## Case Study No. 6

**CHALLENGE CONDITIONS:** *B. subtilis* spores added to stopper bowl. 103 cfu's *B. subtilis* recovered from a contact plate after the fill. ~$10^4$ *B. sphaericus* spores inoculated onto fill nozzle block handle—47 CFU's recovered after the fill.

**FILL CONDITIONS:** Two media fills performed during the first week of the course on July 26, 2001.

MEDIA FILL -- **GROUP 1**
Lot No. **072601-1** (Filled in afternoon)
MEDIA FILL RESULTS

| Tray Number | Number Evaluated | Results |
|---|---|---|
| 1 | 165 | 3* |
| **Total** | **165** | **3** |

***Incubation Conditions:*** *35° ± 2° C, 28 days, inverted.*
** Gram positive rods with spores—B. subtilis.*

*Bulk samples and priming samples were all negative. Pre-filtration bioburden sample was negative.*

### MEDIA GROWTH SUPPORT TEST

| Control Counts | | | | MF Test Samples | | | | |
|---|---|---|---|---|---|---|---|---|
| Organism | (CFU's) | | | Growth (+)/No Growth (-) | | | | Gram |
| | 1 | 2 | Avg | 1 | 2 | 3 | 4 | Stain |
| *B. subtilis* | 82 | 99 | 90 | + | + | + | + | G + rods |
| *S. aureus* | 56 | 62 | 59 | + | + | + | + | G + cocci |
| *P. aeruginosa* | 37 | 41 | 39 | + | + | + | + | G - rods |
| *C. albicans* | 45 | 47 | 46 | + | + | + | + | Yeast |
| *A. niger* | 33 | 39 | 36 | + | + | + | + | Mold |

**Final Result:** ***Valid Media Fill; Media Fill Fails***

### SURFACE MONITORING

| Location Number (NOTE: S = Swab) | Location Identification | Results (CFU's/25 sq. cm.) | Comments |
|---|---|---|---|
| 1 | Staging Shelves | 0 | |
| 2 | Freeze Dryer Door-1 | 0 | |
| 3 | Freeze Dryer Door-2 | 0 | |
| 4 | Pass-Thru Door | 0 | |
| 5S | Entry Door Handle | 3 | *B. sphaericus* |
| 6 | In-feed Turn Table | 0 | |
| 7 | In-feed Tray Loader | 0 | |
| 8 | Vial Pusher, handle | 0 | |
| 9S | Fill Nozzle Support | 0 | |
| 10S | Fill Nozzle | 0 | |
| 11 | Stopper Arm | No Sample | |
| 12 | Vial Star-wheel | 0 | |
| 13 | Left Plexiglas Door | 0 | |
| 14S | Plexiglas Door Handle | 0 | |
| 15 | Control Panel, center bottom | 0 | |
| 16 | Capper Bowl-Outside | 0 | |
| 17 | Stopper Bowl-Outside | 0 | |
| 18 | Stopper Bowl-Inside | 6 | *B. subtilis* |
| 19 | Plexiglas by Stopper Bowl | 0 | |
| 20 | Inside Curtain (left) | 0 | |
| 21 | EM Cart | 0 | |
| 22 | Conveyor | 0 | |
| 23 | Floor--in front of Filler | 0 | |
| 24 | Floor--in front of stopper bowl | 0 | |
| 25 | Floor—in front of exit door | 0 | |
| 26 | Forceps-Trayer | 0 | |
| | Cappers | 0 | |
| | Turntable | 0 | |
| | Back of Turntable | 0 | |
| | Filler | 0 | |

### VIABLE AIR MONITORING

| Sample Location | Sampler Type | Volume of Air Sampled | CFU per Sample | CFU per Volume of Air |
|---|---|---|---|---|
| In-feed Turn Table (by bag set-up) (3:40) | SMA | 60 cu. ft. | 0 | < 0.017/cu. ft. |
| In-feed Turn Table (by bag set-up) (3:45) | SMA | 60 cu. ft. | 0 | < 0.017/cu. ft. |
| In-feed Turn Table (4:10) | SMA | 60 cu. ft. | 0 | <0.017/ cu. ft. |
| Trayer (3:52) | SMA | 60 cu. ft. | 0 | <0.017/ cu. ft. |
| Between Stopper and Capper bowls (3:52) | SMA | 60 cu. ft. | 0 | <0.017/ cu. ft. |
| In-feed Turn Table (4:52) | SMA | 60 cu. ft. | 0 | <0.017/ cu. ft. |
| Trayer (4:52) | SMA | 60 cu. ft. | 0 | <0.017/ cu. ft. |
| Between Stopper and Capper bowls (4:52) | SMA | 60 cu. ft. | 0 | <0.017/ cu. ft. |
| In-feed Turn Table (5:50) | SMA | 60 cu. ft. | 0 | <0.017/ cu. ft. |
| Trayer (5:50) | SMA | 60 cu. ft. | 0 | <0.017/ cu. ft. |
| Between Stopper and Capper bowls (5:50) | SMA | 60 cu. ft. | 0 | <0.017/ cu. ft. |
| Pass-through (4:55) | RCS | 400L | 0 | <0.07/ cu. ft. |
| Staging Rack | RCS | 400L | 0 | <0.07/ cu. ft. |
| Lyophilizer 1 | RCS | 400L | 0 | <0.07/ cu. ft. |
| Pass-through (6:10) | RCS | 400L | 0 | <0.07/ cu. ft. |
| Staging Rack | RCS | 400L | 2 | 0.14/cu. ft. |
| Lyophilizer 1 | RCS | 400L | 1 | 0.07/cu. ft. |
| Filler Deck | Settling Plate | 1 hour | 0 | -- |

### PERSONNEL MONITORING

| Initials | FIPS | | Sleeves | | Chest |
|---|---|---|---|---|---|
| | Right | Left | Right | Left | |
| JC-16:07 | 0 | 0 | NS[1] | NS | NS |
| JC-16:21 | 0 | 0 | NS | NS | NS |
| NL-16:22 | 0 | 0 | NS | NS | NS |
| JC-16:45 | 0 | 0 | 0 | 0 | 0 |
| HW-16:47 | 0 | 0 | NS | NS | NS |
| NL-16:59 | 0 | 0 | NS | NS | NS |
| JG-17:01 | 0 | 0 | NS | NS | NS |
| VM-17:22 | 0 | 0 | NS | NS | NS |
| HW-17:24 | 0 | 0 | 0 | 0 | 0 |
| VM-17:25 | 0 | 0 | NS | NS | NS |
| NL-17:26 | 0 | 0 | NS | NS | NS |
| VM-17:44 | 0 | 0 | 0 | 0 | 19[2] |
| LIN-17:50 | 0 | 1 | 0 | 0 | 0 |
| JG-18:03 | ? | ? | 1 | 0 | 0 |
| NA-18:00 | 0 | 0 | 0 | 1 | 0 |
| JL-18:08 | 0 | 0 | 1 | 0 | 0 |
| MS-18:31 | 0 | 0 | 0 | 0 | 0 |
| EG-18:36 | 0 | 0 | 0 | 0 | 0 |
| TW-18:38 | 0 | 0 | 0 | 0 | 0 |

*1 NS = Not Sampled*

### IDENTIFICATION OF PERSONNEL ISOLATES

All isolates were Gram (+) cocci

MEDIA FILL--**GROUP 2**
Lot No. 072601-2 (Filled in morning)
MEDIA FILL RESULTS

| Tray Number | Number Evaluated | Number Positive |
|---|---|---|
| 1 | 56 | 1* |
| **Total** | **56** | **1** |

***Incubation Conditions:*** *35° ± 2° C, 28 days, inverted.*
** Gram positive rods with spores—B. subtilis.*

*Bulk samples and priming samples were all negative. Pre-filtration bioburden samples were negative.*

### MEDIA GROWTH SUPPORT TEST

| Control Counts | | | | MF Test Samples | | | | |
|---|---|---|---|---|---|---|---|---|
| Organism | (CFU's) | | | Growth (+)/No Growth (-) | | | | Gram |
| | 1 | 2 | Avg | 1 | 2 | 3 | 4 | Stain |
| *B. subtilis* | 82 | 99 | 90 | + | + | + | + | G + rods |
| *S. aureus* | 56 | 62 | 59 | + | + | + | + | G + cocci |
| *P. aeruginosa* | 37 | 41 | 39 | + | + | + | + | G - rods |
| *C. albicans* | 45 | 47 | 46 | + | + | + | + | Yeast |
| *A. niger* | 33 | 39 | 36 | + | + | + | + | Mold |

**Final Result:** ***Valid Media Fill; Media Fill Fails***

### SURFACE MONITORING

| Location Number (NOTE: S = Swab) | Location Identification | Results (CFU's/25 sq. cm.) | Comments |
|---|---|---|---|
| 1S | Staging Shelves | 0 | |
| 2 | Freeze Dryer Door-1 | 0 | |
| 3 | Freeze Dryer Door-2 | 0 | |
| 4 | Pass-Thru Door | 0 | |
| 5S | Entry Door Handle | NS[1] | |
| 6 | In-feed Turn Table | 0 | |
| 7 | In-feed Tray Loader | 0 | |
| 8 | Vial Pusher | 0 | |
| 9S | Fill Nozzle Support | 0 | |
| 10S | Fill Nozzle | 3 | *B. sphaericus* |
| 11 | Stopper Arm | 0 | |
| 12 | Vial Star-wheel | 0 | |
| 13 | Left Plexiglas Door (Class 10,000 side) | 0 | |
| 14S | Plexiglas Door Handle | 0 | |
| 15 | Control Panel | 0 | |
| 16 | Capper Bowl-Outside | 0 | |
| 17 | Stopper Bowl-Outside | 0 | |
| 18 | Stopper Bowl-Inside | NS[1] | |
| 19 | Plexiglas by Stopper Bowl | 0 | |
| 20 | Inside Curtain (left) | 0 | |
| 21 | Set-up Cart | 0 | |
| 22 | Conveyor | 0 | |
| 23 | Floor--in front of Filler | 0 | |
| 24 | Floor--in front of stopper bowl | 0 | |
| 25 | Floor—in front of exit door | 1 | |

*1 = NS = Not Sampled*

### VIABLE AIR MONITORING

| Sample Location | Sampler Type | Volume of Air Sampled | CFU per Sample | CFU per Volume of Air |
|---|---|---|---|---|
| In-feed Turn Table (by bag set-up) (11:30) | SMA | 60 cu. ft. | 0 | <0.017/ cu. ft. |
| In-feed Turn Table (11:40) | SMA | 60 cu. ft. | 0 | <0.017/ cu. ft. |
| Trayer (11:40) | SMA | 60 cu. ft. | 0 | <0.017/ cu. ft. |
| Stopper Bowl (11:40) | SMA | 60 cu. ft. | 0 | <0.017/ cu. ft. |
| Pass-through (11:48) | RCS | 400 L | 0 | <0.07/ cu. ft. |
| Staging Rack (11:28) | RCS | 400 L | 0 | <0.07/ cu. ft. |
| Lyophilizer 1 (12:00) | RCS | 400 L | 0 | <0.07/ cu. ft. |
| In-feed Turn Table (13:00) | SMA | 60 cu. ft. | 0 | <0.017/ cu. ft. |
| Trayer (13:00) | SMA | 60 cu. ft. | 0 | <0.017/ cu. ft. |
| Stopper Bowl (13:00) | SMA | 60 cu. ft. | 0 | <0.017/ cu. ft. |
| Pass-through (12:20) | RCS | 400 L | 0 | <0.07/ cu. ft. |
| Staging Rack (12:12) | RCS | 400 L | 0 | <0.07/ cu. ft. |
| Filler Deck (11:15) | Settling Plate | 1 hr. 45 min. | 0 | -- |
| Filler Deck (13:00) | Settling Plate | 5 min. | 0 | -- |

### PERSONNEL MONITORING

| Initials | FIPS | | Sleeves | | Chest |
|---|---|---|---|---|---|
| | Right | Left | Right | Left | |
| TR-10:15 | 0 | 0 | 0 | 3 | 22[2] |
| DS1-10:56 | 0 | 0 | NS[1] | NS | NS |
| DS1-11:10 | 0 | 1 (mold) | NS | NS | NS |
| DC-11:04 | 5[2] | 0 | NS | NS | NS |
| DC-11:16 | 0 | 2 | NS | NS | NS |
| LH-11:16 | 0 | 0 | NS | NS | NS |
| JL-11:21 | 0 | 0 | NS | NS | NS |
| LH-11:42 | 0 | 0 | NS | NS | NS |
| DL-11:44 | 0 | 0 | NS | NS | NS |
| LH-12:06 | 0 | 0 | NS | NS | NS |
| LH-12:16 | 0 | 0 | NS | NS | NS |
| LH-12:35 | 0 | 0 | NS | NS | NS |
| DS1-12:36 | 0 | 0 | NS | NS | NS |
| DS2-13:00 | 2 | 0 | 0 | 0 | 2 |
| LH-13:05 | 0 | 0 | 0 | 0 | 0 |
| JL-13:20 | 0 | 0 | 0 | 0 | 0 |
| DC-13:26 | 0 | 0 | 0 | 0 | 0 |
| Cori-12:27 | 0 | 0 | 0 | 0 | 0 |
| DS1-13:23 | 0 | 0 | 0 | 0 | 0 |

*1 NS = Not Sampled*

### IDENTIFICATION OF PERSONNEL ISOLATES

FIPs from DC-11:04, DC-11:16 and DS2-13:00 were all *B. sphaericus;* Chest from DS2-13:00 was Gram (+) cocci.

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## Follow-up to Case Study No. 6

**CHALLENGE CONDITIONS**: Inoculated stoppering nest with ~$10^4$ *B. subtilis* spores.

**FILL CONDITIONS:** One product fill and one media fill performed during the second week of the course August 23, 2001--same students as July 26 session.

PRODUCT FILL -- **GROUP 1**
Lot No. 082301-αMGZ69 (Filled in morning)
STERILITY TEST RESULTS

| Tray Number | Number Evaluated | Results |
|---|---|---|
| 1 | 8 | |
| 2 | 8 | |
| 3 | 8 | |
| **Total** | **24** | **No Growth** |

***Test Conditions:*** *All vials reconstituted, pooled and filtered through a Steri-Test System into two canisters. One canister filled with Fluid Thioglycollate Medium, the other with Tryptic Soy Broth (TSB).*
***Incubation Conditions:*** *Thio incubated at 32° ± 2° C, 14 days; TSB incubated at 22 ± 2° C, 14 days. Bulk sterility tests on bulk samples were negative.*

### MEDIA GROWTH SUPPORT TEST

| Control Counts | | | | MF Test Samples | | | | |
|---|---|---|---|---|---|---|---|---|
| Organism | (CFU's) | | | Growth (+)/No Growth (-) | | | | Gram |
| | 1 | 2 | Avg | 1 | 2 | 3 | 4 | Stain |
| *Cl. sporogenes (Thio)* | 30 | 36 | 33 | + | + | + | + | G + rods |
| *S. aureus (Thio.)* | 45 | 54 | 50 | + | + | + | + | G + cocci |
| *P. aeruginosa (Thio.)* | 36 | 51 | 43 | + | + | + | + | G - rods |
| *B. subtilis (TSB)* | 78 | 75 | 77 | + | + | + | + | G + rods |
| *C. albicans (TSB)* | 40 | 52 | 46 | + | + | + | + | Yeast |
| *A. niger (TSB)* | 51 | 63 | 57 | + | + | + | + | Mold |

**Final Result:** ***Valid Sterility Test; Product Sterility Test Passes***

### SURFACE MONITORING

| Location Number (NOTE: S = Swab) | Location Identification | Results (CFU's/25 sq. cm.) | Comments |
|---|---|---|---|
| 1S | Staging Shelves | 0 | S = Swab sample |
| 2 | Freeze Dryer Door-1 | 0 | |
| 3 | Freeze Dryer Door-2 | 0 | |
| 4 | Pass-Thru Door | 0 | |
| 5S | Entry Door Handle | 0 | |
| 6 | In-feed Turn Table | 0 | |
| 7 | In-feed Tray Loader | 0 | |
| 8 | Vial Pusher | 0 | |
| 9S | Fill Nozzle Support | 0 | |
| 10S | Fill Nozzle | 0 | |
| 11 | Stopper Arm | 0 | |
| 12 | Vial Star-wheel | 0 | |
| 13 | Left Plexiglas Door | 0 | |
| 14S | Plexiglas Door Handle | 0 | |
| 15 | Control Panel | 0 | |
| 16 | Capper Bowl-Outside | 0 | |
| 17 | Stopper Bowl-Outside | 0 | |
| 18 | Stopper Bowl-Inside | Not sampled | |
| 19 | Plexiglas by Stopper Bowl | 0 | |
| 20 | Inside Curtain (left) | 0 | |
| 21 | Set-up Cart | 0 | |
| 22 | Conveyor | 0 | |
| 23 | Floor--in front of Filler | 0 | |
| 24 | Floor--by stopper bowl | 0 | |
| 25 | Floor—in front of exit door | 0 | |
| 26 | Pump set-up. Plexiglas door | 0 | |
| 27 | Right Plexiglas door, Class 100 side | 0 | |
| 28S | Stopper nest | 0 | |
| 29 | Vial pusher-vial con-tact | 0 | |
| 30 | Transfer arm of Trayer | 0 | |
| 31 | Forceps-turntable front | 0 | |
| 32 | Forceps-turntable back | 0 | |
| 33 | Forceps-Air location 4 | 0 | |
| 34 | Forceps-stopper bowl | 0 | |
| 35 | Forceps-trayer | 0 | |
| 36 | Forceps-fill cabinet | 0 | |
| 37S | Met-1 key pad | 0 | |
| 38S | RCS key pad | 0 | |
| 39 | Alcohol bottle | 0 | |
| 40S | Left edge of pass-through | 0 | |
| 41S | Pass-through entry door handle | 0 | |
| 42 | Inside Plexiglas PT door | 0 | |
| 43 | Gowning bench | 0 | |

MEDIA FILL--**GROUP 2**
Lot No. 082301-MF1 (Filled in afternoon)
MEDIA FILL RESULTS

| Tray Number | Number Evaluated | Number Positive |
|---|---|---|
| 1 | 199 | 0 |
| 2 | 207 | 0 |
| 3 | 207 | 0 |
| 4 | 195 | 0 |
| 5 | 207 | 0 |
| 6 | 207 | 0 |
| 7 | 46 | 0 |
| **Total** | **1268** | **0** |

***Incubation Conditions:*** *35° ± 2° C, 14 days, inverted.*
*Bulk samples and priming samples were all negative.*

### MEDIA GROWTH SUPPORT TEST

| Control Counts | | | | MF Test Samples | | | | |
|---|---|---|---|---|---|---|---|---|
| Organism | (CFU's) | | | Growth (+)/No Growth (-) | | | | Gram |
| | 1 | 2 | Avg | 1 | 2 | 3 | 4 | Stain |
| *B. subtilis* | 97 | 85 | 91 | + | + | + | + | G + rods |
| *S. aureus* | 34 | 25 | 30 | + | + | + | + | G + cocci |
| *P. aeruginosa* | 28 | 21 | 25 | + | + | + | + | G - rods |
| *C. albicans* | 81 | 97 | 89 | + | + | + | + | Yeast |
| *A. niger* | 91 | 94 | 93 | + | + | + | + | Mold |

**Final Result:** ***Valid Media Fill; Media Fill Passes***

### SURFACE MONITORING

| Location Number (NOTE: S = Swab) | Location Identification | Results (CFU's/25 sq. cm.) | Comments |
|---|---|---|---|
| 1S | Staging Shelves | 0 | |
| 2 | Freeze Dryer Door-1 | 0 | |
| 3 | Freeze Dryer Door-2 | 0 | |
| 4 | Pass-Thru Door | 0 | |
| 5S | Entry Door Handle | 0 | |
| 6 | In-feed Turn Table | 0 | |
| 7 | In-feed Tray Loader | 0 | |
| 8 | Vial Pusher | 0 | |
| 9S | Fill Nozzle Support | 0 | |
| 10S | Fill Nozzle | 0 | |
| 11 | Stopper Arm | 0 | |
| 12 | Vial Star-wheel | 0 | |
| 13 | Left Plexiglas Door | 0 | |
| 14S | Plexiglas Door Handle | 0 | |
| 15 | Control Panel | 0 | |
| 16 | Capper Bowl-Outside | 0 | |
| 17 | Stopper Bowl-Outside | 0 | |
| 18 | Stopper Bowl-Inside | 0 | |
| 19 | Plexiglas by Stopper Bowl | 0 | |
| 20 | Inside Curtain (left) | 0 | |
| 21 | Set-up Cart | 0 | |
| 22 | Conveyor | 0 | |
| 23 | Floor--in front of Filler | 0 | |
| 24 | Floor--in front of stop-per bowl | 0 | |
| 25 | Floor—in front of exit door | 0 | |
| 26 | Pump set-up. Plexiglas door | 0 | |
| 27 | Right Plexiglas door, Class 100 side | 0 | |
| 28S | Stopper nest | 47 | *B. subtilis* |
| 29 | Vial pusher-vial con-tact side | 0 | |
| 30 | Transfer arm of Trayer | 0 | |
| 31 | Forceps-turntable front | 0 | |
| 32 | Forceps-turntable back | 0 | |
| 33 | Forceps-Air location 4 | 0 | |
| 34 | Forceps-stopper bowl | 0 | |
| 35 | Forceps-trayer | 0 | |
| 36 | Forceps-fill cabinet | 0 | |
| 37S | Met-1 key pad | 0 | |
| 38S | RCS key pad | 0 | |
| 39 | Alcohol bottle | 0 | |
| 40S | Left edge of pass-through | 0 | |
| 41S | PT entry door handle | 0 | |
| 42 | Inside PT Plexiglas door | 0 | |

### VIABLE AIR MONITORING

| Set-up of Fill Samples | | | | |
|---|---|---|---|---|
| **Sample Location** | **Sampler Type** | **Volume of Air Sampled** | **CFU per Sample** | **CFU per Volume of Air** |
| In-feed Turn Table (by bag set-up) | SMA | 60 cu. ft. | 0 | < 0.017/cu. ft. |

| End of Fill Samples | | | | |
|---|---|---|---|---|
| **Sample Location** | **Sampler Type** | **Volume of Air Sampled** | **CFU per Sample** | **CFU per Volume of Air** |
| Out-feed Trayer | SMA | 60 cu. ft. | 0 | < 0.017/cu. ft. |
| Stopper Bowl | SMA | 60 cu. ft. | 0 | < 0.017/cu. ft. |
| In-feed Turn Table | SMA | 60 cu. ft. | 0 | < 0.017/cu. ft. |
| Pass through | RCS+ | 1000 liters | 0 | <0.07/cu. ft. |
| Staging rack | RCS+ | 1000 liters | 0 | <0.07/cu. ft. |
| Lyophilizer 2 | RCS+ | 1000 liters | 0 | <0.07/cu. ft. |
| Gowning room | R2S | 60 cu. ft. | 0 | < 0.017/cu. ft. |
| Gowning room | R2S | 60 cu. ft. | 0 | < 0.017/cu. ft. |
| Filler Deck | Settling plate | 60 min. | 0 | -- |

### PERSONNEL MONITORING

| Initials | FIPS | | Sleeves | | Chest |
|---|---|---|---|---|---|
| | Right | Left | Right | Left | |
| JL | 0 | 0 | NS | NS | NS |
| DAS | 0 | 0 | NS | NS | NS |
| LH | 0 | 0 | NS | NS | NS |
| DAS | 0 | 0 | NS | NS | NS |
| DAS | 0 | 0 | NS | NS | NS |
| DAS | 0 | 0 | NS | NS | NS |
| DC | 0 | 0 | NS | NS | NS |
| DC | 0 | 0 | NS | NS | NS |
| JL | 0 | 0 | NS | NS | NS |
| DC | 0 | 0 | NS | NS | NS |
| DC | 0 | 0 | NS | NS | NS |
| LH | 0 | 0 | 0 | 0 | 0 |
| JB | 0 | 0 | 0 | 0 | 0 |
| Dave S | 0 | 0 | 0 | 0 | 2 |
| DC | 0 | 0 | 0 | 0 | 0 |
| JL | 0 | 0 | 0 | 0 | 0 |
| DRS | 0 | 0 | 0 | 0 | 0 |
| DM | 0 | 0 | 0 | 0 | 0 |

*NS = Not Sampled*

**IDENTIFICATION OF PERSONNEL ISOLATES**

Dave S: chest = G(+) cocci; Right sleeve = G(+) cocci & rods.

### VIABLE AIR MONITORING

| Set-up and Beginning of Fill Samples | | | | |
|---|---|---|---|---|
| **Sample Location** | **Sampler Type** | **Volume of Air Sampled** | **CFU per Sample** | **CFU per Volume of Air** |
| In-feed Turn Table (by bag set-up) | SMA | 60 cu. ft. | 0 | < 0.017/cu. ft. |

| End of Fill Samples | | | | |
|---|---|---|---|---|
| **Sample Location** | **Sampler Type** | **Volume of Air Sampled** | **CFU per Sample** | **CFU per Volume of Air** |
| Out-feed Trayer | SMA | 60 cu. ft. | 0 | < 0.017/cu. ft. |
| Out-feed Trayer | SMA | 60 cu. ft. | 0 | < 0.017/cu. ft. |
| Stopper Bowl | SMA | 60 cu. ft. | 0 | < 0.017/cu. ft. |
| Stopper Bowl | SMA | 60 cu. ft. | 0 | < 0.017/cu. ft. |
| In-feed Turn Table | SMA | 60 cu. ft. | 0 | <0.017/ cu. ft. |
| In-feed Turn Table | SMA | 60 cu. ft. | 0 | <0.017/ cu. ft. |
| Pass through | RCS+ | 400L | 0 | < 0.07/cu. ft. |
| Staging rack | RCS+ | 400L | 0 | < 0.07/cu. ft. |
| Lyophilizer 2 | RCS+ | 400L | 0 | < 0.07/cu. ft. |
| Pass through | RCS+ | 400L | 0 | < 0.07/cu. ft. |

### PERSONNEL MONITORING

| Initials | FIPS | | Sleeves | | Chest |
|---|---|---|---|---|---|
| | Right | Left | Right | Left | |
| JC | 0 | 0 | NS | NS | NS |
| EW | 0 | 0 | NS | NS | NS |
| CNY | 0 | 0 | NS | NS | NS |
| HW | 0 | 0 | NS | NS | NS |
| HW | 0 | 0 | NS | NS | NS |
| HW | 0 | 0 | 0 | 0 | 0 |
| JC | 0 | 0 | 0 | 0 | 0 |
| EG | 0 | 0 | 0 | 0 | 0 |
| NA | 0 | 0 | 0 | 0 | 0 |
| JL | 0 | 0 | 0 | 0 | 0 |
| VM | 1 | 0 | 0 | 0 | 0 |
| TW | 0 | 0 | 0 | 0 | 0 |
| JG | 0 | 0 | 0 | 0 | 0 |
| LNY | 0 | 0 | 0 | 0 | 0 |
| LNY | 0 | 0 | 0 | 0 | 0 |
| JL | 0 | 1 | 0 | 0 | 0 |

*NS= Not Sampled—sampled gloves only*

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