

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

Testing Before SAM400®

AeroMetric 797™ Results Summary Sheet

Test Date 09/02/2018

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



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.

Testing After SAM400®

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 (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				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**