**Oncology Plus** 

1070 East Brandon Blvd

Brandon, FL 33511

Report # 62406-1

USP 797 Pharmacy Clean Room Compliancy Inspection

August 14, 2014



Questions or Problems Please Contact our office at (877) 569-8886 or 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	Mic	Michael Klann					
Customer	On	cology 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

6840 Cross Bayou Drive Largo, FL 33777

Occupancy State During Testing Zscholl@OncologyPlus.com

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

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

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

# USP 797 CERTIFICATION EXECUTIVE SUMMARY





Contact	Zachary Scholl	/	Timothy Finn			
Telephone	(813) 689-6303	/	(813) 689-6303			
email address	Zscholl@OncologyPlus.com					
	tfinn@oncologyplus.com					

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

	Flow Hoods, Isolators,			Requires Attention
Віою	gical Safety Cabinets	Pass	Fail	Attention
SN#	1058701101	Х		
SN#	82392 AGR	Х		
SN#				

CUSTOMER NAME (PLEASE PRINT)

CUSTOMER SIGNATURE

Michael Klann

AUTHORIZED SERVICE REP

August 14, 2014

DATE

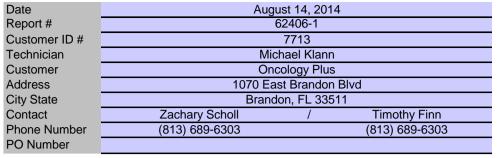
executive summary does not include results of viable air samples.	

## Section 1

USP 797 Pharmacy

Ante Room, IV Room and Chemo Room Summary Reports

#### **ANTE-ROOM SUMMARY**



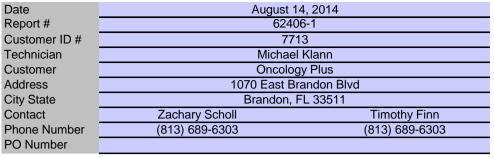


	MEDICAL	OLOGY ASSOCIATES
Overall Status of Room		
ISO 14644-1 1999-E Class 7	at .5 micron Status	Operational
Meets CETA CAG-003-2006 rev 2010	X Pass	Fail N/A
Meets USP 797 to Criteria Tested	X Pass	Fail N/A

PO Number											
Notes:											
Air Change Red Minimum 30 air	quirements:	or ISO 7 and 20 a	ir changes for IS	SO 8							
Total Air Volume	Supplied	894	CFM	Total Number of	f Air Changes	45	per hour	X Pass	Fail	N/A	
Total Air Volume	From PEC		CFM	Air Changes	From PEC		per hour			X N/A	
	essure and/or Di inches positive to the			n is required if utilizing d	isplacement meth	od.					
Pressure monitor	Present?							X YES	NO	N/A	
Static Pressure or Static Pressure or	r Velocity of Ante F r Velocity of Ante F r Velocity of Ante F r Velocity of Ante F	Room to IV Roo Room to Chemo	om o Room	0.111 0.135 -0.0567 k N/A	"W.G. or "W.G. or "W.G. or "W.G. or	N/A N/A N/A N/A	fpm fpm fpm fpm	X Pass X Pass X Pass Pass	Fail Fail Fail	N/A N/A N/A X N/A	
95% UCL is used to Maximum number of	atistical Data 0 .4 o determine ISO class of .5 micron size parti of .5 micron size parti	sification when ni icles allowed for I	ine (9) or less pa SO Class 7	article count locations a	re taken.	352,000 3,520,000	particles per		oron particles and lar	ger)	
ISO Class Achiev	red <b>7</b>	Me	an of Average	es 547	95% UC	CL 590	0	X Pass	Fail	N/A	
HEPA Filter Lea	ak Integrity Test Upstre		n should be gre	eater than 10µg/l and no	leak greater than	0.01% when so	anned. (See Data F	Page for more information	1.)		
Number of filters s Number of leaks s Number of leaks s	detected	2 0 N/A						X Pass	Fail	N/A	
Average Tempe	erature and Rela	ative Humidi	ty:								
Recommended To	emperature < 68° I	F	I	Measured 67.	<u>3</u> °F						
Recommended R	elative Humidity 30	0 to 65%	ľ	Measured 66.	1%Rh						
Smoke Study P		1									
Visual confirmation	on that air flows in t	the direction de	signed for the	type of room.				Pass	Fail	X N/A	

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

### IV / BUFFER ROOM SUMMARY



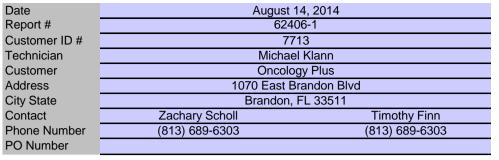


Overall Status of Room		
ISO 14644-1 1999-E Class 7	at .5 micron Status	Operational
Meets CETA CAG-003-2006 rev 2010	X Pass	Fail N/A
Meets USP 797 to Criteria Tested	X Pass	Fail N/A

PO Number (813) 689-6	6303	(813) 689-6303	Meets USP	797 to Criteria Tested	L	X Pass	Fall [	
Notes:								
Air Change Requirements: Minimum 30 air changes required for ISO 7								
Total Air Volume Supplied	899 CFM	Total Number of Air C	Changes 30	per hour	X Pass	Fail	N/A	
Total Air Volume From PEC	CFM	Air Changes With	PEC	per hour			N/A	
Differential Pressure and/or Displ Minimum 0.02 inches positive to the ante are		um 40 fpm is required if utilizin	ng displacement method.					
Pressure monitor Present?					X YES	NO	N/A	
Static Pressure or Velocity of Ante Room Static Pressure or Velocity of IV Room t			V.G. or N/A V.G. or N/A N/A	fpm fpm	X Pass Pass Pass	Fail Fail Fail	N/A   X N/A   X N/A	
IV Room Statistical Data 0 .5 micr 95% UCL is used to determine ISO classifica Maximum number of .5 micron size particles	ation when nine (9) or less p	article count locations are take	· .	t 1 minute sample time at  particles per cu	1 CFM and include 0.5 mor	on particles and large	er)	
ISO Class Achieved 7	Mean of Average	es 130	95% UCL 2	204	X Pass	Fail	N/A	
HEPA Filter Leak Integrity Test: Upstream concentration should be greater the	nan 10μg/l and no leak grea	ter than 0.01% when scanned	. (See Data Page for mo	re information.)				
Number of filters scanned Number of leaks detected Number of leaks sealed	2 0 N/A				X Pass	Fail	N/A	
Average Temperature and Relativ	e 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	•	e type of room.			Pass	Fail	X N/A	

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

### **CHEMO ROOM SUMMARY**





Overall Status of Room			
ISO 14644-1 1999-E Class 7	at .5 micron Status	Opera	tional
Meets CETA CAG-003-2006 rev 2010	X Pass	Fail	N/A
Meets USP 797 to Criteria Tested	X Pass	Fail	N/A

PO Number (813) 689-6303	(81	3) 689-6303		vieets USP 79	7 to Criteria Tested		X Pas	S	Fall	
Notes:										
Air Change Requirements: Minimum 30 air changes required for ISO 7										
Total Air Volume Supplied 995	CFM T	otal Number of Air	Changes	33	per hour	X Pass		Fail	N/A	
Total Air Volume From PEC	CFM	Air Changes Fron	m PEC		per hour			Х	N/A	
<b>Differential Pressure:</b> Minimum -0.01 inches negative pressure to the ante	area.									
Pressure monitor Present?						X YES		NO	N/A	
Static Pressure or Velocity of Ante Room to Che	emo Room		W.G. or W.G. or	N/A N/A	fpm fpm	X Pass		Fail X	N/A N/A	
Static Pressure or Velocity of Ante Room to						Pass		Fail X	N/A	
Chemo Room Statistical Data 0 .5 micro 95% UCL is used to determine ISO classification who Maximum number of .5 micron size particles allowed	en nine (9) or less particle of	count locations are tak	ken.	counts taken at 1	minute sample time at 1 (		moron particles	and larger)		
ISO Class Achieved 7	Mean of Averages	1242	95% UC	CL 182	7	X Pass		Fail	N/A	
HEPA Filter Leak Integrity Test: Upstream concentration should be greater than 10µg	ı/l and no leak greater than	0.01% when scanne	d. (See Data	Page for more	information.)					
Number of filters scanned  Number of leaks detected  Number of leaks sealed  N/A						X Pass		Fail	N/A	
Average Temperature and Relative Hum	idity:									
Recommended Temperature < 68° F	Measu	69.3	°F							
Recommended Relative Humidity 30 to 65%	Measu	63.5	%Rh							
Smoke Study Performed: Visual confirmation that air flows in the direction *This test only performed on unidirectional / uniform r	*	of room.				Pass		Fail X	N/A	

# Section 2

USP 797 Pharmacy

Report Data Inludes Calibration Data

#### **CLEANROOM INSPECTION DATA**

August 14, 2014

Date



Technician		Michael Klann				Report Number	62406-1
Customer ID#		7713	Contact	Zachary S	choll /	. Timo	othy Finn
Customer		Oncology Plus	Telephone	(813) 689-	6303	(813)	689-6303
Address		1070 East Brandon Blvd	email address	Zscholl@Oncolo	gyPlus.com /	/ <u>tfinn@oncologyplus.com</u>	
City State		Brandon, FL 33511					
			_	•			
		ANTE ROOM DIMENSIO	ONS AND PARTICLE CO	DUNT STATISTICAL DATA			
Room Dimension	s recorded in inches		Non	-applicable			
146	W	H		148.03 ft²	// an ath /:a'	Calculations	2
146	146	Room Area in square feet f ###  Room Area in square meters (m²)		148.03 ft <sup>2</sup> m <sup>2</sup>		) X width (in)) x 1 ft²/144 iı (ft²) x 1 m²/10.764 ft²	A1 <sup>-</sup>
		Room Volume in cubic feet (ft³)		.184.22 ft <sup>3</sup>		th (in) x Height (in) x 1 ft³/	/1728 in³
		Number of Sampling Locations		4		√m² rounded up	
Austra Dannin Danitirla (	Second Charletter   Date	(0.11)					
ISO Class	Count Statistical Data 7	Mean of Averages 547	·	e at 1 CFM and include 0.5 micron part  Standard De		Standard Err.	. 18
130 Class	,	ivicali di Avelages	3370 OCL3	Standard De	v <u>55</u>	Standard Err.	10
		IV ROOM DIMENSION	IS AND PARTICLE COL	JNT STATISTICAL DATA			
<b>Room Dimension</b>	s recorded in inches		Non-	-applicable			
L	W	н				Calculations	
220	148	Room Area in square feet ft <sup>2</sup>		226.11 ft <sup>2</sup>		) X width (in)) x 1 ft <sup>2</sup> /144 ii	n²
		Room Area in square meters (m²)		21.01 m <sup>2</sup> .808.89 ft <sup>3</sup>		(ft²) x 1 m²/10.764 ft²	/1720 :3
		Room Volume in cubic feet (ft³) Number of Sampling Locations		.808.89 ft³		th (in) x Height (in) x 1 ft³/ √m² rounded up	1/28 111
B/ Darris Banklala Carr	out Charlet and Date						
IV Room Particle Cou ISO Class	int Statistical Data	Mean of Averages 130		e at 1 CFM and include 0.5 micron part  O4 Standard De		Standard Err.	. 37
130 01033		Medit of Attendages	3370 002	or standard be		Staridard Err.	
		CHEMO ROOM DIMENSI	ONS AND PARTICLE (	COUNT STATISTICAL DATA	A		
Room Dimension	s recorded in inches		Non-	-applicable			
L	W	Н				Calculations	_
220	146	Room Area in square feet ft <sup>2</sup>		223.06 ft <sup>2</sup>		) X width (in)) x 1 ft <sup>2</sup> /144 ii	n²
		Room Area in square meters (m²)  Room Volume in cubic feet (ft³)		20.72 m <sup>2</sup> .784.44 ft <sup>3</sup>		(ft²) x 1 m²/10.764 ft² th (in) x Height (in) x 1 ft³/	/1728 in <sup>3</sup>
		Number of Sampling Locations	-	5		√m² rounded up	1/20 111
						,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
	e Count Statistical Data	_		at 1 CFM and include 0.5 micron part	<u> </u>		
ISO Class	7	Mean of Averages 1242	95% UCL 18	Standard De	2V 717	Standard Err.	. 293
		STERILE PREP / AUX ROOM / CHEMO ANT	E DOOM DIMENSION	S AND DARTICLE COLINT	STATISTICAL DATA		
Poom Dimension	s recorded in inches	STERILE PREF / AOX ROOM / CHEMO ANT	<del>- 1 1</del>	-applicable	STATISTICAL DATA		
ROUIT DITTETISION	W	Н	Non-	-аррисаріе		Calculations	
_	VV	Room Area in square feet ft <sup>2</sup>		0.00 ft <sup>2</sup>	(Length (in)	) X width (in)) x 1 ft²/144 ii	n²
		Room Area in square meters (m²)		0.00 m <sup>2</sup>		(ft²) x 1 m²/10.764 ft²	
		Room Volume in cubic feet (ft³)		0.00 ft <sup>3</sup>		th (in) x Height (in) x 1 ft³/	<sup>1</sup> 1728 in <sup>3</sup>
		Number of Sampling Locations		0		√m² rounded up	
Aux Room Partic	e Count Statistical Dat	a (Particle count	s taken at 1 minute sample time	e at 1 CFM and include 0.5 micron part	icles and larger)		
ISO Class	7	Mean of Averages	95% UCL	Standard De		Standard Err.	

Report Number	62406-1
Report Number	DZ4UD-1

AIR SUPPLY VOLUME MEASUREMENT DATA										
X Direct Mea	surement Method		Velgrid Measurer	ment Method/Multi po	oint array		Single point / velor	neter method		
	for a filter when DII	M cannot be measured:	HEPA filter #	HEPA Filter	Face Area	 Measured	1 CFM	Measured FPM		
		(K-Factor = measi	ured cfm/calculated cfm)			Calculated	d CFM	Correction Factor	r	
	Ante Room									
		Location		Filter Dimensions		Sqft.	K Factor	FPM	CFM	
HEPA Filter #	1		24L	48W	D	7.0			478	
HEPA Filter #	2		L	48 W	D	7.0			416	
HEPA Filter # / Diffuser			L	W	D	0.0				
HEPA Filter # / Diffuser			L	W	D	0.0				
HEPA Filter # / Diffuser			L	W	D	0.0				
HEPA Filter # / Diffuser			L	W	D	0.0				
				IV Ro	om					
		Location		Filter Dimensions		Sqft.	K Factor	FPM	CFM	
HEPA Filter #	1		24L	48 W	D	7.0			484	
HEPA Filter #	2		<u>24</u> L	48W	D	7.0			415	
HEPA Filter # / Diffuser			L	W	D	0.0				
HEPA Filter # / Diffuser			L	W	D	0.0				
HEPA Filter # / Diffuser			L	W	D	0.0				
HEPA Filter # / Diffuser			L	W	D	0.0				
				Chemo	Room					
LIEDA Eiltor #	1	Location	24	Filter Dimensions	D	Sqft. 7.0	K Factor	FPM	CFM	
HEPA Filter #	1		L	48 W	D				529	
HEPA Filter #	2		24L	48 W	D	7.0			466	
HEPA Filter # / Diffuser			L.	W	D	0.0				
HEPA Filter # / Diffuser			L	W	D	0.0				
HEPA Filter # / Diffuser			L	W	D	0.0				
HEPA Filter # / Diffuser			L	W	D	0.0				
			Steri		n/Chemo Ante Roo					
HEPA Filter # / Diffuser		Location	L	Filter Dimensions W	D	Sqft. 0.0	K Factor	FPM	CFM	
HEPA Filter # / Diffuser			L	W	D	0.0				
HEPA Filter # / Diffuser			L	W	D	0.0				
HEPA Filter # / Diffuser			L	W	D	0.0				
HEPA Filter # / Diffuser			L	W	D	0.0				
HEPA Filter # / Diffuser			L	W	D	0.0				

AIR CHANGE AND PRESSURE DATA								
				Ante Room				
Room Volume	1184 Su	pply Air Total	894	Air Changes Per m	inute 0.75	5 Ai	r Changes Per Hour	45
Total Air Volume from F	PEC				Total Air changes Per l	nour with PEC		X Non-applicable
Notes:								
				IV Room				
Room Volume	1809 Su	pply Air Total	899	Air Changes Per m	inute 0.50	) Ai	r Changes Per Hour	30
Total Air Volume from F Notes:	PEC				Total Air changes Per l	hour with PEC		X Non-applicable
-								
				Chemo Room				
Room Volume	1784 Su	pply Air Total	995	Air Changes Per m	inute 0.50	6 Ai	r Changes Per Hour	33
		_						
Total Air Volume from F Notes:	PEC				Total Air changes Per I	hour with PEC		X Non-applicable
			Sterile P	rep / Aux Room / Chemo	o Ante Room			
Room Volume	0 Su	pply Air Total	0	Air Changes Per m		<b>/0!</b> Ai	r Changes Per Hour	#DIV/0!
Total Air Volume from F	DEC	_			Total Air changes Per l	hour with DEC		X Non-applicable
Notes:		_			Total All Changes Fer i	iloui with FEC		A Non-applicable
Pressure/Velocity Monitors Inst	alled?	X YES	NO	N/A				
Pressure monitor Installed and I	Functioning?	X YES	NO	N/A				
Static Pressure Ante to Outside	0.111	"W.G. Si	tatic Pressure Ante to	IV Room 0.13	"W.G.	Static Pressure Ante Roo	om to Chemo	-0.0567 "W.G.
Static Pressure to		measured	"1	W.G. Stati	c Pressure to		measured	"W.G.
Static Pressure to		measured	II1	W.G. Stati	c Pressure to		measured	"W.G.
				Displacement				
Displacement Average Ante	Room to Outside	N/A		MTΔ strongly discourages t	he use of displacem	ent and curtains. If our	aine are utilized enroc	d the curtains at least 24" and
Displacement Average IV roo	om to Ante Room	N/A		measure 48" above the floor	r complete a drawing	and record the reading	s. Any customers usi	d the curtains at least 24" and ng curtains shall be advised to stments.
install a door and if needed low wall registers to allow for pressure adjustments.  N/A  N/A								

62406-1

Report Number

							Report Number	62	2406-1	
			HFPΔ FILTER	INTEGRITY TEST						
		(HEPA filters should be integrity tested			enge concentration	of 10 micrograms per lite	<u></u> :r.)			
				e Room						
	4	Upstream Challenge Location	Calculated Challenge	Measured Before	challenge After	Leak Detecte		Sealed		
HEPA Filter #		Intake near floor in adjacent room	13				No Yes	No	Fail	
HEPA Filter #	2	Intake near floor in adjacent room	13				No Yes	No	Fail	
HEPA Filter #	0						No Yes	No	Fail	
HEPA Filter #	0					Yes	No Yes	No	Fail	
HEPA Filter #	0					Yes	No Yes	No	Fail	
HEPA Filter #	0					Yes	No Yes	No	Fail	
IV Room										
		Upstream Challenge Location	Calculated	Measured						
HEPA Filter #	1	Intake near floor in adjacent room	Challenge 13	Before	After	Leak Detecte Yes X	ed Leak No Yes	Sealed No	Fail	
HEPA Filter #	2	Intake near floor in adjacent room	13				No Yes	No	Fail	
HEPA Filter #	0					Yes	No Yes	No	Fail	
HEPA Filter #	0					Yes	No Yes	No	Fail	
HEPA Filter #	0						No Yes	No	Fail	
HEPA Filter #	0					Yes	No Yes	No	Fail	
TILI AT III.	0					163	110 1103		I all	
				no Room						
		Upstream Challenge Location	Calculated Challenge	Measured Before	challenge After	Leak Detecte	d leal	Sealed		
HEPA Filter #	1	Intake near floor in adjacent room	13	Deloie	Alloi		No Yes	No	Fail	
HEPA Filter #	2	Intake near floor in adjacent room	13			Yes	No Yes	No	Fail	
HEPA Filter #	0					Yes	No Yes	No	Fail	
HEPA Filter #	0					Yes	No Yes	No	Fail	
HEPA Filter #	0					Yes	No Yes	No	Fail	
HEPA Filter #	0					Yes	No Yes	No	Fail	
			Sterile Prep / Aux Ro	om / Chemo Ante R	nom					
		Upstream Challenge Location	Calculated	Measured						
		, , , , , , , , , , , , , , , , , , , ,	Challenge	Before	After	Leak Detecte		Sealed		
HEPA Filter #	0					Yes	No Yes	No	Fail	
HEPA Filter #	0					Yes	No Yes	No	Fail	
HFPA Filter #	0					Yes	No Yes	No	Fail	

Yes

Yes

Yes

No

No

No

Yes

Yes

Yes

No

No

No

Fail

Fail

Fail

HEPA Filter #

HEPA Filter #

HEPA Filter #

0

0

		Report Number 62406-1						
ADDITIONAL DATA								
verage Noise Level N/A dBA Average Temperature N/A °F	Average Relative Humidity Level	N/A %Rh						
Ceiling tiles sealed down/gasketed?  YES  NO  N/A								
Floors have coved edges and corners?  X YES  NO  N/A								
Prawing of room complete?	X YES NO N/A							
rofile of Viable Sample Locations Complete?	X YES NO N/A							
rofile of Particle Count Locations Complete?	X YES NO N/A							
rofile of Room HEPA Filters, Leak/Patches and challenge induction points complete?	X YES NO N/A							
rofile of Room Pressures Complete?	X YES NO N/A							

Profile of Room Air Supply / Return Complete?

Profile of Temperature and Humidity Readings Complete?

XYES

XYES

NO

NO

N/A

N/A

Report Number 62406-1



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					

# Section 3

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	Bra	ndon, FL 335	311								
Contact	Zachary Scholl	/	Timothy Finn								
Telephone	(813) 689-6303	/	(813) 689-6303								
PO Number											

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

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

Maximum number of .5 micron size particles and above allowed for ISO Class 5 is

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



Certification Report		
August 14, 2014	MEDIC	
	Overall Status	X Pass Fail
Michael Klann		
Oncology Plus		X Requires Attention
1070 East Brandon Blvd	2	7740 40507
Brandon, FL 33511	Device ID#  Manufacturer	7713-10587
Zachary Scholl / Timothy Finn (813) 689-6303 / (813) 689-6303	Model	Nuaire NU-425-600 Series 24
(813) 663-6363 / (813) 663-6363	Serial Number	1058701101
	Device Location	Chemo Room
TI (NOT OUT 40		
	or thimble connection to have negative pressure through the air gap an ive pressure. Increasing the external exhaust volume should make the	
The aligap of the carlopy transition is under slightly pos	This cabinet was manufactured in 2001	rentine allyap under negative pressure.
		FINAL RESULTS
ITEREA		Inflow / Face Velocity Tests
ty Tests 100 - 110	Inflow Velocity 110 fpm.	X Pass Fail N/A
<b>Velocity</b> 6575	Downflow Velocity 71 fpm.	į
adings should be within +/- 25% or 16 fpm whichever is		Downflow /Supply Velocity Tests
greater. gs 53 Low 89 Hi	gh 63 Low 85 High	X Pass Fail N/A
		I I
est		!
of 10 micrograms per liter. No leak should exceed 0.01% when	Upstream Concentration 15 μ	g/l
scanned or 0.005% when probed.	Number of leaks Detected 0	HEPA Filter Integrity Test
	Number of leaks Sealed N/A	X Pass Fail N/A
rofile (Particle counts taken at 1 minute sample time	at 1 CFM and include 0.5 micron particles and larger)	Particulate Matter Profile
f .5 micron size particles and above allowed for ISO Class 5 is 3520 particles per cubic meter	ISO Class Achieved 5	X Pass Fail N/A
0.25 "W	.G Duct Pressure 0.004 "W.G Measured at Air	Gap
tern Test		Air Flow Smoke Pattern Test
/iew Screen Retention Test, Sash Seal Containme nd Work Access Opening Retention Test.	at Test	X Pass Fail N/A
est		Site Assessment Test
arm		X Pass Fail N/A
re visualization at exhaust canopy.		Pass X Fail N/A

**Site Assessment Test** Window Sash Alarm

Notes:

**ACCEPTANCE CRITEREA** 

Inflow / Face Velocity Tests

**Downflow / Supply Velocity** 

**Individual Readings** 

**Particulate Matter Profile** 

**Static Pressure Readings** 

**Air Flow Smoke Pattern Test** 

**HEPA Filter Leak Test** 

Negative Pressure visualization at exhaust canopy.

Air Flow Alarms and Interlocks

INSPECTION DATA									Page 2 of	2
Equipment Data  Type of Cabinet  Exhaust Configurati		A Room Dly HEPA Filte		X No Blower		B1	B2 Hard Connect Exhaust Filter		I / Powder Hood ux Blower	Total Exhaust
Filter Size Supply / Exhaust Area Supply / Exhaust Velo Volume Work Access Openin Exhaust Method Ran Notes:	1 ) ocity g Dimensions	21 X 6 11.50 71 818	8 X 6 5 sq.ft. fpm. cfm.	ight DIM	70.41 Range 4	( 1 Width 89 - 538	) 24 X 30  538  Work Access	X 12 sq.ft. fpm. cfm. Opening Area:	Total Volume 4.89 Range N/A	1355 cfm. sq.ft N/A
Downflow/Supply	Velocity Read	linas	6 inc	ch grid				Inflow Readi	ngs (CFM)	
65 69 70 73 75 77	69 66 74 72	65 64 72 69 75 72	67 6 68 6	68 70 68 69	72 72 71			534 540	-	541
	Average	71						Average	538	
HEPA Filter Integrity Test		-				1	Particulate Matter Prof	file		N/A
Zero Leaks				Zero Leaks			#1 O	#2 0	#3 0	
SUMMARY										
MTA warrants that th IES-RP-CC-00 X Manufacturer	-	rs	der the requ			following applica LAF Biosafety Cal <u>1</u> 1999 (E); C	oinetry Annex F	um size particle	Owners Speci	fications erational
Status of System X	after Inspection Certified to t		ndicable C+	andard(s)		☐ Undo	rgoing Corrective Actio	an by NATA		
				le Standard(s).		=	nmended that this Syst	-	d by the Owner Pri	or to any Additional
*indicates dust area		CERTIFI	ICATE OF IN	NSPECTION' exp	oires <u>6</u>	months from	date of issue.			
*indicates duct area										

Report Number

#### **Biological Safety Cabinet Certification Report**

Date	A	August 14, 2014										
Report #												
Technician	Michael Klann											
Customer	Oncology Plus											
Address	1070 East Brandon Blvd											
City State	Bra	andon, FL 335	511									
Contact	Zachary Scholl	1	Timothy Finn									
Telephone	(813) 689-6303	/	(813) 689-6303									
PO Number												

Air Flow Alarms and Interlocks



	MED	DIGAL	TECHI	NOLOG	Y AS	soc	IATES	3
	Overall Status	i	Х	Pass			Fail	-
				_ 		A44 = == 4		
			X	Ke Re	equires	Attent	ion	
	Device ID#			7713-10	0587			
	Manufacturer			Nuai				
	Model		١	NU-425-600	Series 23	}		
	Serial Number			82392 /	AGR			
	Device Location			Chemo F	Room			
ive pressi	ure through the air ga	p and have a	n airflow al	arm / monito	or.			
al exhaus	t volume should mak	e the entire a	rgap under	negative pr	ressure.			
ed in 199	9							· — —,
					L RESU		ctc	
			_	Inflow / Fa	ace veic	city re	:515	
locity	109 fpm.		X	Pass		Fail		N/A
elocity/	66 fpm.							į
			До	wnflow /S	Supply V	elocity	lests	
_ow	79 High		Х	Pass		Fail		N/A
	10	/1						į
ncentrati		μg/l		UEDA EII	tor Into			
aks Dete aks Seal			Γ <sub>ν</sub>	HEPA Fil		grity re Fail		N/A
ans ocan	14/A			_				<b>V</b> /A
d larger)				Particula —	ate Matte	er Profi	ile	
ieved	5		Х	Pass		Fail		N/A
03	"W.G Measured at	: Air Gap						
				Air Flow S	moke P	attern <sup>*</sup>	Test	
			X	Pass		Fail		N/A
				<b>.</b>				
			_	Site As	sessme	nt Tes	t	
			×	Pass	Ш	Fail	Ш	N/A
				Pass	X	Fail		N/A

The current NSF Std. 49 requires a canopy or thimble connection to have negat Notes: The airgap of the canopy transition is under slightly positive pressure. Increasing the external This cabinet was manufactur **ACCEPTANCE CRITEREA** Inflow / Face Velocity Tests Inflow Vel 110 **Downflow / Supply Velocity** 75 Downflow \ Individual point readings should be within +/- 25% or 16 fpm whichever is greater. **Individual Readings** 49 High Low **HEPA Filter Leak Test** Upstream Co Minimum challenge of 10 micrograms per liter. No leak should exceed 0.01% when scanned or 0.005% when probed. Number of lea Number of lea **Particulate Matter Profile** (Particle counts taken at 1 minute sample time at 1 CFM and include 0.5 micron particles and Maximum number of .5 micron size particles and above allowed for ISO Class 5 is ISO Class Achi 3520 particles per cubic meter **Static Pressure Readings** 0.35 "W.G **Duct Pressure** 0.00 **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.

INSPECTION DATA								Page 2 of 2		
Equipment Data  Type of Cabinet  Exhaust Configurat		A1 Room HEPA Filter	X No Blower	A2 X Thim	B1	B2 Hard Connect Exhaust Filter		/ Powder Hood ux Blower	Total Exhaust	
Filter Size ( Supply / Exhaust Area Supply / Exhaust Vel Volume Work Access Openin Exhaust Method Ran Notes:	1 ) 22 a ocity g Dimensions	11.50 sc 66 fp	i.ft. om. m. Height		( 1 ) Vidth - 538	24 X 30  533  Work Access	X 12 sq.ft. fpm. cfm. Opening Area:	Total Volume 4.89 Range N/A	1290 cfm. sq.ft N/A	
Downflow/Supply	Velocity Readir	ngs 6	inch grid				Inflow Reading	ngs (CFM)		
70 72 64	73 70 64 68 60 56 76 70 66	5 57 56	65 67 6 57 57 5 54 60 6	9			532 532	531 535 53	5	
Average 66 Average 533										
HEPA Filter Integrity Test		-			P	articulate Matter Prof	file		N/A	
Zero Leaks			Zero Leaks			#1 0	#2 0	#3 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  X ISO 14644- 1 1999 (E); Class at 0.5 um size particle, Status Operational										
Status of System after Inspection:										
	X 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.									
*indianta di et e e e		CERTIFICATE	OF INSPECTION' expi	res <u>6</u>	months from da	ate of issue.				
*indicates duct area										

Report Number

### ISO 5 Area Certification Report

Date	August 14, 2014								
Report #	62406-4								
Technician	Mic	chael Klanr	1						
Customer	Oncology Plus								
Address	1070 East Brandon Blvd								
City State	Branc	don, FL 335	511						
Contact	Zachary Scholl	/	Timothy Finn						
Telephone	(813) 689-6303	/	(813) 689-6303						
PO Number									

MEDICAL TECHNOLOGY ASSOCIATES							
<b>Overall Status</b>	X 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** FINAL RESULTS **Supply Air Velocity Profile** Х **Supply Air Velocity** Min Max Readings taken at 12" from diffuser 98 Supply Velocity 80 fpm. 100 fpm. Supply Velocity fpm. N/A Individual point readings should be within +/- 20%. Recorded Low and High Values Uniformity X Pass **Individual Readings** High 106 118 High N/A 78 Low Low **Particulate Matter Profile** (Particle counts taken at 1 minute sample time at 1 CFM and include 0.5 moron particles and larger) Maximum number of .5 micron size particles and above allowed for ISO Class 5 is 95% UCL **Particle Counts** Average 0 3520 particles per cubic meter ISO Class Achieved X Pass N/A **HEPA Filter Leak Test Upstream Concentration** N/A Adequate challenge concentration between 10 and 90 micrograms per liter. No leak should exceed 0.01% when scanned. Calculated Upstream Concentration 13 Number of leaks Detected 0 **HEPA Filter Integrity Test** Number of leaks Sealed N/A X Pass N/A **Smoke Test Smoke Test** X Pass Visual Verification that the laminarity of the air is undisturbed by items in the hood N/A and activities in the room (cross drafts). **Induction Leak and Backstreaming Test Induction Leak / Backstreaming Test** Pass Verifies that the device prevents particle intrusion into the clean space by induction through joints or Backstreaming from workspace openings.

Phone: (877) 877-569-8886 6840 Cross Bayou Drive Medical Technology Associates Largo, FL 33777

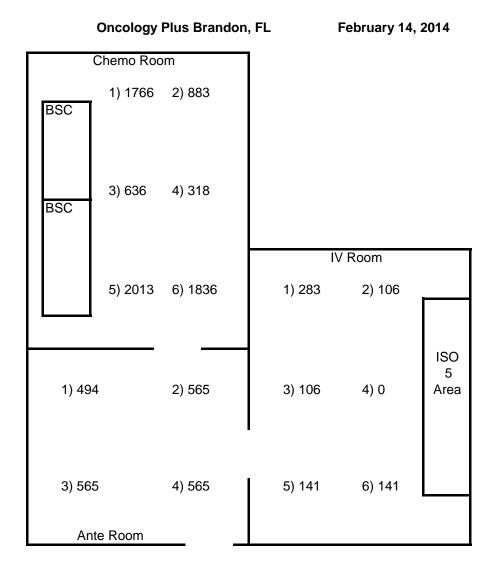
Fax: (727) 548-8622

							Report Number	62406-4
INSPECTION DATA							Page 2 of 2	
Equipment Data Supply	HEPA Filter			Pre-Filter				
1. Filter Size (3) 2. Supply Area 24.00 sq.1 3. Supply Velocity 98 fpm 4. Volume 1881 cfm.				( )	X	X X		
Supply Velocity Profile								
105 100 95	94	98 102	92 9	1	101 10	04 99	100	
104 94 93	97	95 91	94 9	8	106 10	02 97	99	
	Supply V	elocity Average	98					
HEPA Filter Integrity Test				Particu	ılate Matter Pr	ofile		
Zero Leaks	6			# C			#6 0	
SUMMARY								
MTA warrants that this air system	n was tested under the	requirements as set	forth in the follow	wing applicable sta	ndard(s):			
CAG003-2006 v 11 Manufacturer's Specificati	ons			ional-Flow, Clean- <i>F</i> 99 (E); Class <u>5</u>		um size particle,	Owners Specifications Status <b>Operationa</b>	<u> </u>
Status of System after Inspection:  X								

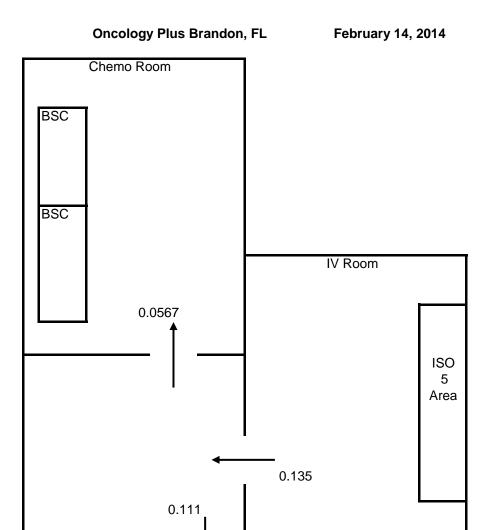
Fax: (727) 548-8622

# Section 4

USP 797 Pharmacy Drawings

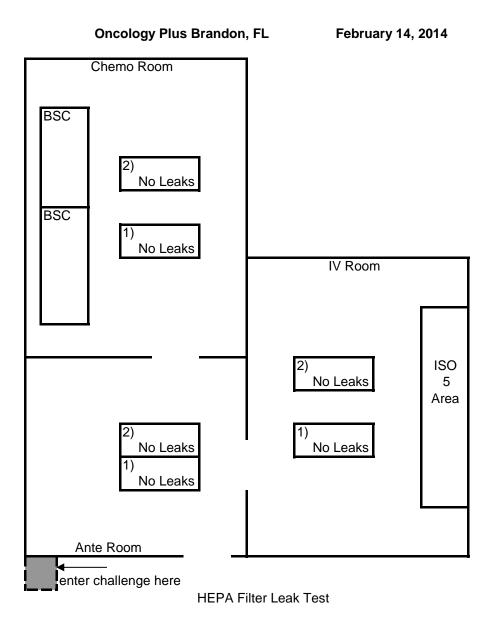


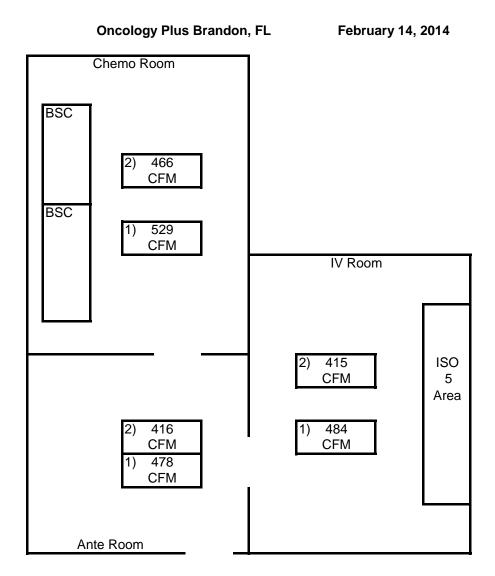
Particle Counts are in Particles Per Cubic Meter (0.5 microns) and (5.0 microns)



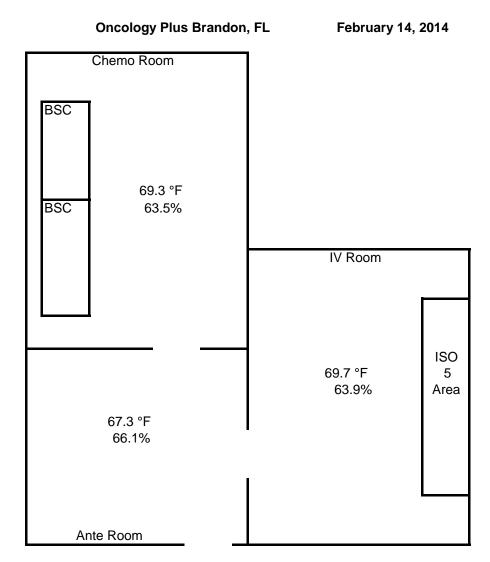
Pressure Differential Readings

Ante Room





Supply Air Volume



Temperature and Humidity Readings