

MICRO CLEAN

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Cincinnati Office
Toll Free: (800) 523-9852

TECHNI-MED, INC.

AURORA, IL 60506

Controlled Environment Testing & Certification

The Ante Room

This preliminary report does not include 3rd party lab results for airborne microbial sampling

Report #124302

10/19/2016

All testing performed in accordance with CE/FA Certification Guide
for Sterile Compounding Facilities (CAG-003)

Individual Test Results

HEPA Leak Test	PASS
Differential Pressure	PASS
Particle Count Testing	PASS
Air Changes Per Hour	PASS

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Controlled Environment Testing Report

Date: 10/19/2016
AIS #: CR-122109-1JP

Report: 124302
Prior Report #: 119791
Retest Due: 04/2017

TECHNI-MED, INC.
340 MARSHALL AVE
AURORA, IL 60506

Contact: LYDIA LESNIAK 800-679-4667

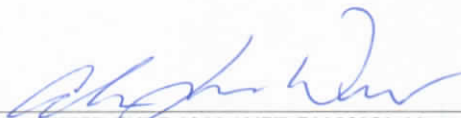
The data presented in this report is an exact record of data collected for the below listed Controlled Environment and was obtained in accordance with procedures as listed where applicable.

Standards and Procedures

ISO-14644	International Standard
IEST-RP-CC-002	Laminar Flow Clean Air Devices
IEST-RP-CC034	H.E.P.A. and U.L.P.A. Filter Leak Tests
IEST-RP-CC006	Testing Cleanrooms
CETA CAG-003	Certification Guide for Sterile Compounding Facilities

Work performed in the following areas: **The Ante Room**

Certification Performed by:


AWEST CNBT 1210 / NSF C0055851-01

Date: 10/19/2016

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Date: 10/19/2016
AIS #: CR-122109-111

Report #: 124302
Prior Report #: 119791
Retest Due: 04/2017

The Ante Room

Filter Number	CFM	Challenge	Leak Test	Leak Result	Comments
1	456	29	0.00300	Pass	N/A
Total	456				

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Customer: TECHNI-MED, INC.

Report #: 124302

Room: The Ante Room

Room Dimensions and Particle Count Location Calculation

Room Sections	Room Length In Inches	Room Width In Inches	Room Area Square Feet	Room Area Square Meters	Number of Locations
Section 1	60	97	40.42	3.76	
Totals			40.42	3.76	2

Ceiling Height and Room Volume Calculations (Cu. Ft. and Cu. M.)

Ceiling Height In Inches	Room Volume Cubic Feet	Room Volume Cubic Meters
96	323.33	9.16
Totals	323.33	9.16

Air Changes Per Hour Calculation (Room and Primary Engineering Control)

Supply Air Volume	Cubic Feet/Hour	Room Air Changes Per Hour
456	27360	84.62
PEC* Air Volume	Cubic Feet/Hour	PEC Air Changes Per Hour
0	0	0.00

* PEC is the Primary Engineering Control (ie. BSC, LFCB, Isolator, etc.)
PEC Air Volume can only be used when the device recirculates HEPA filtered air back into the lab.
Current USP 797 calls for 30 ACPH in a room with a maximum of 15 ACPH coming from the PEC.

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Date: 10/19/2016
AIS #: CR-122109-1JP

Report: 124302
Prior Report #: 119791
Retest Due: 04/2017

TECHNI-MED, INC.
Dynamic Airborne Particle Count Results
The Ante Room
ISO Class 8

Location	0.5 um @ 28.3L/Min.	0.5 um @ 1 cu. M	5.0 um @ 28.3L/Min	5.0 um @ 1cu. M
Location 1	78	2753	9	318
Location 2	102	3601	3	106
Totals	180	6354	12	424

TESTS	RESULTS	
	0.5 Micron	5.0 Micron
1 Cubic Meter Average	3177	212
1 Cubic Foot Average	90	6
1 Cubic Foot Standard Deviation	17	4
1 Cubic Meter Standard Deviation	599	150
95% UCL for 1 Cubic Meter	5846	879
95% UCL Result	PASS	PASS
Location 1	PASS	PASS
Location 2	PASS	PASS

NOTE: 5.0 Micron particle sizes are for information purpose only. USP-797 does not give specifications for this size particle.

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Customer: TECHNI-MED, INC.
Report #: 124302

Certification Equipment List

[REDACTED]				
TTC	Photometer	PH-4	1121	01/2017
TSI	Thermal	966	107360053	09/2016
	Anemometer			
Ahnor	Capture Hood	FB1-721	90423011	12/2016
Bios International	Air Sampler	Super 180	1440-09383	11/2016
Climet	Particle Counter	CF-150	015370	11/2016
Ahnor	Digital Manometer	FB1-721	90745034	04/2017

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Viabale Chain of Custody Form

Collection performed in Accordance with CETA CAG-009 and/or ISO 14698

Customer:		TECHNI-MED, INC.			Samples Collected By:			Adam West			
Contact:		Lydia Lesniak			Sample Date:		10/19/2016		Conditions During Sampling:		
Phone:		800.679.4667	Fax:	N/A		Sample Volume:		1000L			
Email:		thecompounderpharmacy@gmail.com			Work Order #		A20161804		Cert#	124302	
Sample Number	Location Number	Certification #	Data Recorded By: Sean Emerton				Media		ISO		
			Media Lot #	Expiration Date	Sample Identification			TSA 1107	MEA 1108	ISO Class*	
1	N/A	124302	Lab Code: 1152	H16260	Expires: 12/15/2016	AnteRoom		X		N/A	
2	N/A	124302	Lab Code: 1156	H16260	Expires: 12/15/2016	AnteRoom		X		N/A	
3	N/A	124302	Lab Code: 1153	H16257	Expires: 12/12/2016	AnteRoom			X	N/A	
4	N/A	124302	Lab Code: 1157	H16257	Expires: 12/12/2016	AnteRoom			X	N/A	
5	L1	124302	H16260	12/15/2016	AnteRoom		AnteRoom		X		8
6	L1	124302	H16257	12/12/2016	AnteRoom		AnteRoom			X	8
7	L2	124302	H16260	12/15/2016	AnteRoom		AnteRoom		X		8
8	L2	124302	H16257	12/12/2016	AnteRoom		AnteRoom			X	8
9											
10											
11											
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* The ISO Class listed is the recommended ISO Class per USP 797 or the ISO Class defined by the customer.

Equipment Used:			Relinquished By:		Date/Time:	
Model#	S/N#	Cal Due:			10/19/2016	
SAS 180	14-D-09383	Nov-2016			10:00 AM	
Notes: AIS#: CR-122109-1JP			Received By:		Date/Time:	

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Customer	TECHNI-MED, INC.	Test Report #	124301
Address	340 MARSHALL AVE	Date Tested	10/19/2016
City & State	AURORA, IL 60506	Previous Report	119790
Contact	LYDIA LESNIAK 800-679-4667	Manufacturer	Enviroco
Room	IV Prep	Model	10166
Location	1st Floor	S/N	89056814
Department	Pharmacy	Equipment Type	Clean Bench
		Retest Due Date	04/2017
		AIS #	N/A

Laminar Flow Clean Bench

Work Area Height	22.0
Work Area Width	46.0
Media Area	7.03
Airflow (CFM)	666.8
Manufacturer Spec	80 to 100

Test Instrumentation Used

	Anemometer	Photometer
Manufacturer	TSI	TEC
Model	966	PH-4
Serial Number	P07360053	1121
Calibration Due	09/2016	01/2017

Individual Velocity Point Readings

82	84	90	75
112	105	111	100

Airflow Test Result Pass

Max Velocity	112
Min Velocity	75
Average Velocity	94.9

Leak Test Result	Pass
Leak Test Spec	0.01%
Actual Leakage Detected	0.0020%
Aerosol Challenge Concentration	20.2
Simulated Dynamic Smoke Pattern Test	Pass
Smooth flow was observed with no reverse flow or refluxing	

Additional Information

Speed Control	No Change
Mag Gauge	Inoperable
Blower Motor Qty	1

Prefilter Information

Qty	Type	Size	Condition
1	Poly-Foam	22 x 44 x 1	Satisfactory

Particle Counts (Readings taken at 0.5/5.0 Microns per CFM)

Ambient Count	109				
Counts (0.5 Um)	0	0	0	0	0
Counts (5.0 Um)	0	0	0	0	0
Manufacturer	Climet	Model	CI-450		
Serial	045370	Calibration Due	11/2016		
Particle Counts Results (ISO 5)	Pass				

Remarks New blower motor & speed control 12/10.
New HEPA filter 6/09.

This Unit Has Met The Conditions of Manufacturer Specifications

Test Performed by _____ Date 10/19/2016

A. West CNBT 1210 / NSF C0055851-01

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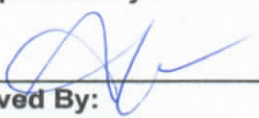
ViabLe Chain of Custody Form

Collection performed in Accordance with CETA CAG-009 and/or ISO 14698

Customer:	TECHNI-MED, INC.		Samples Collected By:	Adam West	
Contact:	Lydia Lesniak		Sample Date:	10/19/2016	Conditions During Sampling:
Phone:	800.679.4667	Fax:	N/A	Sample Volume:	1000L
Email:	thecompounderpharmacy@gmail.com		Work Order #	A20161804	Cert#
					124301

Sample Number	Location Number	Certification #	Data Recorded By: Sean Emerton			Media		ISO	
			Media Lot #	Expiration Date	Sample Identification		TSA 1107	MEA 1108	ISO Class*
1	N/A	124301	Lab Code: 1152	H16260	Expires: 12/15/2016	X		N/A	
2	N/A	124301	Lab Code: 1156	H16260	Expires: 12/15/2016	X		N/A	
3	N/A	124301	Lab Code: 1153	H16257	Expires: 12/12/2016		X	N/A	
4	N/A	124301	Lab Code: 1157	H16257	Expires: 12/12/2016		X	N/A	
5	L1	124301	H16260	12/15/2016	Envirco LAFCB (IV Prep)		X		5
6	L2	124301	H16257	12/12/2016	Envirco LAFCB (IV Prep)			X	5
7									
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9									
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* The ISO Class listed is the recommended ISO Class per USP 797 or the ISO Class defined by the customer.

Equipment Used:			Relinquished By:	Date/Time:
Model#	S/N#	Cal Due:		10/19/2016
SAS 180	14-D-09383	Nov-2016		10:00 AM
Notes: S/N: 89056814			Received By:	Date/Time:

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Customer TECHNICAL-MED, INC.
Address 340 MARSHALL AVE
City & State AURORA, IL 60506
Contact LYDIA LESNIAK 800-679-4667
Room IV Prep
Location 1st Floor
Department Pharmacy

Test Report # 124300
Date Tested 10/19/2016
Previous Report 119789
Manufacturer Enviroco
Model 10166
S/N 66043233
Equipment Type Clean Bench
Retest Due Date 04/2017
AIS # N/A

Laminar Flow Clean Bench

Work Area Height 22.0
Work Area Width 46.0
Media Area 7.03
Airflow (CFM) 655.3
Manufacturer Spec 80 to 100

Test Instrumentation Used

	Anemometer	Photometer
Manufacturer	TSI	TEC
Model	962	PH-4
Serial Number	P09260017	1121
Calibration Due	10/2016	01/2017

Individual Velocity Point Readings

83 89 95 91
97 100 103 88

Airflow Test Result Pass

Max Velocity 103
Min Velocity 83
Average Velocity 93.3

Leak Test Result Pass

Leak Test Spec 0.01%
Actual Leakage Detected 0.0020%
Aerosol Challenge Concentration 20.6
Simulated Dynamic Smoke Pattern Test Pass
Smooth flow was observed with no reverse flow or refluxing

Additional Information

Speed Control No Change
Mag Gauge Black
Blower Motor Qty 1

Pre-filter Information

Qty	Type	Size	Condition
1	Poly-Foam	22 x 44 x 1	Satisfactory

Particle Counts (Readings taken at 0.5/5.0 Microns per CFM)

Ambient Count 109
Counts (0.5 Um) 0 0 0 0 0
Counts (5.0 Um) 0 0 0 0 0

Manufacturer Climet **Model** CI-450
Serial 045370 **Calibration Due** 11/2016

Particle Counts Results (ISO 5) Pass

Remarks New blower motor & HEPA filter 9/05.

This Unit Has Met The Conditions of Manufacturer Specifications

Test Performed by A. West Date 10/19/2016

A. West CNBT 1210 / NSF C0055851-01

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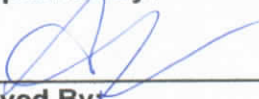
ViabLe Chain of Custody Form

Collection performed in Accordance with CETA CAG-009 and/or ISO 14698

Customer:	TECHNI-MED, INC.		Samples Collected By:	Adam West	
Contact:	Lydia Lesniak		Sample Date:	10/19/2016	Conditions During Sampling:
Phone:	800.679.4667	Fax:	N/A	Sample Volume:	1000L
Email:	thecompounderpharmacy@gmail.com		Work Order #	A20161804	Cert# 124300

Sample Number	Location Number	Certification #	Data Recorded By: Sean Emerton		Sample Identification			Media		ISO
			Media Lot #	Expiration Date	TSA 1107	MEA 1108	ISO Class*			
1	N/A	124300	Lab Code: 1152	H16260	Expires: 12/15/2016	X		N/A		
2	N/A	124300	Lab Code: 1156	H16260	Expires: 12/15/2016	X		N/A		
3	N/A	124300	Lab Code: 1153	H16257	Expires: 12/12/2016		X	N/A		
4	N/A	124300	Lab Code: 1157	H16257	Expires: 12/12/2016		X	N/A		
5	L1	124300	H16260	12/15/2016	Enviroc LAFCB (IV Prep)		X		5	
6	L1	124300	H16257	12/12/2016	Enviroc LAFCB (IV Prep)			X	5	
7										
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* The ISO Class listed is the recommended ISO Class per USP 797 or the ISO Class defined by the customer.

Equipment Used:			Relinquished By:		Date/Time:
Model#	S/N#	Cal Due:			10/19/2016
SAS 180	14-D-09383	Nov-2016			10:00 AM
Notes: S/N: 66043233			Received By:		Date/Time:

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TECHNI-MED, INC.

AURORA, IL 60506

Controlled Environment Testing & Certification

The IV Prep Room

This preliminary report does not include 3rd party lab results for airborne microbial sampling

Report #124303

10/19/2016

All testing performed in accordance with CETA Certification Guide
for Sterile Compounding Facilities (CAG-003)

Individual Test Results

HEPA Leak Test	PASS
Differential Pressure	PASS
Particle Count Testing	PASS
Air Changes Per Hour	PASS

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Controlled Environment Testing Report

Date: 10/19/2016
AIS #: CR-122109-2JP

Report: 124303
Prior Report #: 119792
Retest Due: 04/2017

TECHNI-MED, INC.
340 MARSHALL AVE
AURORA, IL 60506

Contact: LYDIA LESNIAK 800-679-4667

The data presented in this report is an exact record of data collected for the below listed Controlled Environment and was obtained in accordance with procedures as listed where applicable.

Standards and Procedures

ISO-14644	International Standard
IEST-RP-CC-002	Laminar Flow Clean Air Devices
IEST-RP-CC034	H.E.P.A. and U.L.P.A. Filter Leak Tests
IEST-RP-CC006	Testing Cleanrooms
CETA CAG-003	Certification Guide for Sterile Compounding Facilities

Work performed in the following areas: **The IV Prep Room**

Certification Performed by:


AWEST CNBT 1210 / NSF C0055851-01

Date: 10/19/2016

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Date: 10/19/2016
MS #: CR-122109-2JP

Report: 124303
Prior Report #: 119792
Retest Due: 04/2017

The IV Prep Room

Filter Number	CFM	Challenge	Leak Test	Leak Result	Comments
1	308	43	0.00100	Pass	N/A
2	217	62	0.00300	Pass	Reading taken with thermal anemometer and converted to CFM
Total	525				

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Customer: TECHNI-MED, INC.
Report #: 124303
Room: The IV Prep Room

Room Dimensions and Particle Count Location Calculation					
Room Sections	Room Length In	Room Width In	Room Area Square Feet	Room Area Square Meters	Number of Locations
Section 1	121	97	81.51	7.58	
Totals			81.51	7.58	3

Ceiling Height and Room Volume Calculations (Cu Ft and Cu M)		
Ceiling Height In Inches	Room Volume Cubic Feet	Room Volume Cubic Meters
96	652.06	18.46
Totals	652.06	18.46

Air Changes Per Hour Calculation (Room and Primary Engineering Control)		
Supply Air Volume	Cubic Feet/Hour	Room Air Changes Per Hour
525	31500	48.31
PEC* Air Volume	Cubic Feet/Hour	PEC Air Changes Per Hour
1322	79320	121.65

* PEC is the Primary Engineering Control (ie. BSC, FFCB, Isolator, etc.)
PEC Air Volume can only be used when the device recirculates HEPA filtered air back into the lab.
Current USP 797 calls for 30 ACPH in a room with a maximum of 15 ACPH coming from the PEC.

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Date: 10/19/2016
AIS #: CR-122109-2JP

Report: 124303
Prior Report #: 119792
Retest Due: 04/2017

TECHNI-MED, INC.
Dynamic Airborne Particle Count Results
The IV Prep Room
ISO Class 7

Location	0.5 um @ 28.3l/Min.	0.5 um @ 1 cu. M	5.0 um @ 28.3l/Min	5.0 um @ 1 cu. M
Location 1	99	2436	12	424
Location 2	12	424	4	141
Location 3	109	3848	3	106
Totals	190	6707	19	671

TESTS	RESULTS	
	0.5 Micron	5.0 Micron
1 Cubic Meter Average	2236	224
1 Cubic Foot Average	63	6
1 Cubic Foot Standard Deviation	49	5
1 Cubic Meter Standard Deviation	1721	174
95% UCL for 1 Cubic Meter	5117	515
95% UCL Result	PASS	PASS
Location 1	PASS	PASS
Location 2	PASS	PASS
Location 3	PASS	PASS

NOTE: 5.0 Micron particle sizes are for information purpose only. USP⁷⁹ does not give specifications for this size particle.

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Customer: **TECHNE-MED, INC.**
Report #: **124303**

Certification Equipment List

Manufacturer	Equipment	Model	Serial Number	Expiration Date
TTC	Photometer	PH-4	1121	01/2017
TSI	Thermal Anemometer	966	107360053	09/2016
Alnor	Capture Hood	FB1-721	90745034	04/2017
Bios International	Air Sampler	Super 180	14-D-09383	11/2016
Chmet	Particle Counter	CI-450	045370	11/2016
Alnor	Digital Manometer	FB1-721	90423011	12/2016

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Viability Chain of Custody Form

Collection performed in Accordance with CETA CAG-009 and/or ISO 14698

Customer:		TECHNI-MED, INC.			Samples Collected By:		Adam West		
Contact:		Lydia Lesniak			Sample Date:	10/19/2016	Conditions During Sampling:		
Phone:		800.679.4667	Fax:	N/A	Sample Volume:	1000L	Dynamic		
Email:		thecompounderpharmacy@gmail.com			Work Order #	A20161804	Cert#	124303	
Sample Number	Location Number	Certification #	Data Recorded By: Sean Emerton				Media		ISO
			Media Lot #	Expiration Date	Sample Identification			TSA 1107	MEA 1108
1	N/A	124303	Lab Code: 1152	H16260	Expires: 12/15/2016	X		N/A	
2	N/A	124303	Lab Code: 1156	H16260	Expires: 12/15/2016	X		N/A	
3	N/A	124303	Lab Code: 1153	H16257	Expires: 12/12/2016		X	N/A	
4	N/A	124303	Lab Code: 1157	H16257	Expires: 12/12/2016		X	N/A	
5	L1	124303	H16260	12/15/2016	IV Prep	X		7	
6	L1	124303	H16257	12/12/2016	IV Prep		X	7	
7	L2	124303	H16260	12/15/2016	IV Prep	X		7	
8	L2	124303	H16257	12/12/2016	IV Prep		X	7	
9	L3	124303	H16260	12/15/2016	IV Prep	X		7	
10	L3	124303	H16257	12/12/2016	IV Prep		X	7	
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* The ISO Class listed is the recommended ISO Class per USP 797 or the ISO Class defined by the customer.

Equipment Used:			Relinquished By:		Date/Time:
Model#	S/N#	Cal Due:			10/19/2016
SAS 180	14-D-09383	Nov-2016			10:00 AM
Notes: AIS#: CR-122109-2JP			Received By:		Date/Time: