

Certificate of Compliance

ISO Class 4

Micron Air Model# 3 ft. Mic Serial# SL-01

Sector Logics

7220 West Jefferson Avenue, Suite 300

Lakewood, CO

Room Tested/Certified to: ISO 14644-1 Standards



Certifier: C-SCAN TECHNOLOGIES, NEBB CR-138

Technician: Adam Dunaway

Date Tested: December 17, 2008

A handwritten signature in black ink, appearing to read "Charles H. Dodson".



www.c-scantech.com

PHARMACY COMPOUNDING ISOLATOR TEST REPORT

Client Sector Logics CU-12408		Inspection Date 12/17/2008																																					
Address 7220 W. Jefferson Ave., Suite 300		Next Due Date 12/2009																																					
City,State Lakewood CO		Location Electronic Room																																					
Contact GaryJohnson	Phone 3033173002	Technician Adam Dunaway																																					
Manufacturer Micron Air Model # 3 Ft. Mic Serial # SL-01 Type Unidirectional Style Positive		PASS FAIL X Manufacturer's Specifications CETA Application Guide 002-2006 X USP 797 Recommendation for Compounding Isolator [PEC]																																					
2.01 Supply HEPA Velocity Test <table border="1"> <thead> <tr> <th>Pass Through Chamber</th> <th>Main Chamber</th> <th>Pass Through Chamber</th> </tr> </thead> <tbody> <tr> <td>N/A</td> <td>62, 64 68 66 64, 65 68 65 65, 69 67 66</td> <td>N/A</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th>Actual</th> <th>Acceptance</th> </tr> </thead> <tbody> <tr> <td>Fpm Avg 66</td> <td>N/A Fpm Avg</td> </tr> <tr> <td>Uniformity N/A</td> <td>N/AUniformity</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th>Actual</th> <th>Acceptance</th> </tr> </thead> <tbody> <tr> <td>Fpm Avg N/A</td> <td>N/AFpm Avg</td> </tr> <tr> <td>Uniformity N/A</td> <td>N/AUniformity</td> </tr> </tbody> </table>		Pass Through Chamber	Main Chamber	Pass Through Chamber	N/A	62, 64 68 66 64, 65 68 65 65, 69 67 66	N/A	Actual	Acceptance	Fpm Avg 66	N/A Fpm Avg	Uniformity N/A	N/AUniformity	Actual	Acceptance	Fpm Avg N/A	N/AFpm Avg	Uniformity N/A	N/AUniformity	2.02 Chamber Pressure Test <table border="1"> <thead> <tr> <th>Pass Through Chamber</th> <th>Main Chamber</th> <th>Pass Through Chamber</th> </tr> </thead> <tbody> <tr> <td>N/A</td> <td>0 0</td> <td>N/A</td> </tr> </tbody> </table> <table border="1"> <tbody> <tr> <td>Test 1 Pressure Change From</td> <td>N/A to N/A</td> <td>Pass</td> </tr> <tr> <td>Test 2 Pressure Change From</td> <td>N/A to N/A</td> <td>Pass</td> </tr> <tr> <td>Test 3 Pressure Change From</td> <td>N/A to N/A</td> <td>Pass</td> </tr> <tr> <td>Test 3B Pressure Change From</td> <td>N/A to N/A</td> <td>Pass</td> </tr> </tbody> </table> Comments No Gauge		Pass Through Chamber	Main Chamber	Pass Through Chamber	N/A	0 0	N/A	Test 1 Pressure Change From	N/A to N/A	Pass	Test 2 Pressure Change From	N/A to N/A	Pass	Test 3 Pressure Change From	N/A to N/A	Pass	Test 3B Pressure Change From	N/A to N/A	Pass
Pass Through Chamber	Main Chamber	Pass Through Chamber																																					
N/A	62, 64 68 66 64, 65 68 65 65, 69 67 66	N/A																																					
Actual	Acceptance																																						
Fpm Avg 66	N/A Fpm Avg																																						
Uniformity N/A	N/AUniformity																																						
Actual	Acceptance																																						
Fpm Avg N/A	N/AFpm Avg																																						
Uniformity N/A	N/AUniformity																																						
Pass Through Chamber	Main Chamber	Pass Through Chamber																																					
N/A	0 0	N/A																																					
Test 1 Pressure Change From	N/A to N/A	Pass																																					
Test 2 Pressure Change From	N/A to N/A	Pass																																					
Test 3 Pressure Change From	N/A to N/A	Pass																																					
Test 3B Pressure Change From	N/A to N/A	Pass																																					
2.03 Site Installation Assessment <ol style="list-style-type: none"> Airflow Pressure Alarm Test Adjustments Made Door Interlock Verification Building Exhaust System Performance <ol style="list-style-type: none"> Canopy Connection <ul style="list-style-type: none"> Air Gap Smok Test Dust Static Pressure in wc Hard Ducted Connection <ul style="list-style-type: none"> Dust Static Pressure in wc Comments		2.04 HEPA Filter Integrtiy <table border="0"> <tr> <td>Main Chamber</td> <td>Pass Through Chamber</td> </tr> <tr> <td>HEPA Filter Size 1.0</td> <td>HEPA Filter Size N/A</td> </tr> <tr> <td>Challenge Level 100 ug / L</td> <td>Challenge Level N/A ug / L</td> </tr> <tr> <td>Supply PASS</td> <td>Supply NA</td> </tr> <tr> <td>Main Chamber</td> <td>Pass Through Chamber</td> </tr> <tr> <td>HEPA Filter Area 1.0</td> <td>HEPA Filter Area N/A</td> </tr> <tr> <td>Challenge Level 100 ug / L</td> <td>Challenge Level N/A ug / L</td> </tr> <tr> <td>Exhaust PASS</td> <td>Exhaust NA</td> </tr> </table>		Main Chamber	Pass Through Chamber	HEPA Filter Size 1.0	HEPA Filter Size N/A	Challenge Level 100 ug / L	Challenge Level N/A ug / L	Supply PASS	Supply NA	Main Chamber	Pass Through Chamber	HEPA Filter Area 1.0	HEPA Filter Area N/A	Challenge Level 100 ug / L	Challenge Level N/A ug / L	Exhaust PASS	Exhaust NA																				
Main Chamber	Pass Through Chamber																																						
HEPA Filter Size 1.0	HEPA Filter Size N/A																																						
Challenge Level 100 ug / L	Challenge Level N/A ug / L																																						
Supply PASS	Supply NA																																						
Main Chamber	Pass Through Chamber																																						
HEPA Filter Area 1.0	HEPA Filter Area N/A																																						
Challenge Level 100 ug / L	Challenge Level N/A ug / L																																						
Exhaust PASS	Exhaust NA																																						



www.c-scantech.com

PHARMACY COMPOUNDING ISOLATOR TEST REPORT

Client Sector Logics		Manufacturer Micron Air	
Location Electronic Room	Contact GaryJohnson	Model # 3 Ft. Mic	Serial # SL-01

2.08 Smoke Pattern Test

Uni-directional: NA
 The smoke shall show smooth downflow with a minimum of dead spots or reflux (upward flow) at obstructions and across critical work zone and it is moved to the returns without reentry.

Non-uni-directional: NA
 Smoke demonstrates that the airflow gives rapid dilution and dispersal and that there are no standing vortices or local recirculation.

PASS

2.09 Preparation Ingress | Egress Test

Step 1 | Pre-Transfer Main Chamber Particle Level: N/A
 Step 2 | Particle Levels During Transfer: N/A
 Step 3 | Particle Levels After Transfer: N/A

VALUES SHOWN AT 1 CFM AT 0.5 UM AND LARGER

PASS

2.10A Particle Count Test At Rest

Pass Through Chamber	Main Chamber	Pass Through Chamber
N/A	0 5	N/A
	8	
	0 5	

NOTE VALUES AND LOCATIONS AT 1 CFM AT 0.5 UM AND LARGER
 WORK-SURFACE SIZE [WIDTH] 35 X [DEPTH] 24
 AREA IN SQUARE FEET 5.8
 AREA IN CUBIC FEET 9.7

2.10B Particle Count Test Operational

Pass Through Chamber	Main Chamber	Pass Through Chamber
N/A	6 2	N/A
	N/A	
	N/A N/A	

NOTE VALUES AND LOCATIONS AT 1 CFM AT 0.5 UM AND LARGER

EQUIPMENT CALIBRATION DATA:				
Particle Counter:	Make: Met One	Model: A2408	Ser.No.: 960782886	Due Date for Cal.: 8/31/09
Photometer:	Make: ATI	Model: TDA 2H	Ser.No.: 16615	Due Date for Cal.: 7/9/09
Thermo-Anemometer:	Make: TSI	Model: 8346	Ser.No.: 56010738	Due Date for Cal.: 3/09

Comments:
 Particle counts meet Class 10 (ISO 4) specifications. Air velocity is documented.