



Controlled Environment Certification Services  
Cincinnati Office  
Toll Free: (800) 523-9852

**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 #100085839**

**11/29/2017**

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

HEPA Leak Test	<b>PASS</b>
Differential Pressure	<b>PASS</b>
Particle Count Testing	<b>PASS</b>
Air Changes Per Hour	<b>PASS</b>

# MICRO CLEAN<sup>SM</sup>

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## Controlled Environment Testing Report

Date: 11/29/2017  
AIS #: CR-122109-2JP  
MCI: 7H3KMAK

Report: 100085839  
Prior Report #: 347242  
Retest Due: 05/2018

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

CECS Inc. CR-____ MCI	Testing Cleanrooms
CETA CAG-003	Certification Guide for Sterile Compounding Facilities

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

Certification Performed by: \_\_\_\_\_ Date: 11/29/2017  
*TSCHIERING CNBT 528 / NSF C0262304-01*





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**The IV Prep Room**

Filter Number	CFM	Challenge	Leak Test	Leak Result	Comments
1	312	43	0.004%	Pass	N/A
2	536	25	0.001%	Pass	N/A
Total	848				

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**Customer: TECHNI-MED, INC.**  
**Report #: 100085839**  
**Room: The IV Prep 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	121	97	81.51	7.58	
<b>Totals</b>			<b>81.51</b>	<b>7.58</b>	<b>3</b>

### 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
<b>Totals</b>	<b>652.06</b>	<b>18.46</b>

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

Supply Air Volume	Cubic Feet/Hour	Room Air Changes Per Hour
848	50880	78.03
PEC* Air Volume	Cubic Feet/Hour	PEC Air Changes Per Hour
1182	70920	108.76

\* = 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.  
 ISO Class 8 ante or buffer area. The FDA aseptic processing guide recommends a minimum of 20 ACPH for ISO Class 8 zones.



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**TECHNI-MED, INC.**  
**Airborne Particle Count Results**  
**The IV Prep Room**  
**ISO Class 7 at 0.5 µm (≤352,000 ppcm) - Operational per ISO 14644-1:2015**  
**2 Liter Samples For 1 Minute**

Location	0.5 µm @ ppcm
Location 1	1555
Location 2	247
Location 3	212

TESTS	RESULTS
	<b>0.5 Micron</b>
Location 1	PASS
Location 2	PASS
Location 3	PASS



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Certification Equipment List

Manufacturer	Unit	Model	Serial Number	Next Calibration Date
ATI	Photometer	TDA-2G	10937	January 26 2018
TSI	Thermal Anemometer	962	P09260017	December 26 2017
Alnor	Capture Hood	EBT-721	90747027	March 09 2018
Bios International	Air Sampler	Super 180	12-D-08010	October 11 2018
TSI	Particle Counter	9310-02	93101126005	February 01 2018
Alnor	Digital Manometer	EBT-721	90747027	March 09 2018
AIS	Aerosol Generator	Jack II	45145	N/A