

## Clean Room Certification and Balance Report

PM Tool 315 North Park Drive San Antonio, Tx 78216

FED-STD-209E/ISO 14644

#### Clean Room Project and Test Equipment Info Customer/Job Information

Project Name: PM Tool Project Address: 315 North Park Drive City/State/Zip Code: San Antonio, Tx 78216 Site Contact: Anna Wulfe Department/Location: Clean Room Date: 1/17/23 Next Due Date: 7/17/23 **Room Specifications** Room Clean Room ISO Class\_\_\_\_\_8\_\_\_ ISO Class\_\_\_\_\_8\_\_\_\_ Room\_\_\_\_Ante\_\_\_\_ ISO Class \_\_\_\_\_ Room \_\_\_\_\_ ISO Class\_\_\_\_\_ Room\_\_\_\_\_ ISO Class Room ISO Class Room\_\_\_\_ **Test Equipment and Calibration Data** Make\_Met One\_\_\_\_ Model #\_\_\_\_\_A2408\_\_\_ Particle Counter: Serial # 981000092 Date Calibrated 2/12 Make\_\_\_\_\_Alnor\_\_\_ Model #\_\_\_\_\_\_8750\_\_\_\_ Balometer: Serial # 99117051 **Testing Performed By** Technician:\_\_Jay Ratliff\_\_\_\_\_ Lasco Services Inc. 601 Compton Irving, Tx 75061

972-513-1875 office

### **Airflow Analysis**

# Room Name/# Ante HEPA Filters

Yes_x_ No	HEPA filters located in duct system.
Yes Nox_	HEPA filters scanned/probed for leaks.
Yes No_x_	Leaks detected.
Yes No_x_	Leaks Repairable.
Yes No_x_	Leaks Repaired.

#### **Ceiling HEPA Filter Sizes**

<b>HEPA</b> Filter	Sizes:	22"x44	
#1	_ thru1	_=7	Sq. Ft.
#	_ thru	_=	Sq. Ft.
#	_ thru	_=	Sq. Ft.
#	_ thru	_=	Sq. Ft.
#	_ thru	_=	Sq. Ft.
#	_ thru	_=	Sq. Ft.
#	_ thru	_=	Sq. Ft.

# Air Flows

Total Ceiling HEPA Filters CFM=_	630	
Hood CFM (If Required)=	N/A	
Remarks		

#### **Clean Room Test Report**

**Tests Performed** x HEPA Airflows x Pressurization Check x Particle Counts \_\_\_x\_ Room Air Changes Per Hour \_\_x\_Temp/Humidity \_\_\_\_Scan/Probe HEPA Filters Air Viable Testing Room Tested- x As Built Operational 1 Personnel in Room at Time of Test **Specifications** Room Risk Level is \_1\_Low \_\_\_Medium \_\_\_High Pharmacy does Hazardous Drug Compounding (Chemo) \_\_\_Yes \_x\_No \_Low Volume (Less than 5 Per Week) \_\_\_\_High (More than 5 per Week) Room Volume: 400 Cubic Feet **Test Results 1-Particle Counts** Particle Counts taken at .5 Microns and Converted to Cubic Meters. Room Average Particle Count=\_\_360\_ PCF, with the highest single count taken being 624. \_x\_Meets \_\_ Exceeds, the Maximum Allowable Particle Count of\_\_\_100,000\_\_\_ for and ISO\_\_\_8\_ Clean Room 2- Room Air Changes Per Hour \_630\_ CFM x 60 minutes = \_37,800\_\_ CFPH / \_400\_ Room-Volume = \_\_\_\_94.5\_\_\_ Room Changes Per Hour. \_x\_ Meets \_\_\_ Does Not Meet, Minimum Allowable Room Changes per Hour for an ISO Class \_\_8\_ Clean Room. 3- Pressurization Testing Room has Pressure Gauge \_\_\_\_Yes \_x\_ No Room is under \_x\_Positive Pressure \_\_\_\_ Negative Pressure Actual Pressure Differential to Adjacent Room/Corridor: \_.028\_" W.C.

#### **Airflow Analysis**

## Room Name/# Clean Room

#### **HEPA Filters**

Yes_x_ No	HEPA	filters	located	in	duct system.
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Yes\_\_\_ No\_x\_ HEPA filters scanned/probed for leaks.

Yes\_\_\_ No\_x\_ Leaks detected.

Yes\_\_\_ No\_x\_ Leaks Repairable.

Yes\_\_\_ No\_x\_ Leaks Repaired.

#### **Ceiling HEPA Filter Sizes**

HEPA Filte	r Sizes:_22"x46";		
#1	thru5	=35\$	Sq. Ft.
#	thru	=	Sq. Ft.
#	thru	=	Sq. Ft.
#	thru	=	Sq. Ft.
#	thru	=	Sq. Ft.
#	thru	=	Sq. Ft.
#	thru	=	Sq. Ft.

#### **Air Flows**

Total Ceiling HEPA Filters CFM=3,114	
Hood CFM (If Required)=	
Remarks	_

#### **Clean Room Test Report**

**Tests Performed** x HEPA Airflows x Pressurization Check x Particle Counts \_\_x\_Temp/Humidity \_\_\_x\_ Room Air Changes Per Hour Scan/Probe HEPA Filters Air Viable Testing Room Tested- \_x\_As Built Operational 1 Personnel in Room at Time of Test **Specifications** Room Risk Level is x Low Medium High Pharmacy does Hazardous Drug Compounding (Chemo) Yes x No Low Volume (Less than 5 Per Week) High (More than 5 per Week) Room Volume: 4,304 Cubic Feet **Test Results 1-Particle Counts** Particle Counts taken at .5 Microns and Converted to Cubic Meters. Room Average Particle Count; 542 PCF, with the highest reading taken being 978. x Meets \_\_\_ Exceeds, the Maximum Allowable Particle Count of 100,000 for and ISO 8 Clean Room 2- Room Air Changes Per Hour \_3,114\_ CFM x 60 minutes = \_186,840\_ CFPH / \_4,304\_ Room-Volume = \_43\_ Room Changes Per Hour. x Meets Does Not Meet, Minimum Allowable Room Changes per Hour for an ISO Class \_\_8\_ Clean Room. 3- Pressurization Testing Room has Pressure Gauge \_\_\_Yes \_x\_ No Room is under \_x\_Positive Pressure \_\_\_\_Negative Pressure

Actual Pressure Differential to Adjacent Room/Corridor: \_\_\_\_\_.031\_\_" W.C.

**Remarks/Recommendations**- At the time of testing the rooms were observed holding temperature at 65 degrees Fahrenheit, and maintaining a relative humidity level between 44%-47% RH.