

Oncology Plus

1070 East Brandon Blvd

Brandon, FL 33511

Report # 62406-1

USP 797 Pharmacy Clean Room  
Compliance Inspection

August 14, 2014



Questions or Problems Please Contact our office at (877) 569-8886 or [corp@mtausa.com](mailto:corp@mtausa.com)

MTA Corporate Headquarters: 6840 Cross Bayou Drive, Largo, FL 33777 • Phone 727-548-8600 • Fax 727-548-8622



**6840 Cross Bayou Drive  
Largo, FL 33777  
(877) 569-8886  
727-548-8600 Phone  
727-548-8622 Fax**

The Pharmacy Division of MTA, Inc. completed a Pharmacy Clean Room Compliancy Inspection at your facility. All testing will determine if the room meets or exceeds USP 797 code compliance and other applicable federal, state and local requirements.

The following Clean Room tests were performed and are reported:

- HEPA Filter Integrity Test
- Supply Air Flow Volumes
- Air Changes Per Hour
- Air Flow Analysis
- Room Pressures Differentials
- Airborne Particle Count Classification per ISO 14644-1 @ 0.5 microns
- Microbiological Analysis (Viable Count)

The test results documented within this report have not been modified or changed unless noted. Results are confidential and reported directly to the responsible staff members. If there are questions or concerns pertaining to the report we will be happy to arrange a meeting with you and/or your staff.

# CHAIN OF CUSTODY

Date	August 14, 2014	Time	
Report #	62406-1		
Technician	Michael Klann		
Customer	Oncology Plus		
Address	1070 East Brandon Blvd		
City State	Brandon, FL 33511		
Contact	Zachary Scholl	Timothy Finn	
Telephone	(813) 689-6303	(813) 689-6303	
Customer #	7713		



Toll Free (877) 569-8886  
 Phone (727) 548-8600  
 Fax (727) 548-8622

[www.mtausa.com](http://www.mtausa.com)

6840 Cross Bayou Drive  
 Largo, FL 33777

Occupancy State During Testing

Email Address to Send Report: [Zscholl@OncologyPlus.com](mailto:Zscholl@OncologyPlus.com)

**Notes:** client performs their own viable air sampling

Media/Agar Type			
Lot #		Exp. Date	
Sample ID	Sample Location/ Device ID	ISO Class	Sample Volume
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			

Media/Agar Type			
Lot #		Exp. Date	
Sample ID	Sample Location/ Device ID	ISO Class	Sample Volume
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			
26			

# USP 797 CERTIFICATION EXECUTIVE SUMMARY



Date	August 14, 2014	Report Number	62406-1
Technician	Michael Klann		
Device ID#	7713		
Customer	Oncology Plus		
Address	1070 East Brandon Blvd		
City State	Brandon, FL 33511		

Contact	Zachary Scholl	/	Timothy Finn
Telephone	(813) 689-6303	/	(813) 689-6303
email address	<a href="mailto:Zscholl@OncologyPlus.com">Zscholl@OncologyPlus.com</a>		
	<a href="mailto:tfinn@oncologyplus.com">tfinn@oncologyplus.com</a>		

**Notes:** The airgap in the canopy transition of both Bio-Safety Cabinets exhibit slightly positive pressure. Increasing the external exhaust volume should create negative pressure in both of the airgaps.

No viable air samples taken

	Meets or Exceeds requirements of USP 797	Does <u>NOT</u> meet the requirements of USP 797	Non-Applicable
<b>ANTE ROOM</b>			
Particle Count Survey	X		
Differential Pressure	X		
Air Changes	X		
<b>Non-Hazardous (IV/Buffer Room)</b>			
Particle Count Survey	X		
Differential Pressure	X		
Air Changes	X		
<b>Hazardous (IV Room)</b>			
Particle Count Survey	X		
Differential Pressure	X		
Air Changes	X		
<b>Sterile Prep / Auxiliary Room</b>			
Particle Count Survey			X
Differential Pressure			X
Air Changes			X

Laminar Flow Hoods, Isolators, Biological Safety Cabinets			Pass	Fail	Requires Attention
SN#	1058701101		X		
SN#	82392 AGR		X		
SN#					
SN#					
SN#					
SN#					

CUSTOMER NAME (PLEASE PRINT)

CUSTOMER SIGNATURE

Michael Klann  
AUTHORIZED SERVICE REP

August 14, 2014  
DATE

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\*Executive summary does not include results of viable air samples.

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# Section 1

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USP 797 Pharmacy

Ante Room, IV Room and Chemo Room Summary Reports

# ANTE-ROOM SUMMARY



Date	August 14, 2014	
Report #	62406-1	
Customer ID #	7713	
Technician	Michael Klann	
Customer	Oncology Plus	
Address	1070 East Brandon Blvd	
City State	Brandon, FL 33511	
Contact	Zachary Scholl	Timothy Finn
Phone Number	(813) 689-6303	(813) 689-6303
PO Number		

## Overall Status of Room

ISO 14644-1	1999-E	Class	7	at .5 micron	Status	Operational		
Meets CETA CAG-003-2006 rev 2010	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input type="checkbox"/>	N/A		
Meets USP 797 to Criteria Tested	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input type="checkbox"/>	N/A		

Notes:

### Air Change Requirements:

Minimum 30 air changes required for ISO 7 and 20 air changes for ISO 8

Total Air Volume Supplied	894	CFM	Total Number of Air Changes	45	per hour	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input type="checkbox"/>	N/A
Total Air Volume From PEC		CFM	Air Changes From PEC		per hour			<input checked="" type="checkbox"/>			N/A

### Differential Pressure and/or Displacement Velocity:

Minimum 0.02 inches positive to the outside area. Minimum 40 fpm is required if utilizing displacement method.

Pressure monitor Present?		<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>	N/A			
Static Pressure or Velocity of Ante Room to Outside	0.111	"W.G. or	N/A	fpm	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input type="checkbox"/>	N/A
Static Pressure or Velocity of Ante Room to IV Room	0.135	"W.G. or	N/A	fpm	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input type="checkbox"/>	N/A
Static Pressure or Velocity of Ante Room to Chemo Room	-0.0567	"W.G. or	N/A	fpm	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input type="checkbox"/>	N/A
Static Pressure or Velocity of Ante Room to Sterile Prep/Low Risk	N/A	"W.G. or	N/A	fpm	<input type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input checked="" type="checkbox"/>	N/A

### Ante Room Statistical Data 0.5 micron Particles:

(Particle counts taken at 1 minute sample time at 1 CFM and include 0.5 micron particles and larger)

95% UCL is used to determine ISO classification when nine (9) or less particle count locations are taken.

Maximum number of .5 micron size particles allowed for ISO Class 7	352,000	particles per cubic meter
Maximum number of .5 micron size particles allowed for ISO Class 8	3,520,000	particles per cubic meter

ISO Class Achieved	7	Mean of Averages	547	95% UCL	590	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input type="checkbox"/>	N/A
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### HEPA Filter Leak Integrity Test:

Upstream concentration should be greater than 10µg/l and no leak greater than 0.01% when scanned. (See Data Page for more information.)

Number of filters scanned	2					
Number of leaks detected	0					
Number of leaks sealed	N/A					
	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input type="checkbox"/>	N/A

### Average Temperature and Relative Humidity:

Recommended Temperature < 68° F	Measured	67.3	°F
Recommended Relative Humidity 30 to 65%	Measured	66.1	%Rh

### Smoke Study Performed:

Visual confirmation that air flows in the direction designed for the type of room.

\*This test only performed on unidirectional / uniform rooms.

<input type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input checked="" type="checkbox"/>	N/A
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# IV / BUFFER ROOM SUMMARY



Date	August 14, 2014	
Report #	62406-1	
Customer ID #	7713	
Technician	Michael Klann	
Customer	Oncology Plus	
Address	1070 East Brandon Blvd	
City State	Brandon, FL 33511	
Contact	Zachary Scholl	Timothy Finn
Phone Number	(813) 689-6303	(813) 689-6303
PO Number		

## Overall Status of Room

ISO 14644-1	1999-E	Class	7	at .5 micron	Status	Operational		
Meets CETA CAG-003-2006 rev 2010	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input type="checkbox"/>	N/A		
Meets USP 797 to Criteria Tested	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input type="checkbox"/>	N/A		

Notes:

### Air Change Requirements:

Minimum 30 air changes required for ISO 7

Total Air Volume Supplied	899	CFM	Total Number of Air Changes	30	per hour	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input type="checkbox"/>	N/A
Total Air Volume From PEC		CFM	Air Changes With PEC		per hour	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	N/A

### Differential Pressure and/or Displacement Velocity:

Minimum 0.02 inches positive to the ante area or any other area. Minimum 40 fpm is required if utilizing displacement method.

Pressure monitor Present?	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>	N/A				
Static Pressure or Velocity of Ante Room to IV Room	0.135	"W.G. or	N/A	fpm	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input type="checkbox"/>	N/A
Static Pressure or Velocity of IV Room to Outside	N/A	"W.G. or	N/A	fpm	<input type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input checked="" type="checkbox"/>	N/A
			N/A		<input type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input checked="" type="checkbox"/>	N/A

### IV Room Statistical Data 0.5 micron Particles:

(Particle counts taken at 1 minute sample time at 1 CFM and include 0.5 micron particles and larger)

95% UCL is used to determine ISO classification when nine (9) or less particle count locations are taken.

Maximum number of .5 micron size particles allowed for ISO Class 7 352,000 particles per cubic meter

ISO Class Achieved	7	Mean of Averages	130	95% UCL	204	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input type="checkbox"/>	N/A
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### HEPA Filter Leak Integrity Test:

Upstream concentration should be greater than 10µg/l and no leak greater than 0.01% when scanned. (See Data Page for more information.)

Number of filters scanned	2					
Number of leaks detected	0					
Number of leaks sealed	N/A					
	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input type="checkbox"/>	N/A

### Average Temperature and Relative Humidity:

Recommended Temperature < 68° F	Measured	69.7	°F
Recommended Relative Humidity 30 to 65%	Measured	63.9	%Rh

### Smoke Study Performed:

Visual confirmation that air flows in the direction designed for the type of room.

\*This test only performed on unidirectional / uniform rooms.

<input type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input checked="" type="checkbox"/>	N/A
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# CHEMO ROOM SUMMARY



Date	August 14, 2014	
Report #	62406-1	
Customer ID #	7713	
Technician	Michael Klann	
Customer	Oncology Plus	
Address	1070 East Brandon Blvd	
City State	Brandon, FL 33511	
Contact	Zachary Scholl	Timothy Finn
Phone Number	(813) 689-6303	(813) 689-6303
PO Number		

## Overall Status of Room

ISO 14644-1	1999-E	Class	7	at .5 micron	Status	Operational		
Meets CETA CAG-003-2006 rev 2010	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input type="checkbox"/>	N/A		
Meets USP 797 to Criteria Tested	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input type="checkbox"/>	N/A		

Notes:

### Air Change Requirements:

Minimum 30 air changes required for ISO 7

Total Air Volume Supplied	995	CFM	Total Number of Air Changes	33	per hour	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input type="checkbox"/>	N/A
Total Air Volume From PEC		CFM	Air Changes From PEC		per hour			<input checked="" type="checkbox"/>			N/A

### Differential Pressure:

Minimum -0.01 inches negative pressure to the ante area.

Pressure monitor Present?		<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>	N/A			
Static Pressure or Velocity of Ante Room to Chemo Room	-0.0567	"W.G. or	N/A	fpm	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input type="checkbox"/>	N/A
	N/A	"W.G. or	N/A	fpm	<input type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input checked="" type="checkbox"/>	N/A
Static Pressure or Velocity of Ante Room to					<input type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input checked="" type="checkbox"/>	N/A

### Chemo Room Statistical Data 0.5 micron Particles:

(Particle counts taken at 1 minute sample time at 1 CFM and include 0.5 micron particles and larger)

95% UCL is used to determine ISO classification when nine (9) or less particle count locations are taken.

Maximum number of .5 micron size particles allowed for ISO Class 7 352,000 particles per cubic meter

ISO Class Achieved	7	Mean of Averages	1242	95% UCL	1827	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input type="checkbox"/>	N/A
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### HEPA Filter Leak Integrity Test:

Upstream concentration should be greater than 10µg/l and no leak greater than 0.01% when scanned. (See Data Page for more information.)

Number of filters scanned	2						
Number of leaks detected	0						
Number of leaks sealed	N/A						
		<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input type="checkbox"/>	N/A

### Average Temperature and Relative Humidity:

Recommended Temperature < 68° F	Measured	69.3	°F
Recommended Relative Humidity 30 to 65%	Measured	63.5	%Rh

### Smoke Study Performed:

Visual confirmation that air flows in the direction designed for the type of room.

\*This test only performed on unidirectional / uniform rooms.

<input type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input checked="" type="checkbox"/>	N/A
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## Section 2

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USP 797 Pharmacy

Report Data Includes Calibration Data

# CLEANROOM INSPECTION DATA



Date	August 14, 2014
Technician	Michael Klann
Customer ID#	7713
Customer	Oncology Plus
Address	1070 East Brandon Blvd
City State	Brandon, FL 33511

		Report Number	62406-1
Contact	Zachary Scholl	/	Timothy Finn
Telephone	(813) 689-6303		(813) 689-6303
email address	<a href="mailto:Zscholl@OncologyPlus.com">Zscholl@OncologyPlus.com</a>	/	<a href="mailto:tfinn@oncologyplus.com">tfinn@oncologyplus.com</a>

## ANTE ROOM DIMENSIONS AND PARTICLE COUNT STATISTICAL DATA

Room Dimensions recorded in inches				Non-applicable	
L	W	H	Room Area in square feet f ###	148.03	ft <sup>2</sup>
146	146	96	Room Area in square meters (m <sup>2</sup> )	13.75	m <sup>2</sup>
			Room Volume in cubic feet (ft <sup>3</sup> )	1184.22	ft <sup>3</sup>
			Number of Sampling Locations	4	

Calculations  
 (Length (in) X width (in)) x 1 ft<sup>2</sup>/144 in<sup>2</sup>  
 area (ft<sup>2</sup>) x 1 m<sup>2</sup>/10.764 ft<sup>2</sup>  
 (Length (in) X width (in) x Height (in) x 1 ft<sup>3</sup>/1728 in<sup>3</sup>)  
 √m<sup>2</sup> rounded up

Ante Room Particle Count Statistical Data (Particle counts taken at 1 minute sample time at 1 CFM and include 0.5 micron particles and larger)									
ISO Class	7	Mean of Averages	547	95% UCL	590	Standard Dev	35	Standard Err.	18

## IV ROOM DIMENSIONS AND PARTICLE COUNT STATISTICAL DATA

Room Dimensions recorded in inches				Non-applicable	
L	W	H	Room Area in square feet ft <sup>2</sup>	226.11	ft <sup>2</sup>
220	148	96	Room Area in square meters (m <sup>2</sup> )	21.01	m <sup>2</sup>
			Room Volume in cubic feet (ft <sup>3</sup> )	1808.89	ft <sup>3</sup>
			Number of Sampling Locations	5	

Calculations  
 (Length (in) X width (in)) x 1 ft<sup>2</sup>/144 in<sup>2</sup>  
 area (ft<sup>2</sup>) x 1 m<sup>2</sup>/10.764 ft<sup>2</sup>  
 (Length (in) X width (in) x Height (in) x 1 ft<sup>3</sup>/1728 in<sup>3</sup>)  
 √m<sup>2</sup> rounded up

IV Room Particle Count Statistical Data (Particle counts taken at 1 minute sample time at 1 CFM and include 0.5 micron particles and larger)									
ISO Class	7	Mean of Averages	130	95% UCL	204	Standard Dev	91	Standard Err.	37

## CHEMO ROOM DIMENSIONS AND PARTICLE COUNT STATISTICAL DATA

Room Dimensions recorded in inches				Non-applicable	
L	W	H	Room Area in square feet ft <sup>2</sup>	223.06	ft <sup>2</sup>
220	146	96	Room Area in square meters (m <sup>2</sup> )	20.72	m <sup>2</sup>
			Room Volume in cubic feet (ft <sup>3</sup> )	1784.44	ft <sup>3</sup>
			Number of Sampling Locations	5	

Calculations  
 (Length (in) X width (in)) x 1 ft<sup>2</sup>/144 in<sup>2</sup>  
 area (ft<sup>2</sup>) x 1 m<sup>2</sup>/10.764 ft<sup>2</sup>  
 (Length (in) X width (in) x Height (in) x 1 ft<sup>3</sup>/1728 in<sup>3</sup>)  
 √m<sup>2</sup> rounded up

Chemo Room Particle Count Statistical Data (Particle counts taken at 1 minute sample time at 1 CFM and include 0.5 micron particles and larger)									
ISO Class	7	Mean of Averages	1242	95% UCL	1827	Standard Dev	717	Standard Err.	293

## STERILE PREP / AUX ROOM / CHEMO ANTE ROOM DIMENSIONS AND PARTICLE COUNT STATISTICAL DATA

Room Dimensions recorded in inches				Non-applicable	
L	W	H	Room Area in square feet ft <sup>2</sup>	0.00	ft <sup>2</sup>
			Room Area in square meters (m <sup>2</sup> )	0.00	m <sup>2</sup>
			Room Volume in cubic feet (ft <sup>3</sup> )	0.00	ft <sup>3</sup>
			Number of Sampling Locations	0	

Calculations  
 (Length (in) X width (in)) x 1 ft<sup>2</sup>/144 in<sup>2</sup>  
 area (ft<sup>2</sup>) x 1 m<sup>2</sup>/10.764 ft<sup>2</sup>  
 (Length (in) X width (in) x Height (in) x 1 ft<sup>3</sup>/1728 in<sup>3</sup>)  
 √m<sup>2</sup> rounded up

Aux Room Particle Count Statistical Data (Particle counts taken at 1 minute sample time at 1 CFM and include 0.5 micron particles and larger)									
ISO Class	7	Mean of Averages		95% UCL		Standard Dev		Standard Err.	



**AIR CHANGE AND PRESSURE DATA**

**Ante Room**

Room Volume	1184	Supply Air Total	894	Air Changes Per minute	0.75	Air Changes Per Hour	45
Total Air Volume from PEC				Total Air changes Per hour with PEC		<input checked="" type="checkbox"/>	Non-applicable
Notes: _____							

**IV Room**

Room Volume	1809	Supply Air Total	899	Air Changes Per minute	0.50	Air Changes Per Hour	30
Total Air Volume from PEC				Total Air changes Per hour with PEC		<input checked="" type="checkbox"/>	Non-applicable
Notes: _____							

**Chemo Room**

Room Volume	1784	Supply Air Total	995	Air Changes Per minute	0.56	Air Changes Per Hour	33
Total Air Volume from PEC				Total Air changes Per hour with PEC		<input checked="" type="checkbox"/>	Non-applicable
Notes: _____							

**Sterile Prep / Aux Room / Chemo Ante Room**

Room Volume	0	Supply Air Total	0	Air Changes Per minute	#DIV/0!	Air Changes Per Hour	#DIV/0!
Total Air Volume from PEC				Total Air changes Per hour with PEC		<input checked="" type="checkbox"/>	Non-applicable
Notes: _____							

Pressure/Velocity Monitors Installed?  YES  NO  N/A

Pressure monitor Installed and Functioning?  YES  NO  N/A

Static Pressure Ante to Outside	0.111	"W.G.	Static Pressure Ante to IV Room	0.135	"W.G.	Static Pressure Ante Room to Chemo	-0.0567	"W.G.
Static Pressure to		measured			"W.G.	Static Pressure to		measured
Static Pressure to		measured			"W.G.	Static Pressure to		measured

**Displacement**

Displacement Average Ante Room to Outside	N/A
Displacement Average IV room to Ante Room	N/A
Displacement Average Ante Room to Chemo Room	N/A

MTA strongly discourages the use of displacement and curtains. If curtains are utilized spread the curtains at least 24" and measure 48" above the floor complete a drawing and record the readings. Any customers using curtains shall be advised to install a door and if needed low wall registers to allow for pressure adjustments.

**HEPA FILTER INTEGRITY TEST**

(HEPA filters should be integrity tested at each certification with a minimum upstream challenge concentration of 10 micrograms per liter.)

**Ante Room**

HEPA Filter #	Upstream Challenge Location	Calculated Challenge	Measured challenge		Leak Detected		Leak Sealed		Fail
			Before	After	Yes	No	Yes	No	
1	Intake near floor in adjacent room	13			<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Fail
2	Intake near floor in adjacent room	13			<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Fail
0					<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Fail
0					<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Fail
0					<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Fail
0					<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Fail

**IV Room**

HEPA Filter #	Upstream Challenge Location	Calculated Challenge	Measured challenge		Leak Detected		Leak Sealed		Fail
			Before	After	Yes	No	Yes	No	
1	Intake near floor in adjacent room	13			<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Fail
2	Intake near floor in adjacent room	13			<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Fail
0					<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Fail
0					<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Fail
0					<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Fail
0					<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Fail

**Chemo Room**

HEPA Filter #	Upstream Challenge Location	Calculated Challenge	Measured challenge		Leak Detected		Leak Sealed		Fail
			Before	After	Yes	No	Yes	No	
1	Intake near floor in adjacent room	13			<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Fail
2	Intake near floor in adjacent room	13			<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Fail
0					<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Fail
0					<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Fail
0					<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Fail
0					<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Fail

**Sterile Prep / Aux Room / Chemo Ante Room**

HEPA Filter #	Upstream Challenge Location	Calculated Challenge	Measured challenge		Leak Detected		Leak Sealed		Fail
			Before	After	Yes	No	Yes	No	
0					<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Fail
0					<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Fail
0					<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Fail
0					<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Fail
0					<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Fail
0					<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Fail

**ADDITIONAL DATA**

Average Noise Level N/A dBA      Average Temperature N/A °F      Average Relative Humidity Level N/A %Rh

Ceiling tiles sealed down/gasketed?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO	<input type="checkbox"/> N/A			
Floors have coved edges and corners?	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A			
Drawing of room complete?				<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
Profile of Viable Sample Locations Complete?				<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
Profile of Particle Count Locations Complete?				<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
Profile of Room HEPA Filters, Leak/Patches and challenge induction points complete?				<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
Profile of Room Pressures Complete?				<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
Profile of Room Air Supply / Return Complete?				<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
Profile of Temperature and Humidity Readings Complete?				<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A







Medical Technology Associates, Inc.  
 6840 Cross Bayou Drive  
 Largo, FL 33777  
 Toll Free: 877-569-8886  
 Fax: 727-548-8622

The list below is a list of the equipment that the MTA technician has on hand for use while performing work at your facility. Some of the equipment may or may not have been utilized. All instruments are calibrated by the manufacturer or other qualified vendor at least on an annual basis. All the instruments have been calibrated using Calibration Standards which are NIST (National Institute of Standards and Technology) traceable. If you need copies of the actual calibration certificate please contact our corporate office at: (877) 569-8886 or corp@mtausa.com

Technician Michael Klann

CALIBRATION DATA					
Equipment	Manufacturer	Model #	Serial #	Calibration Date	Calibration Due
Particle Counter	Met One	2400	1001059001	Dec-13	Dec-14
Thermal Anemometer	TSI	AVM440	AVM441112001	Sep-13	Sep-14
Photometer	Tech Services	PH-4	1410	Dec-13	Dec-14
Balometer	Alnor/TSI	EBT 721	90952009	Oct-13	Oct-14
Air Volume Capute hood					
Air Sampler	Buck	B30120	C101246	daily	daily

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## Section 3

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**USP 797 Pharmacy  
Hood Reports**

# Biological Safety Cabinet Certification Report



Date	August 14, 2014		
Report #			
Technician	Michael Klann		
Customer	Oncology Plus		
Address	1070 East Brandon Blvd		
City State	Brandon, FL 33511		
Contact	Zachary Scholl	/	Timothy Finn
Telephone	(813) 689-6303	/	(813) 689-6303
PO Number			

**Overall Status**  Pass  Fail  
 **Requires Attention**

Device ID#	7713-10587
Manufacturer	Nuaire
Model	NU-425-600 Series 24
Serial Number	1058701101
Device Location	Chemo Room

**Notes:** The current NSF Std. 49 requires a canopy or thimble connection to have negative pressure through the air gap and have an airflow alarm / monitor.  
 The airgap of the canopy transition is under slightly positive pressure. Increasing the external exhaust volume should make the entire airgap under negative pressure.  
 This cabinet was manufactured in 2001

## ACCEPTANCE CRITEREA

**Inflow / Face Velocity Tests**      100 - 110

Inflow Velocity      110 fpm.

**Downflow / Supply Velocity**      65 - 75

Downflow Velocity      71 fpm.

Individual point readings should be within +/- 25% or 16 fpm whichever is greater.

Individual Readings      53 Low      89 High

63 Low      85 High

## HEPA Filter Leak Test

Minimum challenge of 10 micrograms per liter. No leak should exceed 0.01% when scanned or 0.005% when probed.

Upstream Concentration      15 µg/l

Number of leaks Detected      0

Number of leaks Sealed      N/A

## Particulate Matter Profile (Particle counts taken at 1 minute sample time at 1 CFM and include 0.5 micron particles and larger)

Maximum number of .5 micron size particles and above allowed for ISO Class 5 is 3520 particles per cubic meter

ISO Class Achieved      5

**Static Pressure Readings**      0.25 "W.G

Duct Pressure      0.004 "W.G Measured at Air Gap

## Air Flow Smoke Pattern Test

Downflow Test, View Screen Retention Test, Sash Seal Containment Test and Work Access Opening Retention Test.

## Site Assessment Test

Window Sash Alarm

Negative Pressure visualization at exhaust canopy.

Air Flow Alarms and Interlocks

**FINAL RESULTS**

**Inflow / Face Velocity Tests**  
 Pass     Fail     N/A

**Downflow /Supply Velocity Tests**  
 Pass     Fail     N/A

**HEPA Filter Integrity Test**  
 Pass     Fail     N/A

**Particulate Matter Profile**  
 Pass     Fail     N/A

**Air Flow Smoke Pattern Test**  
 Pass     Fail     N/A

**Site Assessment Test**

<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input type="checkbox"/>	N/A
<input type="checkbox"/>	Pass	<input checked="" type="checkbox"/>	Fail	<input type="checkbox"/>	N/A
<input type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input checked="" type="checkbox"/>	N/A

**INSPECTION DATA**

**Equipment Data**

Type of Cabinet  A1  A2  B1  B2  Class I / Powder Hood

Exhaust Configuration  Room  No Blower  Thimble  Hard Connect  Aux Blower  Total Exhaust

Supply HEPA Filter				Exhaust Filter					
Filter Size	( 1 )	21	X 68	X 6	( 1 )	24	X 30	X 12	
Supply / Exhaust Area	11.50 sq.ft.						sq.ft.		
Supply / Exhaust Velocity	71 fpm.						fpm.		
Volume	818 cfm.						538 cfm.		
Work Access Opening Dimensions				10	Height	70.41	Width	Work Access Opening Area: 4.89 sq.ft.	
Exhaust Method Range		N/A	-	N/A	DIM Range		489	-	538
Restricted Access Range						N/A	-	N/A	

Notes:

**Downflow/Supply Velocity Readings** 6 inch grid

65	69	70	69	66	65	64	67	68	70	72
73	75	77	74	72	72	69	68	68	69	72
63	77	83	85	81	75	72	69	68	68	71
Average <u>71</u>										

**Inflow Readings (CFM)**

534	540	536	537	541
Average <u>538</u>				

**HEPA Filter Integrity Test**

Zero Leaks	Zero Leaks
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**Particulate Matter Profile**  N/A

#1	#2	#3
0	0	0

**SUMMARY**

MTA warrants that this air system was tested under the requirements as set forth in the following applicable standard(s):

IES-RP-CC-002.2; Heap Filters  NSF 49: Class II LAF Biosafety Cabinetry Annex F  Owners Specifications

Manufacturer's Specifications  ISO 14644- 1 1999 (E); Class at 0.5 um size particle, Status Operational

**Status of System after Inspection:**

- Certified to the Above Applicable Standard(s).
- Undergoing Corrective Action by MTA.
- Not Certified to the Above Applicable Standard(s).
- It is Recommended that this System be Corrected by the Owner Prior to any Additional Testing.

CERTIFICATE OF INSPECTION' expires 6 months from date of issue.

\*indicates duct area

# Biological Safety Cabinet Certification Report



Date	August 14, 2014	
Report #		
Technician	Michael Klann	
Customer	Oncology Plus	
Address	1070 East Brandon Blvd	
City State	Brandon, FL 33511	
Contact	Zachary Scholl	/ Timothy Finn
Telephone	(813) 689-6303	/ (813) 689-6303
PO Number		

**Overall Status**  Pass  Fail  
 **Requires Attention**

Device ID#	7713-10587
Manufacturer	Nuaire
Model	NU-425-600 Series 23
Serial Number	82392 AGR
Device Location	Chemo Room

**Notes:** The current NSF Std. 49 requires a canopy or thimble connection to have negative pressure through the air gap and have an airflow alarm / monitor.  
 The airgap of the canopy transition is under slightly positive pressure. Increasing the external exhaust volume should make the entire airgap under negative pressure.  
 This cabinet was manufactured in 1999

## ACCEPTANCE CRITEREA

**Inflow / Face Velocity Tests** 100 - 110

Inflow Velocity 109 fpm.

**Downflow / Supply Velocity** 65 - 75

Downflow Velocity 66 fpm.

Individual point readings should be within +/- 25% or 16 fpm whichever is greater.

Individual Readings 49 Low 82 High

54 Low 79 High

## HEPA Filter Leak Test

Minimum challenge of 10 micrograms per liter. No leak should exceed 0.01% when scanned or 0.005% when probed.

Upstream Concentration 16 µg/l  
 Number of leaks Detected 0  
 Number of leaks Sealed N/A

## Particulate Matter Profile (Particle counts taken at 1 minute sample time at 1 CFM and include 0.5 micron particles and larger)

Maximum number of .5 micron size particles and above allowed for ISO Class 5 is 3520 particles per cubic meter

ISO Class Achieved 5

**Static Pressure Readings** 0.35 "W.G

Duct Pressure 0.003 "W.G Measured at Air Gap

## Air Flow Smoke Pattern Test

Downflow Test, View Screen Retention Test, Sash Seal Containment Test and Work Access Opening Retention Test.

## Site Assessment Test

Window Sash Alarm

Negative Pressure visualization at exhaust canopy.

Air Flow Alarms and Interlocks

**FINAL RESULTS**

**Inflow / Face Velocity Tests**  
 Pass  Fail  N/A

**Downflow /Supply Velocity Tests**  
 Pass  Fail  N/A

**HEPA Filter Integrity Test**  
 Pass  Fail  N/A

**Particulate Matter Profile**  
 Pass  Fail  N/A

**Air Flow Smoke Pattern Test**  
 Pass  Fail  N/A

**Site Assessment Test**

<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input type="checkbox"/>	N/A
<input type="checkbox"/>	Pass	<input checked="" type="checkbox"/>	Fail	<input type="checkbox"/>	N/A
<input type="checkbox"/>	Pass	<input type="checkbox"/>	Fail	<input checked="" type="checkbox"/>	N/A

**INSPECTION DATA**

**Equipment Data**

Type of Cabinet  A1  A2  B1  B2  Class I / Powder Hood

Exhaust Configuration  Room  No Blower  Thimble  Hard Connect  Aux Blower  Total Exhaust

Supply HEPA Filter				Exhaust Filter					
Filter Size	( 1 )	21	X 68	X 6	( 1 )	24	X 30	X 12	
Supply / Exhaust Area	11.50 sq.ft.						sq.ft.		
Supply / Exhaust Velocity	66 fpm.						fpm.		
Volume	757 cf.						533 cf.		
Work Access Opening Dimensions				10	Height	70.41	Width	Work Access Opening Area: 4.89 sq.ft.	
Exhaust Method Range		N/A	-	N/A	DIM Range		489	-	538
Restricted Access Range						N/A	-	N/A	

Notes: \_\_\_\_\_

**Downflow/Supply Velocity Readings** 6 inch grid

78	78	79	73	70	64	64	63	65	67	66
70	72	64	68	60	56	57	56	57	57	59
78	73	75	76	70	66	60	54	54	60	62
Average <u>66</u>										

**Inflow Readings (CFM)**

532	532	531	535	535
Average <u>533</u>				

**HEPA Filter Integrity Test**

Zero Leaks	Zero Leaks
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**Particulate Matter Profile**  N/A

#1	#2	#3
0	0	0

**SUMMARY**

MTA warrants that this air system was tested under the requirements as set forth in the following applicable standard(s):

IES-RP-CC-002.2; Hepa Filters  NSF 49: Class II LAF Biosafety Cabinetry Annex F  Owners Specifications

Manufacturer's Specifications  ISO 14644- 1 1999 (E); Class at 0.5 um size particle, Status Operational

**Status of System after Inspection:**

- Certified to the Above Applicable Standard(s).
- Undergoing Corrective Action by MTA.
- Not Certified to the Above Applicable Standard(s).
- It is Recommended that this System be Corrected by the Owner Prior to any Additional Testing.

CERTIFICATE OF INSPECTION' expires 6 months from date of issue.

\*indicates duct area

# ISO 5 Area Certification Report



Date	August 14, 2014	
Report #	62406-4	
Technician	Michael Klann	
Customer	Oncology Plus	
Address	1070 East Brandon Blvd	
City State	Brandon, FL 33511	
Contact	Zachary Scholl /	Timothy Finn
Telephone	(813) 689-6303 /	(813) 689-6303
PO Number		

**Overall Status**  Pass  Fail  
 Requires Attention

Device ID#	ISO 5 Area
Manufacturer	Carter
Model	N/A
Serial Number	N/A
Device Location	IV Room

Notes: Certification based on Particle Counts Only

## ACCEPTANCE CRITEREA

### Supply Air Velocity Profile

Min	Max	Readings taken at	<input type="checkbox"/> 6"	<input checked="" type="checkbox"/> 12" from diffuser
Supply Velocity 80 fpm.	Supply Velocity 100 fpm.	Supply Velocity 98 fpm.		

Individual point readings should be within +/- 20%.

Individual Readings	78	Low	118	High
Recorded Low and High Values	91	Low	106	High

### Particulate Matter Profile

(Particle counts taken at 1 minute sample time at 1 CFM and include 0.5 micron particles and larger)

Maximum number of .5 micron size particles and above allowed for ISO Class 5 is 3520 particles per cubic meter	Average	0	95% UCL	0
	ISO Class Achieved	5		

### HEPA Filter Leak Test

Adequate challenge concentration between 10 and 90 micrograms per liter. No leak should exceed 0.01% when scanned.

Upstream Concentration	N/A
Calculated Upstream Concentration	13
Number of leaks Detected	0
Number of leaks Sealed	N/A

### Smoke Test

Visual Verification that the laminarity of the air is undisturbed by items in the hood and activities in the room (cross drafts).

### Induction Leak and Backstreaming Test

Verifies that the device prevents particle intrusion into the clean space by induction through joints or Backstreaming from workspace openings.

## FINAL RESULTS

**Supply Air Velocity**  
 Pass  Fail  N/A

**Uniformity**  
 Pass  Fail  N/A

**Particle Counts**  
 Pass  Fail  N/A

**HEPA Filter Integrity Test**  
 Pass  Fail  N/A

**Smoke Test**  
 Pass  Fail  N/A

**Induction Leak / Backstreaming Test**  
 Pass  Fail  N/A

**INSPECTION DATA**

**Equipment Data**

Supply HEPA Filter ( 3 ) 24 X 48 X  
 Pre-Filter ( ) X X  
 ( ) X X  
 1. Filter Size ( 3 ) 24 X 48 X  
 2. Supply Area 24.00 sq.ft.  
 3. Supply Velocity 98 fpm.  
 4. Volume 1881 cfm.

**Supply Velocity Profile**

105	100	95	94	98	102	92	91	101	104	99	100
104	94	93	97	95	91	94	98	106	102	97	99
Supply Velocity Average <b>98</b>											

**HEPA Filter Integrity Test**

Zero Leaks

**Particulate Matter Profile**

#1	#2	#3	#4	#5	#6
0	0	0	0	0	0

**SUMMARY**

MTA warrants that this air system was tested under the requirements as set forth in the following applicable standard(s):

- CAG--003-2006 v 11
- IES-RP-CC-002.3 Unidirectional-Flow, Clean-Air Devices
- Owners Specifications
- Manufacturer's Specifications
- ISO 14644- 1 1999 (E); Class 5 at 0.5 um size particle, Status Operational

**Status of System after Inspection:**

- Certified to the Above Applicable Standard(s).
- Undergoing Corrective Action by MTA.
- Not Certified to the Above Applicable Standard(s).
- It is Recommended that this System be Corrected by the Owner Prior to any Additional Testing.

CERTIFICATE OF INSPECTION' expires 6 months from date of issue.



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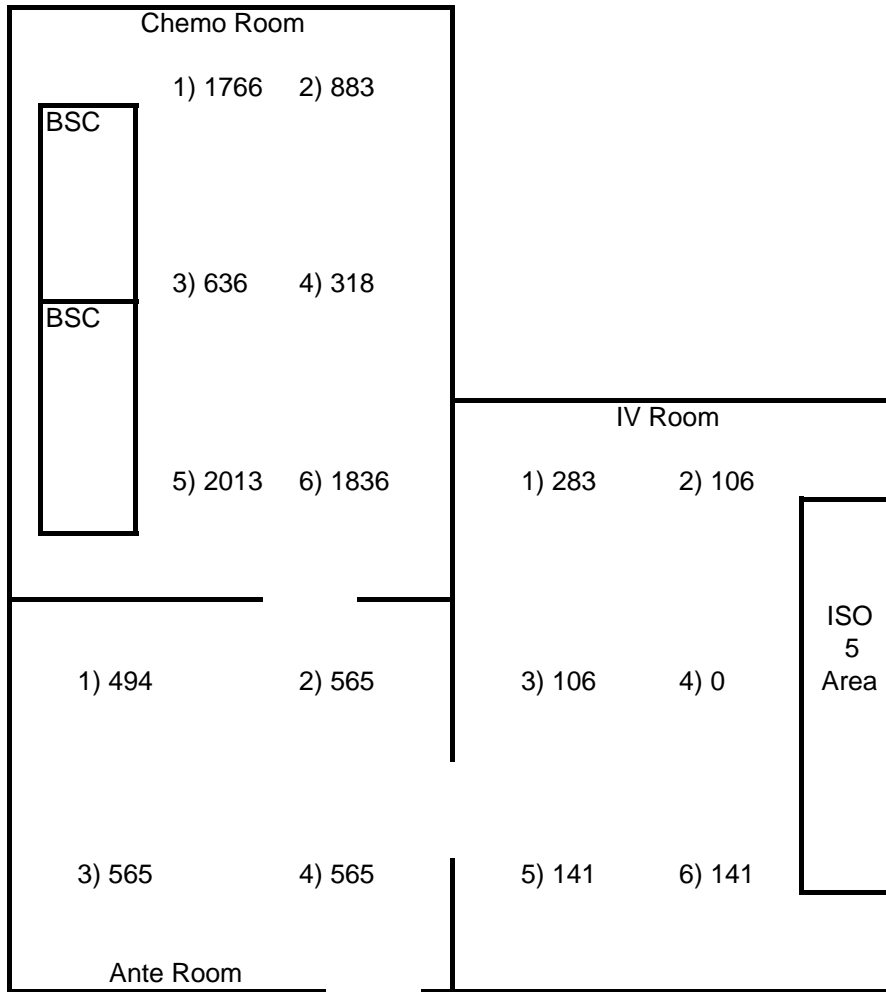
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# Section 4

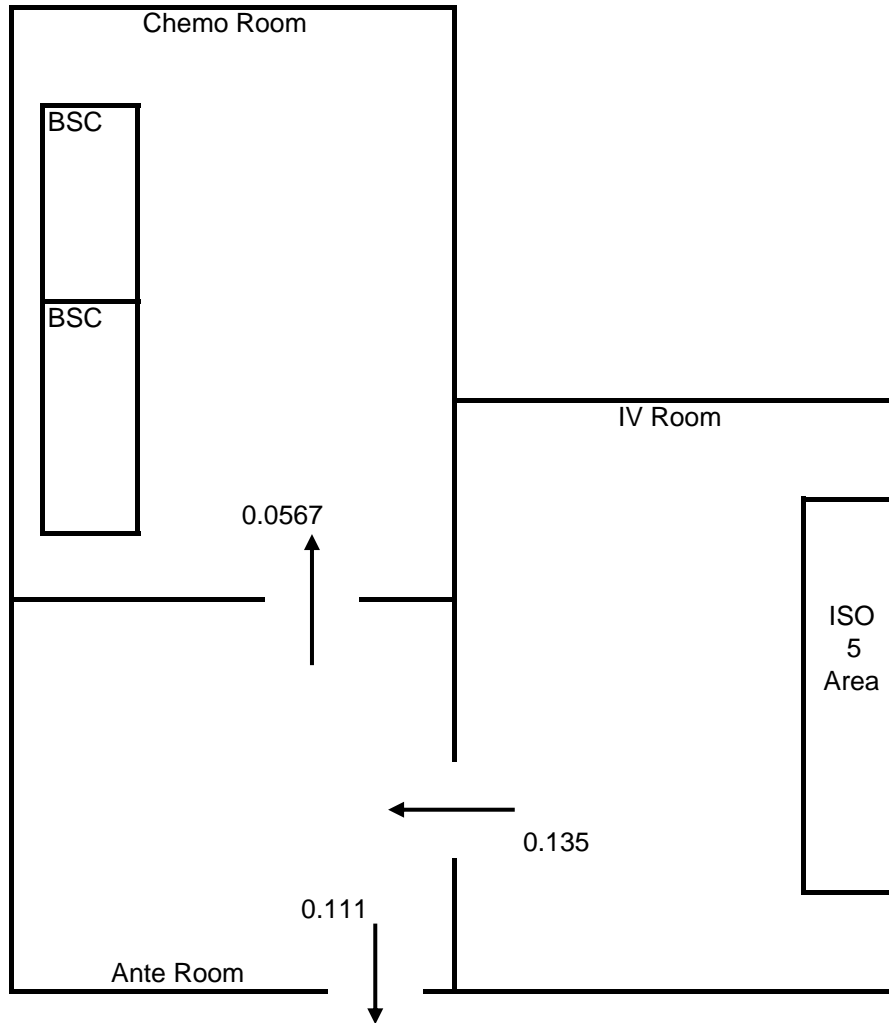
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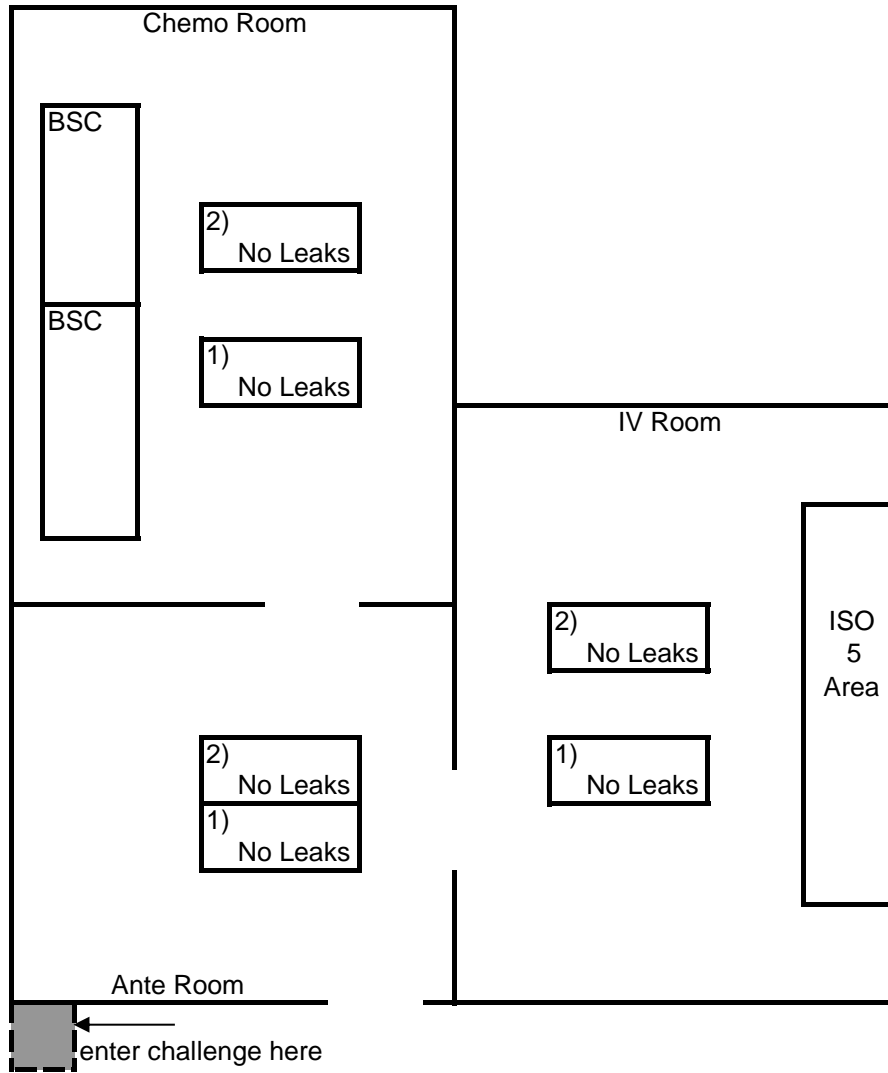
USP 797 Pharmacy  
Drawings

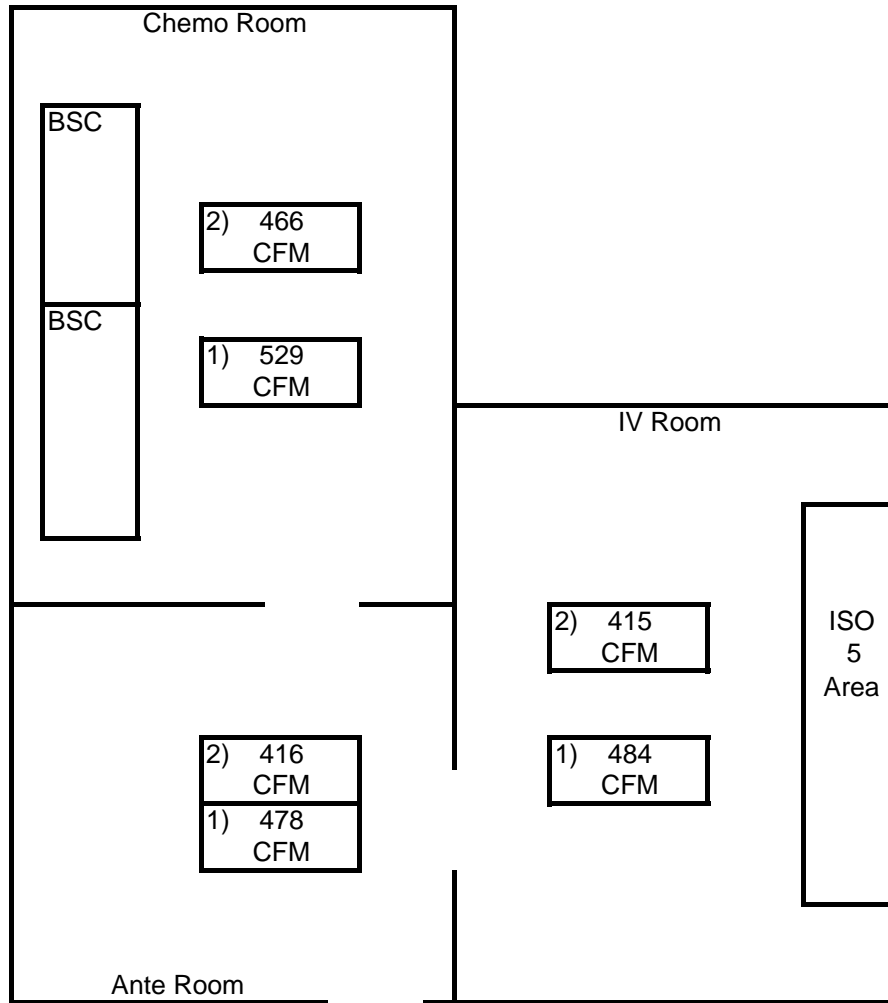


Particle Counts are in Particles Per Cubic Meter (0.5 microns) and (5.0 microns)

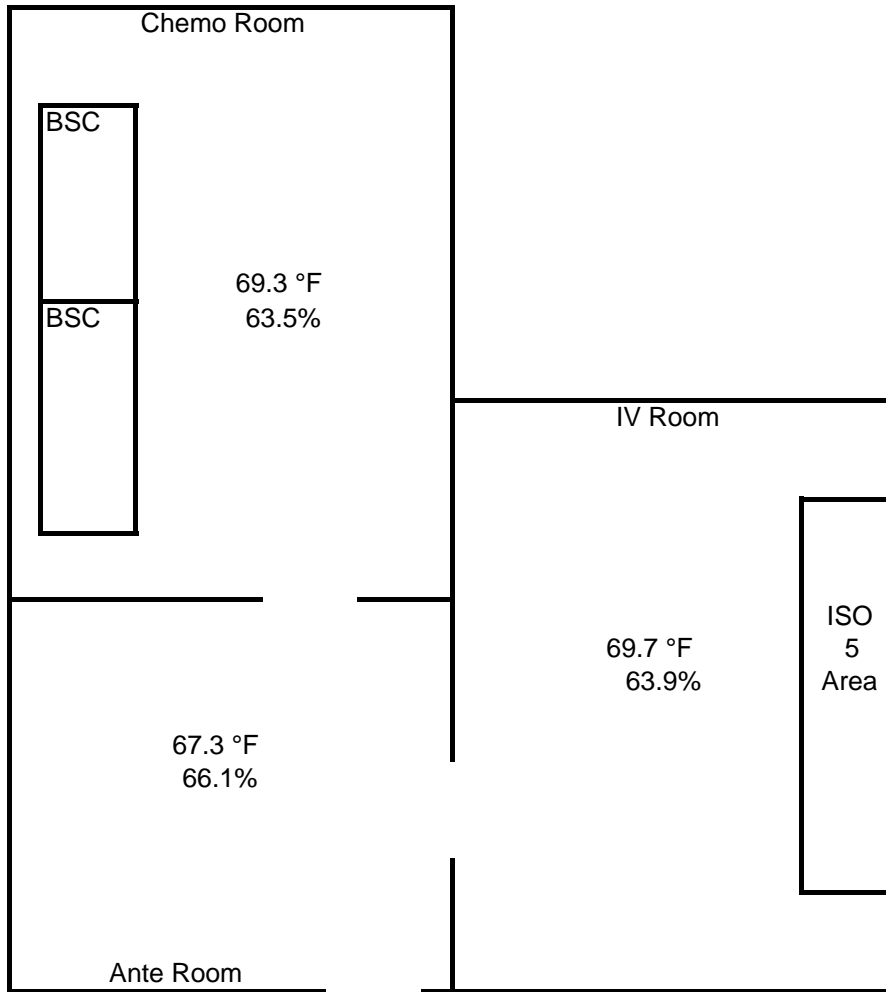


Pressure Differential Readings





Supply Air Volume



Temperature and Humidity Readings