

September 2018 - Florida Hospital Compounding Pharmacy uses SAM400® to PASS requirements for USP797 - CAG-009.

AeroMetric 797™ Results Summary Sheet

Test Date 09/02/2018

| Sample location | Class | Pass | Acpt | O.O.C | Cause |
|--------------------------------------|-------|------|------|-------|-----------------------------------|
| 1A I.V. Room | 7 | | | | |
| 2A Passthrough #1 (Double Interlock) | 7 | | | | |
| 3A Ante Room | 7 | | | | |
| 4A Ante Room | 7 | | | | |
| 5A Passthrough #2 (Double Interlock) | 8 | | | | |
| 6A Chemo Room | 7 | | | | |
| 7A BVBI-6SS-RX {S#6S-15-BVBI-16574} | 5 | | | | |
| 8A BZ-655-RX (65-15-BH-16573) | 5 | | | | |
| 9A NV-425-400 (105725041106) | 5 | | | | |
| 1B I.V. Room | 7 | | | | |
| 2B Pssthrough #1 (Double Interlock) | 7 | | | | |
| 3B Ante Room | 7 | | | | |
| 4B Ante Room | 7 | | | | Maximum cont for Class 7 exceeded |
| 5B Passthrough #2 (Double Interlock) | 8 | | | | |
| 6B Chemo Room | 7 | | | | Maximum cont for Class 7 exceeded |
| 7B BVBI-6SS-RX(S#6S-15-BVBI-16574} | 5 | | | | |
| 8B Z-6SS-RX (6S-15-BH-16573) | 5 | | | | |
| 9B NV-425-400(105725041106) | 5 | | | | |

FAILED

No growth of microorganisms. Sample in compliance with USP 797 and CAG-009.

Growth of microorganisms. Sample in compliance with USP 797 and CAG-009.

O.O.C. - Out of Compliance. Unacceptable concentrations or presence of actionable microorganisms. Sample not in compliance wh USP 797 and CAG-009.

SAMPLE #4B Ante Room

FAIL

Lab Sample #: 18021805-013

Sample Location : Client Sample# 4B

Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2 Positive Hole
Corrected Result: 2 CFU/m³

Organism(s) Isolated : **Bacillus species Non-sporulating colony**

| Raw Count | CFU/m ³ | % TOTAL | MRL |
|-----------|--------------------|---------|-----|
| 1 | 1 | 50 | 1 |
| 1 | 1 | 50 | 1 |
| 2 | 2 | ~100% | |

Sample was incubated for 7days at 26 °C Bacteria colonies counted on MEA plate per client request.

Positive Hole: 300 Air Volume: 1000 (L) MRL: 1

COMMENTS

O.O.C. 2 CFU/m³

SAMPLE #6B Chemo Room

FAIL

Lab Sample #: 18021805-015

Sample Location : Client Sample# 6B

Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2 Positive Hole
Corrected Result: 1 CFU/m³

Organism(s) Isolated : **Aspergillus flavus**

| Raw Count | CFU/m ³ | % TOTAL | MRL |
|-----------|--------------------|---------|-----|
| 1 | 1 | 50 | 1 |
| | | | 1 |
| 1 | 1 | ~100% | |

Sample was incubated for 7days at 26 °C Bacteria colonies counted on MEA plate per client request.

Positive Hole: 300 Air Volume: 1000 (L) MRL: 1

COMMENTS

O.O.C. 1 CFU/m³

**Compounding Pharmacy places SAM400® in failed test locations.
USP-797-CAG-009 Re-tested after SAM placement = PASS.**

AeroMetric 797™ Results Summary Sheet

Test Date 09/28/2018

| Sample location | Class | Pass | Acpt | O.O.C | Cause |
|--------------------------------------|-------|------|------|-------|--|
| 1A I.V. Room | 7 | | | | |
| 2A Passthrough #1 (Double Interlock) | 7 | | | | |
| 3A Ante Room | 7 | | | | |
| 4A Ante Room | 7 | | | | |
| 5A Passthrough #2 (Double Interlock) | 8 | | | | |
| 6A Chemo Room | 7 | | | | |
| 7A BVBI-6SS-RX {S#6S-15-BVBI-16574} | 5 | | | | |
| 8A BZ-655-RX (6S-15-BH-16573) | 5 | | | | |
| 9A NV-425-400 (105725041106) | 5 | | | | |
| 1B I.V. Room | 7 | | | | |
| 2B Pssthrough #1 (Double Interlock) | 7 | | | | |
| 3B Ante Room | 7 | | | | |
| 4B Ante Room | 7 | | | | No growth of microorganisms. Compliance with USP 797 and CAG-009 |
| 5B Passthrough #2 (Double Interlock) | 8 | | | | |
| 6B Chemo Room | 7 | | | | No growth of microorganisms. Compliance with USP 797 and CAG-009 |
| 7B BVBI-6SS-RX(S#6S-15-BVBI-16574} | 5 | | | | |
| 8B Z-6SS-RX (6S-15-BH-16573) | 5 | | | | |
| 9B NV-425-400(105725041106) | 5 | | | | |

No growth of microorganisms. Sample in compliance with USP 797 and CAG-009.

SAMPLE #4B Ante Room**PASS**

Lab Sample #: 18026208-001 (Lot# 118206)

Sample Location : Client Sample# 4B

Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2

Positive Hole Corrected Result: **NO GROWTH**Sample was incubated for **7days at 26 °C** Bacteria colonies counted on MEA plate per client request.

Positive Hole: 300 Air Volume: 1000 (L) MRL: 1

COMMENTS**No Growth****SAMPLE #6B Chemo Room****PASS**

Lab Sample #: 18026208-002 (Lot# 118206)

Sample Location : Client Sample# 6B

Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2

Positive Hole Corrected Result: **NO GROWTH**Sample was incubated for **7days at 26 °C** Bacteria colonies counted on MEA plate per client request.

Positive Hole: 300 Air Volume: 1000 (L) MRL: 1

COMMENTS**No Growth**

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