Northern Air Flow

Pharmacy Cleanroom Testing and Sampling Report

Test Date: May 5, 2021
Data Report # 050521

Prepared for:
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CETA National Board of Testing Registered Certification Professional™
STERILE COMPOUNDING FACILITIES
Jared Mikulecky
Valid Until July 1, 2023

NSF
NSF ACCREDITED CLASS II BIOSAFETY CABINET FIELD CERTIFIER
ENHANCED

CETA™ Controlled Environment Testing Association

CNBT™ CETA National Board of Testing

SUMMARY

CETA Certification Guide for Sterile Compounding Facilities CAG-003-2006-13 (2015) was used as a guide for the evaluation and certification process. The revised USP 797 was published June 1, 2019, however, USP is postponing the official date of the revised USP 797 until further notice.

The Primary Engineering Controls

The primary engineering control units (PECs) were tested and certified. This includes two laminar airflow workstations, one containment ventilated enclosure and one compounding safety enclosure. The PECs met relevant standards and specifications. The standards are listed on the individual reports. The PECs maintain the sterility and cleanliness of critical zones and are the primary safeguard for CSPs. The direct compounding area met the USP 797 recommended air quality as determined by nonviable particle count and viable air and surface samples (ISO Class 5 air and not more than 1 colony forming unit (cfu) for air samples and not more than 3 cfus for surface samples).

Viable Environmental Sampling

The USP 797 recommended viable environmental air and surface sampling was performed inside the PECs, in the buffer areas and ante-area. Environmental air and surface monitoring procedures were in accordance with CETA application guide CAG-009 (2020) "Viable Environmental Monitoring for Sterile Compounding Facilities." The USP 797 recommended sampling method of volumetric impaction at locations prone to contamination was followed. Two air and two surface samples were taken in the PECs, the buffer areas and ante-area. One cubic meter of air was sampled. The samples used a collecting plate that contained a medium that supports the growth of bacteria and one that supports the growth of fungi. The samples were incubated and analyzed at U.S. Micro-Solutions. The laboratory reporting document included with this report provides opinions and interpretations. USP 797 states, "Counts of cfu are to be used as an approximate measure of the environmental microbial bioburden. Action levels are determined on the basis of cfu data gathered at each sampling location and trended over time… Highly pathogenic microorganisms (e.g., Gram-negative rods, coagulase positive staphylococcus, molds and yeasts) can be potentially fatal to patients receiving CSPs and must be immediately remedied, regardless of cfu count…" The viable samples resulted in colony forming unit counts below USP 797 action levels. Past results are listed on the trending chart on page 10.

Nonviable Environmental Particle Test

A discrete particle counter was used for this test that specifies the measurement of airborne particles .5 microns and larger. The particle count results along with the recommended ISO class for each location can be found on page 9. The maps on pages 7 and 8 show the locations of the air samples. This test is intended to directly measure the performance of the engineering controls used to create the various levels of air cleanliness. The USP 797 recommended air cleanliness levels for the direct compounding zone, the buffer areas and the ante-area were met.

SUMMARY

Air Change Per Hour & Pressure Differential

Pressure differential and HEPA filtered supply air was measured for the buffer area and ante-area. The air changes per hour were calculated. The acceptance criteria, recommended levels and results for each room can be found on pages 4 and 5.

HEPA Filter Leak Testing

The ceiling HEPA filters were leak tested. All the filters in the buffer area, ante-area and the CSP prep room passed this test. Testing procedure and results can be found on page 6.

Technician: *Jared Mikulecky - NSF accredited #4F970-04, CETA accredited #1333*

Testing equipment, calibration reports will be provided on request.

Air Sampler Mfg: SAS, Model Super 180, Serial # 17-D-11913, calibrated: September 3, 2020

VelociCalc Air Velocity Meter Mfg: TSI, Model# 9565-P, Serial # 9565P1830028, Calibrated: August 20, 2020

Micromanometer/Balometer Mfg: TSI, Model #EBT731, Serial #EBT731941003, Calibrated: October 14, 2020

Aerosol Photometer Mfg: ATI, Model# TGA-2G, Serial # 12376, Calibrated: January 27, 2021

Aerosol Generator Mfg: ATI, Model 6D, Serial # 30720; Gauge Serial # 36588, Calibrated: February 25, 2021

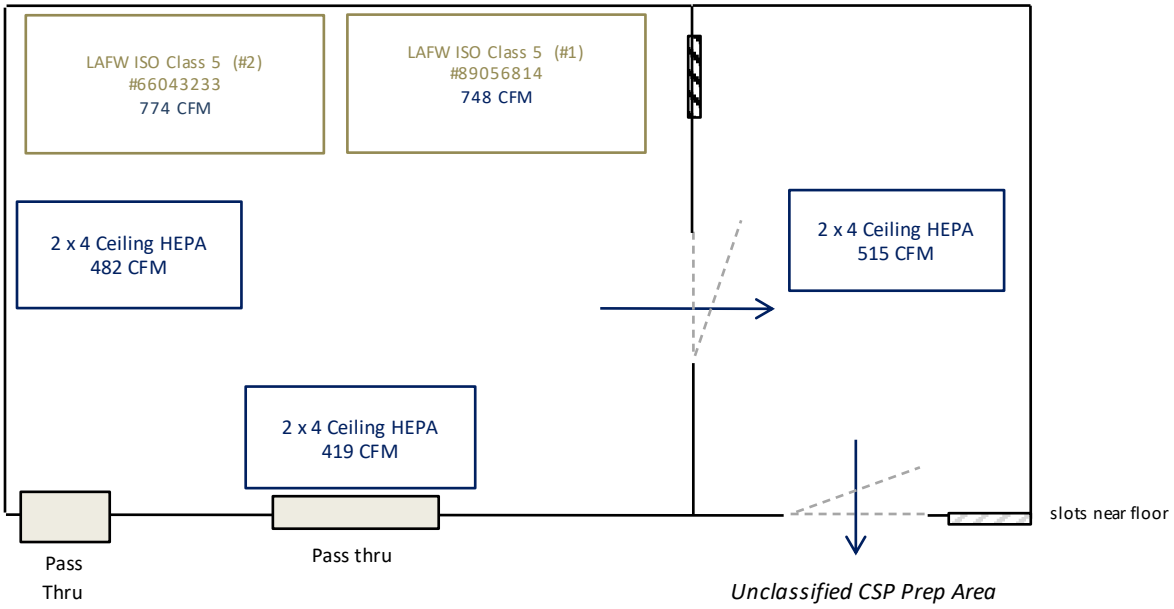
Fog Generator Mfg: Degree Controls, Model C' Breeze # FM51300-A01, Serial # 1547-1084941-001

Particle counter Mfg: Solair, Model 3200+, Serial # 080339003, Calibrated: March 29, 2021

AIR CHANGES PER HOUR

Sterile Compounding Buffer Room
ISO Class 7
652 cubic feet (97" x 121" x 96")

Ante-Area
ISO Class 8
323 cubic feet (60" x 97" x 96)



HEPA filtered supply air was measured with an airflow capture hood, measuring directly in airflow volume (cfm).
Measured HEPA filtered supply air volume listed above.

USP 797 acceptance criteria for an ISO Class 7 sterile compounding buffer room:

> 30 ACPH with at least 15 coming from the air supply through the ceiling HEPA filters.

Ceiling HEPA supply air: (482 + 419) x 60/ 652 = 83 ACPH.

LAFW recirculated HEPA filtered air: 1522 x 60/652 = 140 ACPH

Results

Pass, 83 ACPH from ceiling HEPA filter.
140 ACPH from the PECs
223 ACPH combined.

USP 797 acceptance criteria for an ISO Class 8 ante- area:

Minimum ACPH for an ISO Class 8 ante-area is not specified in the current version of USP 797. The revised USP 797 will require > 20 ACPH.

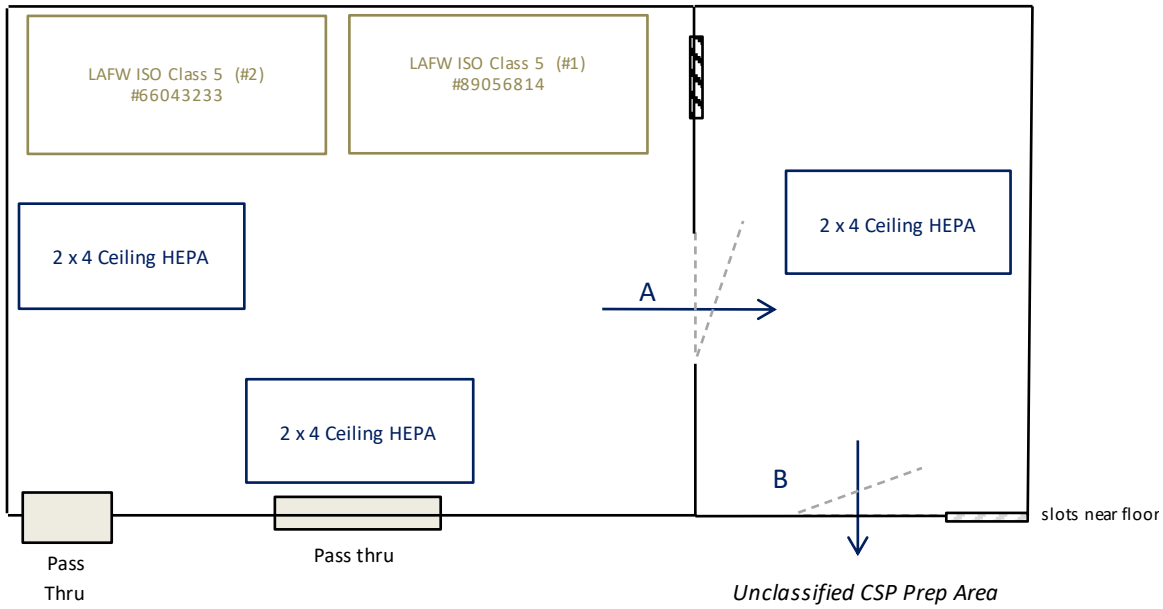
Ceiling HEPA supply air: 515 x 60/323 = 96 ACPH

Pass, 96 ACPH

PRESSURE DIFFERENTIAL

Sterile Compounding Buffer Room
ISO Class 7
652 cubic feet (97" x 121" x 96")

Ante-Area
ISO Class 8
323 cubic feet (60" x 97" x 96)



USP 797 acceptance criteria for an ISO Class 7 sterile compounding buffer room:

A, Pressure differential must not be less than 0.02" W.C. positive pressure relative to the adjacent ante-area.

Results:
Pass, +0.121" W.C. measured

USP 797 acceptance criteria for an ISO Class 8 ante area.

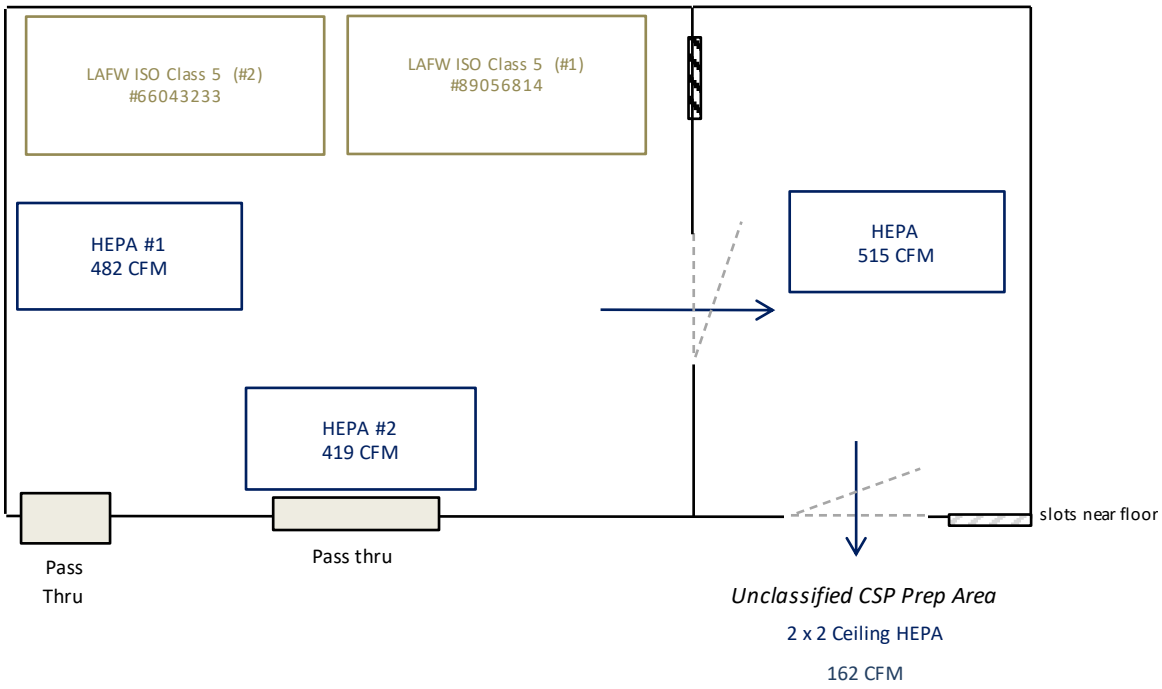
B, Positive pressure differential >0.02" W.C. relative to adjacent unclassified area.

Pass, +0.081" W.C. measured

CEILING HEPA FILTER LEAK TEST

Sterile Compounding Buffer Room
ISO Class 7
652 cubic feet (97" x 121" x 96")

Ante-Area
ISO Class 8
323 cubic feet (60" x 97" x 96)



Procedure, Introduce a polydisperse aerosol (PAO) upstream of the filters at a distance that ensures a concentration that is uniform over the entire upstream face of the filter. The HEPA filters have room access aerosol ports. Scan the downstream filter face with an aerosol photometer. The sampling probe is moved in a series of parallel, slightly overlapping strokes across the test area one inch from the filter face at a scan rate of 2 inches per second. Testing is in accordance with IEST-RP-CC034.3 section 6.2.1

Acceptance criteria: The leak penetration cannot exceed 0.01 % of the upstream concentration.

Compounding Buffer Room — **Results:**

Filter 1: 481 cfm. 14 μg/L of aerosol was introduced upstream of the filter. The HEPA filter was scanned without any significant aerosol detection, < 0.001%. — Pass

Filter 2: 419 cfm. 16 μg/L of aerosol was introduced upstream of the filter. The HEPA filter was scanned without any significant aerosol detection, < 0.003%. — Pass

Ante-Area

Filter: 515 cfm. 13 μg/L of aerosol was introduced upstream of the filter. The HEPA filter was scanned without any significant aerosol detection, < 0.004%. — Pass

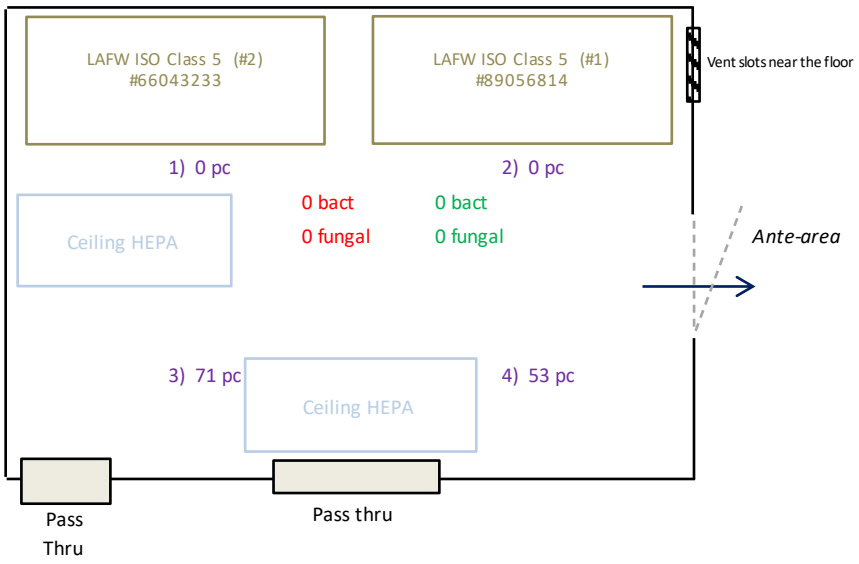
CSP Prep Area

Filter: 162 cfm. 42 μg/L of aerosol was introduced upstream of the filter. The HEPA filter was scanned without any significant aerosol detection, < 0.005%. — Pass

STERILE COMP0UNDING BUFFER ROOM

ISO Class 7 Area, 652 cubic feet

Environmental Viable & Nonviable Sampling



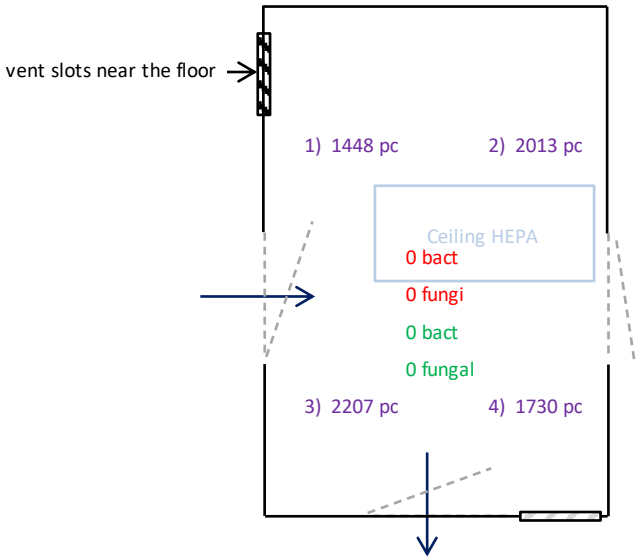
USP 797 acceptance criteria for an ISO Class 7 buffer area:	*Results*
The maximum concentration limit for an ISO Class 7 room; 352,000 particles 0.5μ and larger per cubic meter of air. Results and locations shown on the map.	Pass
Viable air samples, ≤ 10 cfu: One cubic meter of air sampled in the center of the room.	Pass, < 1 cfu bacteria, < 1 cfu fungal
Viable surface samples, ≤ 5 cfu: Two surface samples on top of cart.	Pass, < 1 cfu bacteria, < 1 cfu fungal

Viable air and surface sampling was performed in the ISO Class 5 laminar airflow workstations. The results can be found on the individual certification reports, 050521-66043233 and 050521-89056814.

Per USP 797, 2019: The cleanroom suite should be maintained at a temperature of 68 °F or cooler and a relative humidity below 60% to minimize the risk for microbial proliferation and provide comfortable conditions for compounding personnel attired in the required garb.	70 ° F, Measured 49% Relative Humidity

ANTE-AREA
ISO Class 8 Area, 323 cubic feet

Environmental Viable & Nonviable Sampling



Unclassified CSP Prep Area

USP<797> acceptance criteria for an ISO Class 8 ante- area:	Results
The maximum concentration limit for an ISO Class 8 room; 3,520,000 particles 0.5μ and larger per cubic meter of air. Results and locations shown on the map.	Pass
Viable air samples, ≤ 10 cfu: One cubic meter of air sampled in the center of the room.	Pass, < 1 cfu bacteria, < 1 cfu fungal
Viable surface samples, ≤ 5 cfu: Two surface samples on top of the counter.	Pass, < 1 cfu bacteria, < 1 cfu fungal
Per USP 797, 2019: The cleanroom suite should be maintained at a temperature of 68 ^{o}F or cooler and a relative humidity below 60% to minimize the risk for microbial proliferation and provide comfortable conditions for compounding personnel attired in the required garb.	71 ^{o}F, Measured 48% Relative Humidity

ENVIRONMENTAL NONVIABLE PARTICLE TEST

Instrument: Particle counter Mfg: Solair, Model 3200+, Serial # 080339003, Calibrated: March 29, 2021

The nonviable air sampling test is to assure compliance to ISO 14644-1:2015, Cleanrooms and Associated Controlled Environments, Part 1: Classification of Air Cleanliness. The air sampling was performed with the cleanroom suite in the dynamic operating state. The results show particle concentrations calculated from the raw data based on the chosen "cubic meter" setting.

The considered particle size: 0.5 microns and larger per cubic meter of air.

The volume of air sampled: 56.6 Liters.

Location		Particle Count (per cubic meter)	USP 797, 800 Required Class	Pass/Fail
Sterile Compounding Buffer Room Inside the Laminar Airflow Workstation Serial #89056814		0	5	Pass
		0		
		0		
		0		
Sterile Compounding Buffer Room Inside the Laminar Airflow Workstation Serial #66043233		0	5	Pass
		0		
		0		
		0		
Sterile Compounding Buffer Room	1	0	7	Pass
	2	0		
	3	71		
	4	53		
Ante-Area	1	1448	8	Pass
	2	2013		
	3	2207		
	4	1730		

Maximum concentration limits for particles equal to and larger than the considered size.

ISO Class 5: < 3520 particles .5µ and larger per cubic meter

ISO Class 7: < 352,000 particles .5µ and larger per cubic meter

ISO Class 8: < 3,520,000 particles .5µ and larger per cubic meter

VIABLE and NONVIABLE ENVIRONMENTAL SAMPLE TRENDS

Location	Sterile Compounding Buffer Area															
	Laminar Airflow Workstation Serial #89056814								Laminar Airflow Workstation Serial #66043233							
ISO Class	5								5							
9/12/18	0b	0f	0b	0f	0	0	0	0	0b	0f	0b	0f	0	0	35	0
3/6/19	0b	0f	0b	0f	0	0	0	0	0b	0f	0b	0f	0	0	0	0
11/13/19	0b	0f	0b	0f	0	0	0	0	0b	0f	0b	0f	0	0	0	0
5/13/20	0b	0f	0b	0f	0	0	0	0	0b	0f	0b	0f	0	0	0	0
11/11/20	0b	0f	0b	0f	0	0	0	0	0b	0f	0b	0f	0	0	0	0
5/5/21	0b	0f	0b	0f	0	0	0	0	0b	0f	0b	0f	0	0	0	0

Location	Sterile Compounding Buffer Area								Ante-Area							
ISO Class	7								8							
9/12/18	0b	0f	0b	0f	106	0	0	177	0b	0f	0b	0f	3,319	1,024	22,104	3,213
3/6/19	0b	0f	0b	0f	0	0	141	0	0b	0f	0b	0f	318	1,766	742	706
11/13/19	0b	0f	0b	0f	0	71	388	1,342	0b	0f	0b	0f	1,624	1,695	2,013	3,778
5/13/20	0b	0f	0b	0f	0	0	71	106	0b	0f	0b	0f	847	600	4,661	5,085
11/11/20	0b	0f	0b	0f	0	0	318	565	1b	0f	0b	0f	212	989	706	3,178
5/5/21	0b	0f	0b	0f	0	0	71	53	0b	0f	0b	0f	1,448	2,013	2,207	1,730

Environmental Sampling

Viable Air Sample, total colony forming units - b-bacteria, f-fungi

Viable Surface Sample, total colony forming units - b-bacteria, f- fungi

Nonviable Particle Count, 0.5μ and larger per cubic meter of air.

USP 797 and 800 recommended limits for each ISO Class

ISO Class	Viable Air Sample	Surface samples	Nonviable Particle Count
ISO Class 5	≤1	≤3	< 3520 particles .5µ and larger per cubic meter
ISO Class 7	≤10	≤5	< 352,000 particles .5µ and larger per cubic meter
ISO Class 8	≤100	≤100	< 3,520,000 particles .5µ and larger per cubic meter