absent | <0.10 | Absent |
| | 5432 | Top Toilet Seat | 1 | Absent | <0.10 | Absent |
| | 5432 | Bed Rail Foot | 2.87 | Absent | 0.80 | Absent |
| | 5431 | Bed Rail Foot | 21.10 | Absent | 30.00 | Absent |
| | 5431 | Bedside Table | >300 | Absent | <0.10 | Absent |
| | 5431 | Top Toilet Seat | 14.10 | Absent | <0.10 | Absent |
| | 5138 | Bedside Table | 2.60 | Absent | 0.73 | Absent |
| | 5138 | Bed Rail Foot | 3.70 | Absent | <0.10 | Absent |
| | 5138 | Top Toilet Seat | >300 | Absent | <0.10 | Absent |
| | 5135 | Bedside Table | 1.17 | Absent | <0.10 | Absent |
| | 5135 | Top Toilet Seat | 17.40 | Absent | <0.10 | Absent |
| | 5135 | Bed Rail Foot | 0.20 | Absent | <0.10 | Absent |

Table 5: Results for samples collected on May 29, 2019 before and after the PCS cleaning process reported in average CFU/cm² and Presence/absence of *C. difficile*.

| PCS Cleaning Process | | | | | | |
|----------------------|------|-----------------|-----------------------------|---------------------------------------|-----------------------------|---------------------------------------|
| | | | Before | | After | |
| Date | Room | Item | Average CFU/cm ² | <i>C. difficile</i> Present or Absent | Average CFU/cm ² | <i>C. difficile</i> Present or Absent |
| 5/29/2019 | 5127 | Bedside Table | 1.83 | Absent | 0.43 | Absent |
| | 5127 | Bed Rail Foot | 1.47 | Absent | 0.13 | Absent |
| | 5127 | Top Toilet Seat | >300 | Absent | 0.23 | Absent |
| | 5129 | Bedside Table | 0.20 | Absent | <0.10 | Absent |
| | 5129 | Call Button | 1.43 | Absent | 0.10 | Absent |
| | 5129 | Top Toilet Seat | 3.10 | Absent | <0.10 | Absent |
| | 5124 | Bedside Table | 2.77 | Absent | <0.10 | Absent |
| | 5124 | Call Button | 0.73 | Absent | 0.10 | Absent |
| | 5124 | Top Toilet Seat | 20.20 | Absent | 1.07 | Absent |
| | 5123 | Bedside Table | >300 | Absent | 4.13 | Absent |
| | 5123 | Bed Rail Foot | >300 | Absent | <0.10 | Absent |
| | 5123 | Top Toilet Seat | >300 | Absent | 0.27 | Absent |
| | 5132 | Bedside Table | 1.90 | Absent | <0.10 | Absent |
| | 5132 | Bed Rail Foot | 0.43 | Absent | <0.10 | Absent |
| | 5132 | Top Toilet Seat | 0.93 | Absent | <0.10 | Absent |

Table 6: Results for samples collected on May 30, 2019 before and after the PCS cleaning process reported in average CFU/cm² and Presence/absence of *C. difficile*.

| PCS Cleaning Process | | | | | | |
|----------------------|-----------------|-----------------|-----------------------------|---------------------------------------|-----------------------------|---------------------------------------|
| | | | Before | | After | |
| Date | Room | Item | Average CFU/cm ² | <i>C. difficile</i> Present or Absent | Average CFU/cm ² | <i>C. difficile</i> Present or Absent |
| 5/30/2019 | 5430 | Bedside Table | 1.83 | Absent | N/A | N/A |
| | 5430 | Sink | N/A | N/A | 1.57 | Absent |
| | 5430 | Bed Rail Foot | 2.93 | Absent | <0.10 | Absent |
| | 5430 | Top Toilet Seat | >300 | Absent | 1.30 | Absent |
| | 5432 | Bedside Table | 10.50 | Absent | 2.53 | Absent |
| | 5432 | Bed Rail Foot | 0.17 | Absent | <0.10 | Absent |
| | 5432 | Top Toilet Seat | 0.57 | Absent | <0.10 | Absent |
| | 5437 | Bedside Table | 6.67 | Absent | <0.10 | Absent |
| | 5437 | Bed Rail Foot | 0.99 | Absent | <0.10 | Absent |
| | 5437 | Top Toilet Seat | 12.10 | Absent | 0.10 | Absent |
| | 5138 | Bedside Table | 1.20 | Absent | <0.10 | Absent |
| | 5138 | Bed Rail Foot | 8.87 | Absent | 0.13 | Absent |
| | 5138 | Top Toilet Seat | >300 | Absent | 0.63 | Absent |
| | 5137 | Bedside Table | 12.90 | Absent | <0.10 | Absent |
| | 5137 | Bed Rail Foot | 2.77 | Absent | 0.10 | Absent |
| 5137 | Top Toilet Seat | 2.33 | Absent | <0.10 | Absent | |

Table 7: Results for samples collected on July 16, 2019 after application of the PCS cleaning process. Data reported in average CFU/cm² and Presence/absence of *C. difficile*.

| PCS Cleaning Process | | | | | | |
|----------------------|------|-----------------|-----------------------------|---------------------------------------|-----------------------------|---------------------------------------|
| | | | Before | | After | |
| Date | Room | Item | Average CFU/cm ² | <i>C. difficile</i> Present or Absent | Average CFU/cm ² | <i>C. difficile</i> Present or Absent |
| 7/16/2019 | 5423 | Bedside Table | N/A | N/A | 4.47 | Absent |
| | 5423 | Top Toilet Seat | N/A | N/A | 0.40 | Absent |
| | 5423 | Bed Rail Foot | N/A | N/A | >23.5 | Absent |
| | 5424 | Bedside Table | N/A | N/A | 0.43 | Absent |
| | 5424 | Top Toilet Seat | N/A | N/A | <0.10 | Absent |
| | 5424 | Bed Rail Foot | N/A | N/A | <0.10 | Absent |
| | 5425 | Bedside Table | N/A | N/A | 2.17 | Absent |
| | 5425 | Top Toilet Seat | N/A | N/A | <0.10 | Absent |
| | 5425 | Bed Rail Foot | N/A | N/A | 2.33 | Absent |
| | 5427 | Bedside Table | N/A | N/A | 6.97 | Absent |
| | 5427 | Top Toilet Seat | N/A | N/A | 1.03 | Absent |
| | 5427 | Bed Rail Foot | N/A | N/A | 4.80 | Absent |
| | 5430 | Bedside Table | N/A | N/A | <0.10 | Absent |
| | 5430 | Top Toilet Seat | N/A | N/A | <0.10 | Absent |
| | 5430 | Bed Rail Foot | N/A | N/A | 1.23 | Absent |

Table 8: Descriptive Statistics of Total CFU/cm² for the total of 195 samples collected throughout the study.

| | Total Before | Sporicide | PCS |
|--------------------|--------------|-----------|-------|
| Number of values | 75 | 60 | 60 |
| Minimum | <0.10 | <0.10 | <0.10 |
| Maximum | >30.0 | >30.0 | >30.0 |
| Range | >30.0 | >30.0 | >30.0 |
| Mean | 10.9 | 4.61 | 1.53 |
| Std. Deviation | 12.10 | 9.82 | 4.95 |
| Std. Error of Mean | 1.39 | 1.27 | 0.64 |

Table 9: Descriptive statistics of total CFU/cm² after cleaning by item sampled (n=120).

| | Sporicide | | | | | PCS | | | | |
|--------------------|---------------|-------------|-----------------|---------------|-------|---------------|-------------|-----------------|---------------|-------|
| | Bedside Table | Call Button | Top Toilet Seat | Bed Rail Foot | Other | Bedside Table | Call Button | Top Toilet Seat | Bed Rail Foot | Other |
| Number of values | 15 | 3 | 22 | 13 | 7 | 19 | 2 | 20 | 18 | 1 |
| Minimum | <1.00 | <1.00 | <1.00 | <1.00 | <1.00 | <1.00 | 0.10 | <1.00 | <1.00 | 1.57 |
| Maximum | 14.70 | 0.60 | >30.0 | >30.0 | >30.0 | 6.97 | 0.10 | 1.3 | >30.0 | 1.57 |
| Mean | 1.85 | 0.30 | 6.65 | 5.42 | 4.43 | 1.15 | 0.10 | 0.26 | 3.51 | 1.57 |
| Std. Deviation | 4.10 | 0.30 | 11.83 | 11.11 | 11.28 | 2.01 | 0 | 0.42 | 8.61 | 0 |
| Std. Error of Mean | 1.06 | 0.17 | 2.52 | 3.08 | 4.26 | 0.46 | 0 | 0.09 | 2.03 | 0 |

Table 10: Unpaired t test of total CFU/cm². For the statistical analysis, values reported as <0.10 and >300 CFU/cm² were converted to 0 and 300, respectively, for statistical calculation.

| | PCS vs. Sporicide | Total Before Cleaning vs After Sporicide use | Total Before Cleaning vs. After PCS use |
|-------------------------------------|-------------------|--|---|
| P value | 0.0324 | 0.0013 | <0.0001 |
| P value summary | * | ** | **** |
| Significantly different (P < 0.05)? | Yes | Yes | Yes |
| One- or two-tailed P value? | Two-tailed | Two-tailed | Two-tailed |
| t, df | t=2.165, df=118 | t=3.278, df=133 | t=5.660, df=133 |
| F test to compare variances | | | |
| F, DFn, Dfd | 3.931, 59, 59 | 1.506, 74, 59 | 5.919, 74, 59 |
| P value | <0.0001 | 0.1043 | <0.0001 |
| P value summary | **** | ns | **** |
| Significantly different (P < 0.05)? | Yes | No | Yes |

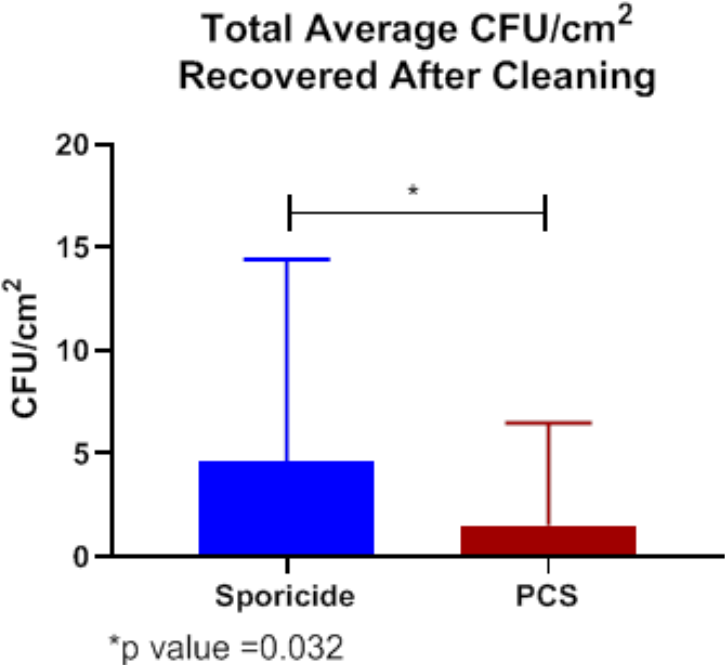


Figure 1: Total average CFU/cm² recovered after each cleaning process. Graph shows the average value with standard deviation bars.

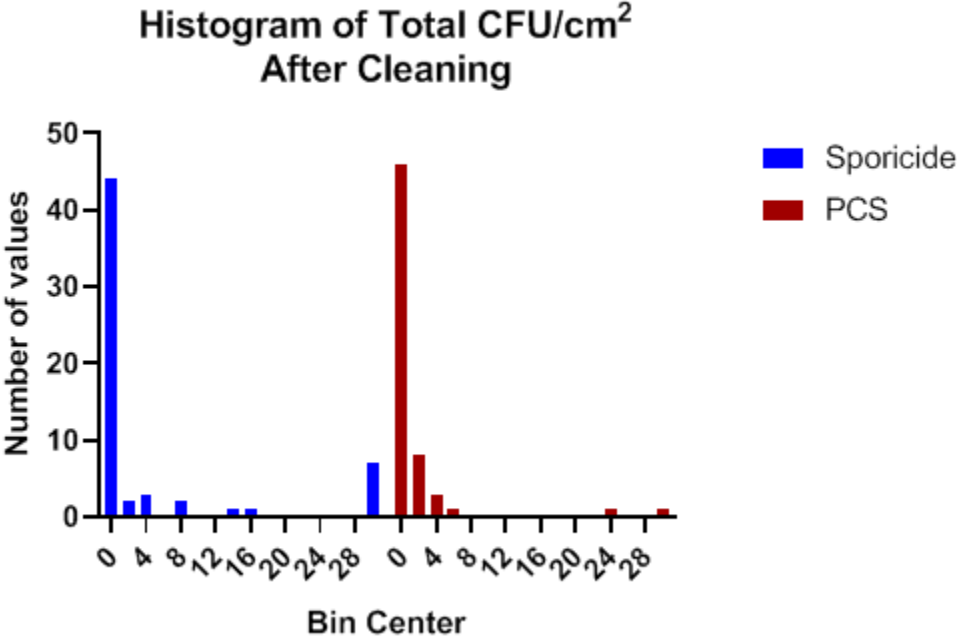


Figure 2: Histogram of total CFU/cm² after cleaning for each cleaning process.

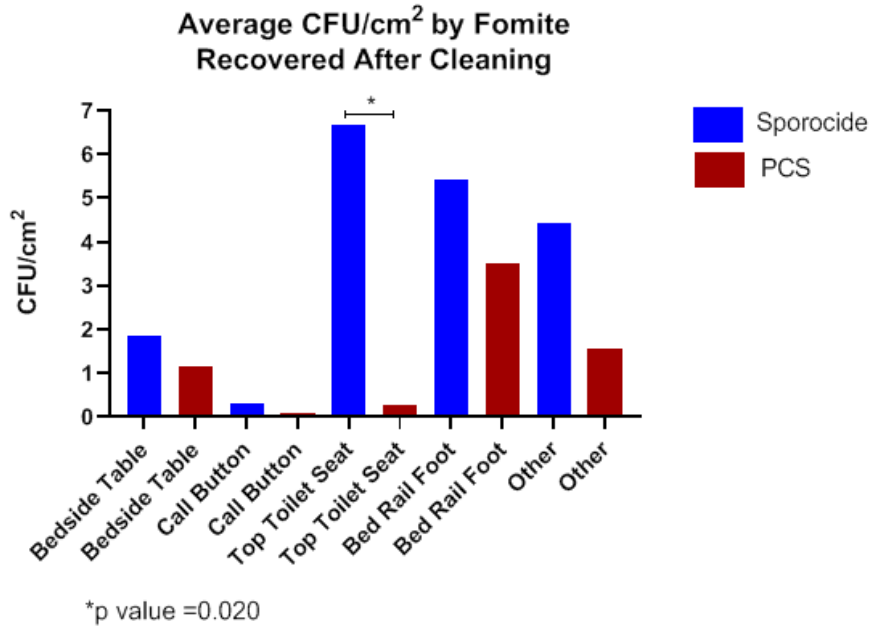


Figure 3: Average CFU/cm² recovered after cleaning for each cleaning process.