

# **EMPOWER PHARMACY**

12123 Jones Rd. Houston, Texas 77070

**CLEANROOM REPORT** 

January 31, 2014

1710 Preston, Suite A • Pasadena, TX 77503 Phone: 713-477-9247 • Fax: 713-477-9248 1-888-561-2932

> Website: www.slsi.net Email: service@slsi.net

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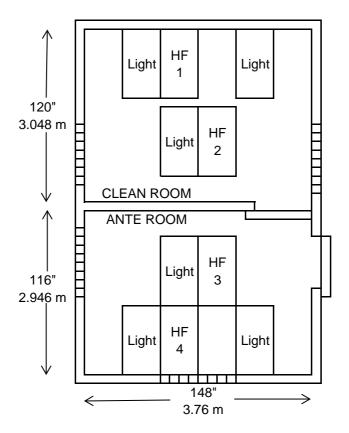
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# **TEST OUTLINE**

| 1 | Perform | Site | Anal | ysis |
|---|---------|------|------|------|
|---|---------|------|------|------|

- 2 Perform Viable Samples Test
- 3 Perform HEPA Filter Leak Test
- 4 Perform Room Particle Count
- 5 Perform Airflow ProfileMake Airflow Adjustments as Needed
- 6 Perform Pressure Tests
- 7 Perform Temperature and Humidity Test
- 8 Perform Clean Benches Certification
- 9 Generate Report

# HEPA FILTER LOCATIONS



(HF) = HEPA Filter

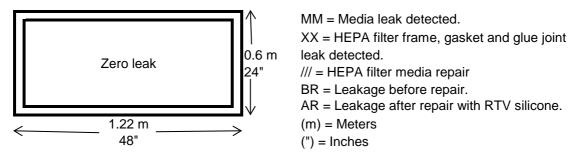
- (m) = Meters
- (") = Inches

# NOTES:

1 Ceiling height: 2.44 meters or 96 inches or 8 feet

# HEPA FILTER No 1 (CLEANROOM)

# HEPA FILTER INTEGRITY LEAK TEST



A minimum 10 micro-grams/liter PAO introduced upstream, 100% scan conducted dowstream, leak test results indicated on diagram.

| Upstream PAO concentration | 100%    |
|----------------------------|---------|
| Airflow Avg (cfm)          | 491     |
| Final Penetration          | ≤ 0.01% |
| Acceptance (Pass / Fail)   | Pass    |

Acceptance Criteria: The aerosol penetration shall not exceed 0.03% of the upstream concentration at any point.

#### HEPA FILTER MEDIA PATCH SIZE

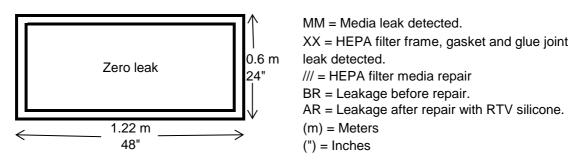
| Media Area Square Feet         | 7.02 |
|--------------------------------|------|
| Patch Size Dimensions (Inches) | 0    |
| Patch Size Percentage          | 0%   |
| Acceptance (Pass / Fail)       | Pass |

# Notes:

Acceptance Criteria: The preferred industry standard for patch size is 3% of the entire filter face area and a single patch can be not greater than 1.5 inches (3.8 cm) in the lesser dimension.

# HEPA FILTER No 2 (CLEANROOM)

# HEPA FILTER INTEGRITY LEAK TEST



A minimum 10 micro-grams/liter PAO introduced upstream, 100% scan conducted dowstream, leak test results indicated on diagram.

| Upstream PAO concentration | 100%    |
|----------------------------|---------|
| Airflow Avg (cfm)          | 500     |
| Final Penetration          | ≤ 0.01% |
| Acceptance (Pass / Fail)   | Pass    |

Acceptance Criteria: The aerosol penetration shall not exceed 0.03% of the upstream concentration at any point.

# HEPA FILTER MEDIA PATCH SIZE

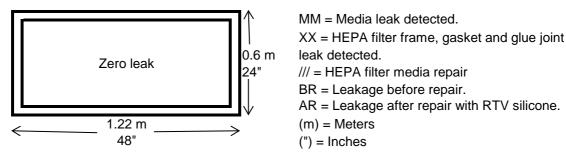
| Media Area Square Feet         | 7.02 |
|--------------------------------|------|
| Patch Size Dimensions (Inches) | 0    |
| Patch Size Percentage          | 0%   |
| Acceptance (Pass / Fail)       | Pass |

# Notes:

Acceptance Criteria: The preferred industry standard for patch size is 3% of the entire filter face area and a single patch can be not greater than 1.5 inches (3.8 cm) in the lesser dimension.

# HEPA FILTER No 3 (ANTEROOM)

# HEPA FILTER INTEGRITY LEAK TEST



A minimum 10 micro-grams/liter PAO introduced upstream, 100% scan conducted dowstream, leak test results indicated on diagram.

| Upstream PAO concentration | 100%    |
|----------------------------|---------|
| Airflow Avg (cfm)          | 479     |
| Final Penetration          | ≤ 0.01% |
| Acceptance (Pass / Fail)   | Pass    |

Acceptance Criteria: The aerosol penetration shall not exceed 0.03% of the upstream concentration at any point.

# HEPA FILTER MEDIA PATCH SIZE

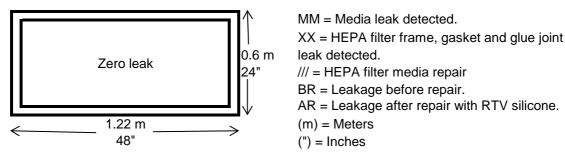
| Media Area Square Feet         | 7.02 |
|--------------------------------|------|
| Patch Size Dimensions (Inches) | 0    |
| Patch Size Percentage          | 0%   |
| Acceptance (Pass / Fail)       | Pass |

# Notes:

Acceptance Criteria: The preferred industry standard for patch size is 3% of the entire filter face area and a single patch can be not greater than 1.5 inches (3.8 cm) in the lesser dimension.

# HEPA FILTER No 4 (ANTEROOM)

# HEPA FILTER INTEGRITY LEAK TEST



A minimum 10 micro-grams/liter PAO introduced upstream, 100% scan conducted dowstream, leak test results indicated on diagram.

| Upstream PAO concentration | 100%    |
|----------------------------|---------|
| Airflow Avg (cfm)          | 585     |
| Final Penetration          | ≤ 0.01% |
| Acceptance (Pass / Fail)   | Pass    |

Acceptance Criteria: The aerosol penetration shall not exceed 0.03% of the upstream concentration at any point.

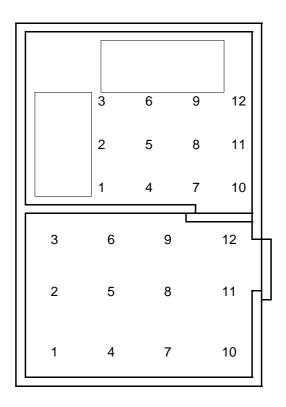
# HEPA FILTER MEDIA PATCH SIZE

| Media Area Square Feet         | 7.02 |
|--------------------------------|------|
| Patch Size Dimensions (Inches) | 0    |
| Patch Size Percentage          | 0%   |
| Acceptance (Pass / Fail)       | Pass |

#### Notes:

Acceptance Criteria: The preferred industry standard for patch size is 3% of the entire filter face area and a single patch can be not greater than 1.5 inches (3.8 cm) in the lesser dimension.

# PARTICLE COUNTS POINT LOCATIONS



#### Notes:

- 1 Room Particle Counts conducted 42 inches (1.07 meters) above floor under "Operational" conditions.
- 2 Each Particle Count was conducted using one minute sample time at one cubic feet per a minute air volume (28.3 L/min). (Exceeding the require 2 liters, with a minimum sampling time at each location of 1 minute).
- 3 Statistical analysis and 95% Upper Confidence Limit (UCL) were not performed due to count locations exceeding nine counts per each room. ISO 14644.1:1999(E) " When only a single location is sampled, or when more than nine are sampled, the 95% upper confidence limit is not applicable".

Clean room report

Particle Count Cleanroom Report Tested at 0.5 Micron or larger

| Class ISO 7. Tested "Dynamic" |            |                |                 |             |  |
|-------------------------------|------------|----------------|-----------------|-------------|--|
| ROOM                          | GRID POINT | PER CUBIC FEET | PER CUBIC METER | Pass / Fail |  |
| ISO CLASS 7                   | 1          | 1              | 35              | Pass        |  |
|                               | 2          | 6              | 212             | Pass        |  |
|                               | 3          | 12             | 424             | Pass        |  |
|                               | 4          | 89             | 3,143           | Pass        |  |
|                               | 5          | 8              | 283             | Pass        |  |
|                               | 6          | 0              | 0               | Pass        |  |
|                               | 7          | 34             | 1,201           | Pass        |  |
|                               | 8          | 104            | 3,673           | Pass        |  |
|                               | 9          | 80             | 2,825           | Pass        |  |
|                               | 10         | 131            | 4,626           | Pass        |  |
|                               | 11         | 98             | 3,461           | Pass        |  |
|                               | 12         | 108            | 3,814           | Pass        |  |
| Mean Size                     |            | 56             | 1,975           |             |  |

Acceptance: < 352,000 Particles Per Cubic Meter.

Particle Count Ante Room Report Tested at 0.5 Micron or larger

| Class ISO 7. Tested "Dynamic" |            |                |                 |             |  |
|-------------------------------|------------|----------------|-----------------|-------------|--|
| ROOM                          | GRID POINT | PER CUBIC FEET | PER CUBIC METER | Pass / Fail |  |
| ISO CLASS 7                   | 1          | 289            | 10,206          | Pass        |  |
|                               | 2          | 411            | 14,515          | Pass        |  |
|                               | 3          | 489            | 17,269          | Pass        |  |
|                               | 4          | 279            | 9,853           | Pass        |  |
|                               | 5          | 47             | 1,660           | Pass        |  |
|                               | 6          | 103            | 3,637           | Pass        |  |
|                               | 7          | 899            | 31,748          | Pass        |  |
|                               | 8          | 386            | 13,632          | Pass        |  |
|                               | 9          | 192            | 6,781           | Pass        |  |
|                               | 10         | 814            | 28,747          | Pass        |  |
|                               | 11         | 384            | 13,561          | Pass        |  |
|                               | 12         | 420            | 14,832          | Pass        |  |
| Mean Size                     |            | 393            | 13,870          |             |  |

Acceptance: < 352,000 Particles Per Cubic Meter.

# AIR FLOW VOLUME READINGS

|        |     |     | CLEAN ROOM        |                   |
|--------|-----|-----|-------------------|-------------------|
| FILTER | FPM | CFM | Meters Per Second | Liters Per Second |
|        | -   | -   |                   |                   |
| 1      | 70  | 491 | 0.355             | 232               |
| 2      | 71  | 500 | 0.362             | 236               |
| Total  |     | 991 |                   | 468               |

|        |     |      | ANTE ROOM         |                   |
|--------|-----|------|-------------------|-------------------|
| FILTER | FPM | CFM  | Meters Per Second | Liters Per Second |
|        | •   | -    |                   |                   |
| 3      | 68  | 479  | 0.347             | 226               |
| 4      | 83  | 585  | 0.423             | 276               |
| Total  |     | 1064 |                   | 502               |

# NOTES:

- Metric (S-1) figures have been calculated from English (I-P) using standard conversion factors. Airflow volumes were taken with a  $(2 \times 4)$  Flow hood and digital volume meter. 1
- 2

# AIR CHANGES PER HOUR

| ROOM                        | CLEAN ROOM | ANTE ROOM |
|-----------------------------|------------|-----------|
| Room Area<br>(m²)           | 11.46      | 11.07     |
| Room Volume<br>(m³)         | 27.94      | 27.00     |
| Room Area<br>(ft²)          | 123.33     | 119.2     |
| Room Volume<br>(ft³)        | 986.64     | 953.6     |
| Total Air Volume<br>(cfm)   | 991        | 1,064     |
| Air Change Rate<br>(ACH)(*) | 60.3       | 66.9      |

(m<sup>2</sup>) = Square meter

(m³) = Cubic meter

(ft²) = Square feet

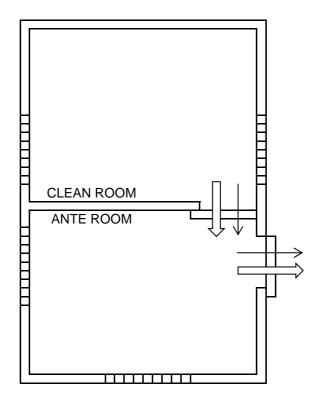
 $(ft^3)$  = Cubic feet

(cfm) = Cubic feet per a minute.

(ACH) = Air changes per a hour.

(\*) Air Changes Per Hour = Total Air Volume \* 60 / Room Volume

# **ROOM PRESSURE DIFFERENTIALS**



# Adjustable dampers

(" W.G.) = Measured in inches water gage.

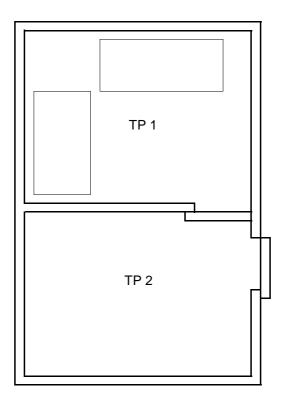
= Actual room pressurazation direction.

 $\Rightarrow$  = Design room pressurazation direction.

| Room Pressurization (*) | Test Criteria | Test Results | Pass / Fail |
|-------------------------|---------------|--------------|-------------|
| Clean room              | ≥ 0.02        | 0.027        | Pass        |
| Ante room               | ≥ 0.02        | 0.037        | Pass        |

(\*) = IEST-RP-CC006.3

# SECONDARY TEST



TP = Test Point Locations.
TEMPERATURE AND RELATIVE HUMIDITY TEST

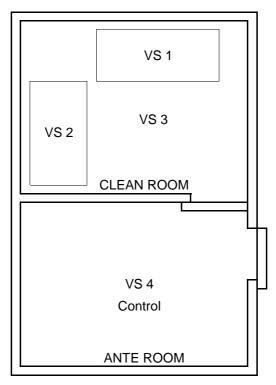
| ROOM                        | CLEAN ROOM   | ANTE ROOM    |
|-----------------------------|--------------|--------------|
| Temperature<br>(°C) - (°F)  | 27.55 - 72.3 | 27.27 - 72.3 |
| Relative Humidity<br>(% RH) | 41           | 43           |

(°C) = Celsius degree.

(°F) = Farenheit degree.

(%RH) = Percentage of Relative Humidity.

# VIABLE SAMPLE POINT LOCATIONS



VS = Viable Sample point

| LOT No  | EXP. DATE  |
|---------|--|
| 1331708 | 3/5/2014   |
| 1332402 | 2/26/2014  |
|         |  |
| LOT No  | EXP. DATE  |
| 1331708 | 3/5/2014   |
| 1332402 | 2/26/2014  |
|         |  |
| LOT No  | EXP. DATE  |
| 1331708 | 3/5/2014   |
| 1332402 | 2/26/2014  |
|         |  |
| LOT No  | EXP. DATE  |
| 1331708 | 3/5/2014   |
| 1332402 | 2/26/2014  |
|         |  |
| LOT No  | EXP. DATE  |
| 1331708 | 3/5/2014   |
| 1332402 | 2/26/2014  |
|         | 1331708<br>1332402<br>LOT No<br>1331708<br>1332402<br>LOT No<br>1331708<br>1332402<br>LOT No<br>1331708<br>1332402<br>LOT No<br>1331708<br>1332402 |

# **EQUIPMENT LIST**

|   | EQUIPMENT DATA  | PURPOSE   |
|---|---|---|
| 1 | TSI Thermoanemometer<br>Model: 8386A<br>S/N: 03040053<br>Exp: Sept. 2014                | Airflow Velocity Pressure test Temperature test Humidity Test |
| 2 | Particle Counter<br>TSI Aero Track APC 9310-01<br>S/N: 93100922005<br>Exp: Feb 16, 2014 | Particle Count  |
| 3 | Flow Hood AccuBalance<br>Model 8375<br>S/N: 91112034<br>Exp: Apr. 2014                  | Volume (CFM)  |
| 4 | Smoke tubes   | Airflow direction   |
| 5 | Phototmeter TEC Services<br>Model: PH-5<br>S/N: 1324<br>Exp: Jan 07, 2015               | HEPA filter leak test   |

**PAO** Generator

6 ATI Aerosol Generator

#### **SUMMARY**

On January 31, 2014 Superior Laboratory Services, Inc. performed the cleanroom performance test on the cleanroom at Empower Pharmacy located at 12123 Jones Rd, Houston Texas, 77070.

Testing including HEPA filter leak test, room airflow volume test, particle count test, pressure differential test, viable sample test, temperature test, humidity test and two clean benches certifications.

The Cleanroom and the Anteroom were tested "Dynamic" and at 0.5 microns and larger class ISO 7 (<352,000 particles per cubic meter) as specified by ISO 14644.1:1999.

The Cleanroom and the Ante room were tested "Dynamic" as specified by USP 797:2004.

We calculated the grid point layout using this formula NL=  $\sqrt{A}$  where "NL" is the minimum number of sampling locations, and "A" is the area of the cleanroom or clean zone in square meters. ISO 14644-1:1999(E).

Superior Laboratory Services, Inc particle count locations exceeds ISO minimum requirements.

Documents and guidelines for this test were:

ISO 14644.1:1999 IEST-RP-CC-006.3 IEST-RP-CC-034.2 USP 797:2004

The Clean room and the Ante room meet or exceed class ISO 7 at 0.5 micrometers (<352,000 particles per cubic meter) as specified by ISO 14644.1:1999.

The Clean room and the Ante room meet or exceed USP 797.

SLSI will, upon request, provide a cost quotation to perform any repairs, replacements or correction you may deem necessary to achieve the level of performance you desire. Thank you for the opportunity to inspect your Cleanrooms. We value Empower Pharmacy as a client, as well as the opportunity to continue serving you.

We will contact you to schedule the next certification service. Please call if you have any questions or need further assistance.

Alex Rosales Certification specialist



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# **CLEAN BENCH CERTIFICATION REPORT**

|        |   |        |          |      |         |         |          |       |         |       | Unit C     | ertified      | Yes                     | V              | ]        | No     |     |
|--------|---|--------|----------|------|---------|---------|----------|-------|---------|-------|------------|---------------|-------------------------|----------------|----------|--------|-----|
| Test   | Date  | 1      | 31       | 20   | )14     | ]       | Ехр.     | Date  | 7       | 2014  |            | Cer           | tificati                | ion #          |          | 3678   | A01 |
|        |   |        | E        | mpow | ver Ph  | arma    | су       |       | Job     | 36    | 78         |               | r                       | GERMFREE       |          |        |     |
|        | Date   1   31   2014   Exp. Date   7   2014   Certification #   3678 Ad   3678 Ad |        |          |      |         |         |          |       |         |       |            |               |                         |                |          |        |     |
|        |   |        |          |      |         |         |          |       | _       |       |            |               |                         | 65-1           |          | 13/51  |     |
|        |   | in     |          |      |         |         |          |       |         |       |            | _             |                         | 10/            |          | 00)    |     |
| E-1116 | Test Date   |        |          |      |         |         |          |       |         |       |            |               |                         |                |          |        |     |
| ISO 1  | Test Date   |        |          |      |         |         |          |       |         |       |            |               |                         |                |          |        |     |
|        |   |        |          | Sı   | upply \ | /elocit | ies (fp  | m)    |         |       |            | I             | HEPA fi                 | lter pa        | rticle t | est    |     |
| 93     |   |        |          |      |         |         |          |       |         |       |            |               |                         |                |          |        |     |
| 92     | 95  | 86     | 89       | 81   | 85      | 93      | 93       | 98    |         |       |            |               | 0                       | 0              | 0        | n      | 1   |
| 94     |   |        |          |      |         |         |          |       |         |       |            |               | Ŭ                       | Ŭ              | Ŭ        | Ů      |     |
| 101    | 102   | 100    | 101      | 85   | 94      | 97      | 97       | 98    |         |       |            | 0             | 0                       | 0              | 0        | 0      |     |
|        |   |        |          |      |         |         |          |       |         |       |            | Tes           | sted at 0               | .5 micro       | on and   | larger | Į.  |
|        |   |        |          |      |         |         |          |       |         |       |            |               |                         |                |          |        |     |
| Supr   | olv Ar  | ea     |          | 16   | .65     | ft²     | Ma       | n. Sp | ecs.    | 1     | Mag        | ınehelic: (   | Inches                  | of wa          | iter)    | N      | /A  |
|        |   |        | <b>/</b> |      |         | 1       |          | •     |         | 1     |            |               |                         |                |          |        |     |
|        |   |        |          | 15   | 555     | 1 '.    | 1332     | to    | 1665    | 1     |            |               |                         |                |          | N      | /A  |
|        | -   |        |          |      |         | •       | НЕ       | ΈΡΔ Ε | II TFI  | RIFAK | TEST       |               | -                       |                |          |        |     |
|        |   |        |          |      |         |         |          | / / - |         |       |            | Media Le      | ak                      |                |          |        |     |
|        |   |        |          |      |         |         |          |       |         |       |            |               |                         | int / G        | asket    | leak   |     |
| Left   |   |        |          |      |         |         |          |       |         | Ri    |            | ,             | , , .                   |                |          |        |     |
|        |   |        |          |      |         |         |          |       |         | c.    | الل برامور | EDA filtor    |                         | ^              | 0/       |        |     |
| PΔC    | Con   | contro | ation:   | 1 1  | 2       | uα/l    |          |       | Calcula |       |            |               | lo #) / T               | U<br>atal airf | , -      |        | ass |
|        |   |        |          |      |         | _       | nt Chall |       |         |       |            | Laskiii iiozz | 1 <del>C #</del> ) / 10 | Jiai aiii      | IOW CI   | IVI    |     |
|        |   |        |          |      |         |         |          | -     |         | •     |            | at any point  |                         |                |          |        |     |
|        |   |        |          |      |         | 1       | 1        | ]     |         |       |            | <del></del>   | Re                      | eplaced        | the filt | ers    | No  |
|        |   |        |          |      |         |         |          | J     |         |       |            |               |                         |                |          |        |     |
| Co     | mmer  | nts:   |          |      |         |         |          |       |         |       |            |               |                         |                |          |        |     |
|        |   |        |          |      |         |         |          |       |         |       |            |               |                         |                |          |        |     |
|        |   |        |          |      |         |         |          |       |         |       |            |               |                         |                |          |        |     |
|        |   |        |          |      |         |         |          |       |         |       |            |               |                         |                |          |        |     |
|        |   |        |          |      |         |         |          |       |         |       |            |               |                         |                |          |        |     |
|        |   |        |          |      |         |         |          |       |         |       |            |               |                         |                |          |        |     |
|        | Alex  | x Ros  | ales     |      | •       |         |          |       |         |       |            |               |                         |                |          |        |     |



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# **CLEAN BENCH CERTIFICATION REPORT**

|              |  |         |          |           |       |      |         |         |             |               | Unit C | Certified                     | Yes                   | ٧               | ]                   | No     |          |
|--------------|--|---------|----------|-----------|-------|------|---------|---------|-------------|---------------|--------|-------------------------------|-----------------------|-----------------|---------------------|--------|----------|
| Test         | Date   | 1       | 31       | 20        | 14    | ]    | Ехр.    | Date    | 7           | 2014          |        | Cert                          | ificati               | on#             |                     | 3678   | A01      |
|              | pany   |         | Е        | mpow      | er Ph | arma | су      |         | Job         | 367           | 8      | _Hood Mfr                     |                       |                 | RMFF                |        |          |
| Cont<br>Addr |  |         |          | 12123     | long  | o D4 |         |         | PO<br>Rm    | Clean F       | 200m   | _Model<br>Serial              |                       |                 | Z-6SS<br>5-BH-      |        | )        |
| City,        |  |         |          | lousto    |       |      |         |         | Ph          | 832-678       |        |                               |                       | 00-10           | <u>л-ып-</u><br>n/a | 10/02  | <u>.</u> |
| E-ma         |  | in      |          | mpow      |       |      |         | m       | Fax         | 832-678       |        | _                             |                       | ISC             | ) 5 (1              | 00)    |          |
| c            |  | <u></u> | . 5 9 0  |           | JAP   |      | 25,100  | <u></u> |             | 002 070       |        |                               |                       |                 | ( !                 | /      |          |
| ISO 1        | 14644  | .1:19   | 99       | $\sqrt{}$ |       | Ma   | n. Spe  | ecs.    | V           | Othe          | r:     |                               |                       |                 |                     |        | -        |
|              | Supply Velocities (fpm)  HEPA filter particle test |         |          |           |       |      |         |         |             |               |        |                               |                       |                 |                     |        |          |
| 94           | 93   | 95      | 99       | 92        | 92    | 98   | 95      | 96      |             |               |        |                               |                       |                 |                     |        |          |
| 94           | 94   | 96      | 99       | 97        | 99    | 100  | 99      | 98      |             |               |        | 0                             | 0                     | 0               | 0                   | 0      |          |
| 106          | 95   | 102     | 94       | 95        | 96    | 101  | 100     | 105     |             |               |        |                               | L Č                   |                 |                     |        |          |
| 107          | 96   | 95      | 102      | 104       | 97    | 92   | 95      | 105     | ļ           |               |        | 0                             | 0                     | 0               | 0                   | 0      |          |
|              |  |         |          |           |       |      |         |         |             |               |        | Tost                          | ad at 0               | 5 micro         | on and              | largor | ]        |
| Width        | Width 70.5 Height 34                               |         |          |           |       |      |         |         |             |               |        |                               |                       |                 |                     |        |          |
|              | oly Ar   |         |          | 16        | .65   | ft²  | Mai     | n. Sp   | ecs.        | ]             |        | <b>jnehelic:</b> (lr          |                       |                 |                     | N      | I/A      |
|              |  | locity  |          |           | 8     | fpm  | 80      | to      | 100         |               |        | ply Voltage                   |                       |                 |                     |        | l/A      |
| Supp         | oly Vo   | lume    | <b>)</b> | 16        | 26    | cfm  | 1332    | to      | 1665        | ]             | Elec   | tric and Po                   | olarity               | Test            | :                   | N      | l/A      |
|              |  |         |          |           |       |      | HE      | PA F    | <u>ILTE</u> | R LEAK T      | EST    |                               |                       |                 |                     |        |          |
|              |  |         |          |           |       |      |         |         |             |               |        | Media Lea                     |                       |                 |                     |        |          |
|              |  |         |          |           |       |      |         |         |             |               |        | Frame / G                     | lue jo                | int / G         | asket               | leak   |          |
| Left         |  |         |          |           |       |      |         |         |             | Rig           | ht     |                               |                       |                 |                     |        |          |
|              |  |         |          |           |       |      |         |         |             | Q             |        | EDA filtor                    |                       | 0               | %                   |        | 200      |
| РΔС          | Con  | centra  | ation:   | 1         | 2     | μg/L |         | (       | Salcula     |               |        | EPA filter<br>* Laskin nozzle | #) / To               | U<br>Ital airfl |                     |        | ass      |
|              |  |         |          |           |       | _    | t Chall |         |             | ed upstream   |        | Laskiii iiuzzit               | ; <del>π</del> ) / 10 | nai ailli       | IOW CF              | IVI    |          |
|              |  |         |          |           |       |      |         | -       |             |               |        | at any point.                 |                       |                 |                     |        |          |
|              | efilter s  |         | 12.25    | х         | 36.25 | х    | 1       | ,       |             | ount of pre-f |        | 2                             | Re                    | placed          | I the filt          | ers    | No       |
|              |  | -       |          |           |       |      | •       | ı       |             |               |        |                               |                       | ,               |                     | -      |          |
| Co           | mmei   | nts:    |          |           |       |      |         |         |             |               |        |                               |                       |                 |                     |        |          |
|              |  |         |          |           |       |      |         |         |             |               |        |                               |                       |                 |                     |        |          |
|              |  |         |          |           |       |      |         |         |             |               |        |                               |                       |                 |                     |        |          |
|              |  |         |          |           |       |      |         |         |             |               |        |                               |                       |                 |                     |        |          |
|              |  |         |          |           |       |      |         |         |             |               |        |                               |                       |                 |                     |        |          |
|              |  |         |          |           |       |      |         |         |             |               |        |                               |                       |                 |                     |        |          |
|              | Ale  | x Ros   | ales     |           |       |      |         |         |             |               |        |                               |                       |                 |                     |        |          |







# **CERTIFICATE OF CALIBRATION**

TSI Incorporated, 500 Cardigan Road, Shoreview, MN 55126 USA TEL:1-800-874-2811 1-651-490-2811 FAX: 1-651-490-3824 www.tsi.com

| Environment Condition |      |      | _ |
|-----------------------|------|------|---|
| TEMPERATURE           | 22.6 | °C   | _ |
| RELATIVE HUMIDITY     | 20.0 | % RH |   |
| BAROMETRIC PRESSURE   | 981  | hPa  | _ |

MODEL AccuBalance® 8375

SERIAL NO. 91112034

CALIBRATION STANDARDS USED

Manometer Calibration Bench 1

| CALIBRATION DATA |                         |                      |                    |                         |                      |                    |  |  |  |  |
|------------------|-------------------------|----------------------|--------------------|-------------------------|----------------------|--------------------|--|--|--|--|
| TESTING          | BAROMETE                | UC PRESSURE MEAS     | SURED IN hPa       | Different               | TAL PRESSURE MEA     | SURED IN Pa        |  |  |  |  |
| POINTS           | Calibration<br>Standard | Instrument<br>Output | Allowable<br>Range | CALIBRATION<br>STANDARD | Instrument<br>Output | Allowable<br>Range |  |  |  |  |
| 1                | 669                     | 668                  | 656 ~ 682          | 23.2                    | 23.2                 | 22.5 ~ 23.9        |  |  |  |  |
| 2                | 981                     | 981                  | 961 ~ 1001         | 118                     | 118                  | 115 ~ 121          |  |  |  |  |
| 3                | 1170                    | 1169                 | 1147 ~ 1193        | 707                     | 707                  | 693 ~ 721          |  |  |  |  |
| 4                | -                       | -                    | -                  | 2964                    | 2964                 | 2905 ~ 3024        |  |  |  |  |
|                  | -                       |                      | -                  | 3711                    | 3711                 | 3637 ~ 3785        |  |  |  |  |

| TESTING<br>POINTS | Темр                    | ERATURE MEASURE      | ED IN °C           | HUMIDITY MEASURED IN %RII |                      |                    |  |  |
|-------------------|-------------------------|----------------------|--------------------|---------------------------|----------------------|--------------------|--|--|
|                   | CALIBRATION<br>STANDARD | Instrument<br>Output | Allowable<br>Range | CALIBRATION<br>STANDARD   | INSTRUMENT<br>OUTPUT | Allowable<br>Range |  |  |
| 1                 | -38.9                   | -38.9                | -38.3 ~ -39.4      | 71.4                      | 71.5                 | 71.3 ~ 71.5        |  |  |
| 2                 | -15.0                   | -15.0                | -14.8 ~ -15.2      | 5.6                       | 5.7                  | 5.5 ~ 5.7          |  |  |
| 3                 | 25.0                    | 25.0                 | 24.9 ~ 25.1        |                           |                      | -                  |  |  |
| 4                 | 70.0                    | 70.0                 | 69.9 ~ 70.1        |                           |                      | -                  |  |  |
| 5                 | 110.0                   | 110.0                | 109.8 ~ 110.2      | -                         | •                    | -                  |  |  |

<sup>\*</sup> Indicates out of tolerance condition

TSI Incorporated does hereby certify that the above described instrument conforms to the original manufacturer's specifications (not applicable to As Found data) and has been calibrated using standards whose accuracies are traceable to the National Institute of Standards and Technology within the limitations of NIST's calibration services or have been derived from accepted values of natural physical constants or have been derived by the ratio type of self calibration techniques. The calibration ratio for this instrument is at least 6.7:1 for barometric pressure and 3:1 for differential pressure. TSI is registered to ISO-9001:2008 and complies with ISO 10012:2003, Quality Assurance Requirements for Measuring Equipment. This report may not be reproduced, except in full, unless permission for the publication of an approved abstract is obtained in writing from the calibration organization issuing this report.

| Measurement Variable | System ID Number | Date Last Calibrated | Calibration Due Date |
|----------------------|------------------|----------------------|----------------------|
| DC Voltage           | E002798          | 07-13-12             | 01-13-14             |
| DC Voltage           | E002797          | 07-13-12             | 01-13-14             |
| Pressure             | E002173          | 12-06-12             | 06-06-13             |
| Pressure             | E002447          | 06-12-12             | 06-12-13             |

Calibration procedure used: 10000000787B

all King

Apr. 9, 2013

Calibration Date

ISI P/N 2300157



# **CERTIFICATE OF CALIBRATION**

TSI Incorporated, 500 Cardigan Road, Shoreview, MN 55126 USA TEL:1-800-874-2811 1-651-490-2811 FAX: 1-651-490-3824 www.tsi.com

| Environment Condition |       |      |
|-----------------------|-------|------|
| TEMPERATURE           | 72.6  | °F   |
| RELATIVE HUMIDITY     | 20.0  | % RH |
| BAROMETRIC PRESSURE   | 28.99 | inHg |

 MODEL
 AccuBalance® 8375

 SERIAL NO.
 91112034

CALIBRATION STANDARDS USED

Manometer Calibration Bench 1

| Calibration Data |                         |                      |                    |                         |                      |                    |  |
|------------------|-------------------------|----------------------|--------------------|-------------------------|----------------------|--------------------|--|
| TESTING          | BAROMETR                | IC PRESSURE MEAS     | URED IN in.Hg      | DIFFERENTIA             | L PRESSURE MEASI     | URED IN in.H2O     |  |
| POINTS           | CALIBRATION<br>STANDARD | INSTRUMENT<br>OUTPUT | ALLOWABLE<br>RANGE | CALIBRATION<br>STANDARD | INSTRUMENT<br>OUTPUT | ALLOWABLE<br>RANGE |  |
| 1                | 19.76                   | 19.74                | 19.37 ~ 20.15      | 0.093                   | 0.093                | 0.091 ~ 0.095      |  |
| 2                | 28.98                   | 28.98                | 28.41 ~ 29.55      | 0.473                   | 0.473                | 0.463 ~ 0.483      |  |
| 3                | 34.54                   | 34.53                | 33.85 ~ 35.23      | 2.84                    | 2.84                 | 2.79 - 2.89        |  |
| 4                | -                       |                      | -                  | 11.9                    | 11.9                 | 11.7 ~ 12.1        |  |
| 5                | -                       | -                    | -                  | 14.9                    | 14.9                 | 14.7 ~ 15.1        |  |

| TESTING | Темр                    | ERATURE MEASURI      | ED IN °F           | Hum                     | HUMIDITY MEASURED IN %RH |                    |  |  |
|---------|-------------------------|----------------------|--------------------|-------------------------|--------------------------|--------------------|--|--|
| POINTS  | CALIBRATION<br>STANDARD | INSTRUMENT<br>OUTPUT | Allowable<br>Range | CALIBRATION<br>STANDARD | Instrument<br>Output     | Allowable<br>Range |  |  |
| 1       | -38.0                   | -38.0                | -37.0 ~ -39.0      | 71.4                    | 71.5                     | 71.3 ~ 71.5        |  |  |
| 2       | 5.0                     | 5.0                  | 4.7 ~ 5.3          | 5.6                     | 5.7                      | 5.5 ~ 5.7          |  |  |
| 3       | 77.0                    | 77.0                 | 76.8 ~ 77.2        | -                       | -                        | -                  |  |  |
| 4       | 158.0                   | 158.0                | 157.8 ~ 158.2      | -                       | •                        | -                  |  |  |
| 5       | 230.0                   | 230.0                | 229.7 ~ 230.3      | -                       | •                        | -                  |  |  |

<sup>\*</sup> Indicates out of tolerance condition

TSI Incorporated does hereby certify that the above described instrument conforms to the original manufacturer's specifications (not applicable to As Found data) and has been calibrated using standards whose accuracies are traceable to the National Institute of Standards and Technology within the limitations of NIST's calibration services or have been derived from accepted values of natural physical constants or have been derived by the ratio type of self calibration techniques. The calibration ratio for this instrument is at least 6.7:1 for barometric pressure and 3:1 for differential pressure. TSI is registered to ISO-9001:2008 and complies with ISO 10012:2003, Quality Assurance Requirements for Measuring Equipment. This report may not be reproduced, except in full, unless permission for the publication of an approved abstract is obtained in writing from the calibration organization issuing this report.

| Measurement Variable | System ID Number | Date Last Calibrated | Calibration Due Date |
|----------------------|------------------|----------------------|----------------------|
| DC Voltage           | E002798          | 07-13-12             | 01-13-14             |
| DC Voltage           | E002797          | 07-13-12             | 01-13-14             |
| Pressure             | E002173          | 12-06-12             | 06-06-13             |
| Pressure             | E002447          | 06-12-12             | 06-12-13             |
|                      |                  |                      |                      |

Calibration procedure used: 10000000787B

Later By

Apr. 9, 2013

Calibration Date

1,0000



# Particle Counter

# **CALIBRATION CERTIFICATE**

| Мо  | Model# APC 9310 Serial# 93100922005  |              |  |   |                           |  |  |  |
|---|--|--------------|--|---|---------------------------|--|--|--|
| This certifies the above named instrument performed in conformance with the original specifications in effect at time of manufacture. Calibration services have been performed comparing the instrument reading with the readings registered on industry standard equipment. The accuracy and stability of standards maintained by LASERLENZ are traceable to the standards of The National Institute of Standards and Technology or have been derived from responses consistent with natural physical constants. Compliant to ISO 21501, ANSI Z540-1/Mil-STD 45662A.  A record of all work performed is maintained by LASERLENZ  Calibration was performed at a temperature of |  |              |  |   |                           |  |  |  |
| C-encor   | Model #  | Serial #     |  |   | Calibration Certificate # |  |  |  |
| STERENT OF  | Fluke 87   | 69500075     | 12-28-2012   | 12-28-2013  | 17-B28MW-1-1              |  |  |  |
| SERVESSE  | CME 50A-2-1AID   | 13768        | 8-9-2012   | 8-9-2013  | F12181                    |  |  |  |
| STANKS OF STANKS  | Tektronix TDS220   | B035178      | 1-3-2013   | 1-3-2014  | 17-B28MW-2-1              |  |  |  |
| 25  | Particle size <u>0.203µ</u> Lot #  Particle size <u>0.296µ</u> Lot #  Particle size <u>0.498µ</u> Lot #  Particle size <u>0.994µ</u> Lot # |              | Lot # 36489<br>Lot # 36926<br>Lot # 38882<br>Lot # 39086<br>Lot # 38726<br>Lot # 40421 | Threshold v<br>Threshold v<br>Threshold v<br>Threshold v<br>Threshold v | oltage                    |  |  |  |
|   |  | Next calibra | ition on this instrume   | ent is due: $2-16$  | -2014                     |  |  |  |
|   |  |              | LASERLEN   | Z Representative: Lec   | onard Formanek            |  |  |  |
|   | Date: 2-16-2013  |              |  |   |                           |  |  |  |



# CERTIFICATE OF CALIBRATION AND TESTING

TSI Incorporated, 500 Cardigan Road, Shoreview, MN 55126 USA Tel: 1-800-874-2811 1-651-490-2811 Fax: 1-651-490-3824 http://www.tsi.com

| ENVIRONMENT CONDITION |               |                   |  |  |  |
|-----------------------|---------------|-------------------|--|--|--|
| TEMPERATURE           | 73.8 (23.2)   | °F (°C')          |  |  |  |
| RELATIVE HUMIDITY     | 41            | ° <sub>0</sub> RH |  |  |  |
| BAROMETRIC PRESSURE   | 29 24 (990.2) | inHg (hPa)        |  |  |  |

| Model         | 8386A    |
|---------------|----------|
| SERIAL NUMBER | 03040053 |

| ☐ AS LEFT  | ☑ IN TOLERANCE     |
|------------|--------------------|
| ☐ As Found | ☐ OUT OF TOLERANCE |

#### - CALIBRATION VERIFICATION RESULTS-

| TEMPERATURE VERIFICATION |            |            | S                    | YSTEM T-119 |              | Unit: °F ( °C ) |                         |
|--------------------------|------------|------------|----------------------|-------------|--------------|-----------------|-------------------------|
| #                        | STANDARD   | MEASURED   | ALLOWABLE RANGE      | #           | STANDARD     | MEASURED        | ALLOWABLE RANGE         |
|                          | 32.0 (0.0) | 32.2 (0.1) | 31.5~32.5 (=0.3~0.3) | 2           | 140.0 (60.0) | 139.7 (59.8)    | 139.5~140.5 (59.7~60.3) |

| PRESSURE VERIFICATION |                     |                     | S                                  | System V-110 |                    |                    |                                  |
|-----------------------|---------------------|---------------------|------------------------------------|--------------|--------------------|--------------------|----------------------------------|
| #                     | STANDARD            | MEASURED            | ALLOWABLE RANGE                    | #            | STANDARD           | MEASURED           | ALLOWABLE RANGE                  |
| l                     | -4.074<br>(-1014-4) | -4.083<br>(-1016.7) | -4.120~-4.028<br>(-1025.8~-1003.0) | 3            | 8.062 (2007.4)     | 8.049 (2004.2)     | 7.976~8.148 (1986.1~2028.8)      |
| 2                     | 2.104 (523.9)       | 2.088 (519.9)       | 2.078~2.130 (517.4~530.4)          | 4            | 14.024<br>(3492.0) | 14 001<br>(3486.2) | 13.879~14.169<br>(3455.8~3528.1) |

| HUMIDITY VERIFICATION |          |          |                 | SYSTEM H-102 |          |          |                 |  |
|-----------------------|----------|----------|-----------------|--------------|----------|----------|-----------------|--|
| #                     | STANDARD | MEASURED | ALLOWABLE RANGE | #            | STANDARD | MEASURED | ALLOWABLE RANGE |  |
|                       | 10.0     | 9.9      | 7.0~13.0        | 4            | 70.0     | 70.1     | 67.0~73.0       |  |
| 2                     | 30.0     | 29.6     | 27.0~33.0       | 5            | 90.0     | 91.0     | 87.0~93.0       |  |
| 3                     | 50.0     | 49.9     | 47.0~53.0       |              |          |          |                 |  |

| Vı | ELOCITY VER | IFICATION  |                     | Unit: ft/min ( m/s ) |              |              |                         |
|----|-------------|------------|---------------------|----------------------|--------------|--------------|-------------------------|
| #  | STANDARD    | MEASURED   | ALLOWABLE RANGE     | #                    | STANDARD     | MEASURED     | ALLOWABLE RANGE         |
| 1  | 0 (0.00)    | 0 (0.00)   | -3~3 (-0.02~0.02)   | 7                    | 644 (3 27)   | 647 (3.29)   | 625~664 (3.18~3.37)     |
| 2  | 35 (0.18)   | 35 (0.18)  | 32~38 (0.16~0.19)   | 8                    | 996 (5.06)   | 989 (5.03)   | 966~1026 (4.91~5.21)    |
| 3  | 65 (0.33)   | 64 (0.33)  | 62~68 (0.32~0.35)   | 9                    | 1468 (7.46)  | 1474 (7.49)  | 1424~1512 (7.24~7.68)   |
| 4  | 100 (0.51)  | 99 (0.50)  | 97~103 (0.49~0.52)  | 10                   | 2486 (12.63) | 2495 (12.67) | 2411~2560 (12.25~13.01) |
| 5  | 160 (0.81)  | 158 (0.80) | 155~164 (0.79~0.84) | 11                   | 4520 (22.96) | 4547 (23.10) | 4384~4655 (22.27~23.65) |
| 6  | 332 (1.69)  | 331 (1.68) | 322~342 (1.64~1.74) | 12                   | 7979 (40.53) | 8034 (40.81) | 7740~8219 (39.32~41.75) |

TSI does hereby certify that the above described instrument conforms to the original manufacturer's specification (not applicable to As Found data) and has been calibrated using standards whose accuracies are traceable to the United States National Institute of Standards and Technology (NIST) or has been verified with respect to instrumentation whose accuracy is traceable to NIST, or is derived from accepted values of physical constants. TSI's calibration system is registered to ISO-9001.2008 and meets the requirements of ISO 10012-2003.

| Measurement Variable | System ID | Last Cal. | Cal. Due | Measurement Variable | System 1D | Last Cal | Cal Due  |
|----------------------|-----------|-----------|----------|----------------------|-----------|----------|----------|
| Temperature          | E001800   | 07-10-13  | 01-10-14 | Temperature          | E001799   | 07-10-13 | 01-10-14 |
| DC Voltage           | E001658   | 07-13-12  | 01-13-14 | Temperature          | E004402   | 05-23-13 | 11-23-13 |
| Pressure             | E001719   | 06-06-13  | 12-06-13 | Pressure             | E001721   | 06-06-13 | 12-06-13 |
| Barometric Pressure  | E001992   | 04-04-13  | 04-04-14 | Velocity             | E004603   | 09-19-12 | 09-19-17 |
| Humidity             | E003539   | 08-21-13  | 08-21-14 |                      |           |          |          |

CALIBRATED

September 13, 2013

DATE

SI P/N 2300157



# CERTIFICATE OF CALIBRATION AND TESTING

TS1 Incorporated, 500 Cardigan Road, Shoreview, MN 55126 USA Tel: 1-800-874-2811 1-651-490-2811 Fax: 1-651-490-3824 http://www.tsi.com

| Environment Condition |               |            |
|-----------------------|---------------|------------|
| TEMPERATURE           | 74.1 (23.4)   | °F (°C)    |
| RELATIVE HUMIDITY     | 40            | %RH        |
| BAROMETRIC PRESSURE   | 29.24 (990.2) | inHg (hPa) |

| Model         | 8386A    |
|---------------|----------|
| SERIAL NUMBER | 03040053 |

| ☐ AS LEFT   | ☐ IN TOLERANCE     |  |
|---|--------------------|--|
| ■ As Found     ■ As Found | ☐ OUT OF TOLERANCE |  |

#### - CALIBRATION VERIFICATION RESULTS-

| V | ELOCITY VER | IFICATION  |                     | S  | SYSTEM V-110 |              | Unit: ft/min ( m/s )    |  |  |
|---|-------------|------------|---------------------|----|--------------|--------------|-------------------------|--|--|
| # | STANDARD    | MEASURED   | ALLOWABLE RANGE     | #  | STANDARD     | MEASURED     | ALLOWABLE RANGE         |  |  |
| ī | 0 (0.00)    | 0 (0.00)   | -3~3 (-0.02~0.02)   | 7  | 651 (3.31)   | 642 (3.26)   | 631~671 (3.21~3.41)     |  |  |
| 2 | 35 (0.18)   | 33 (0.17)  | 32~38 (0.16~0.19)   | 8  | 996 (5.06)   | 984 (5.00)   | 966~1026 (4.91~5.21)    |  |  |
| ٤ | 64 (0.33)   | 63 (0.32)  | 61~67 (0.31~0.34)   | 9  | 1464 (7.43)  | 1472 (7.48)  | 1420~1507 (7.21~7.66)   |  |  |
| 4 | 99 (0.50)   | 97 (0.49)  | 96~102 (0.49~0.52)  | 10 | 2503 (12.72) | 2484 (12.62) | 2428~2578 (12.33~13.10) |  |  |
| 5 | 160 (0.81)  | 156 (0.79) | 155~165 (0.79~0.84) | 11 | 4516 (22.94) | 4484 (22.78) | 4381~4651 (22.25~23.63) |  |  |
| 6 | 336 (1.70)  | 331 (1.68) | 325~346 (1.65~1.76) | 12 | 7992 (40.60) | 7918 (40.22) | 7752~8231 (39.38~41.81) |  |  |

| TEMPERATURE VERIFICATION |            |            |                      | System T-119 |              |              |                         |  |  |
|--------------------------|------------|------------|----------------------|--------------|--------------|--------------|-------------------------|--|--|
| #                        | STANDARD   | MEASURED   | ALLOWABLE RANGE      | #            | STANDARD     | MEASURED     | ALLOWABLE RANGE         |  |  |
| 1                        | 32.0 (0.0) | 32.2 (0.1) | 31.5~32.5 (-0.3~0.3) | 2            | 140.0 (60.0) | 139.7 (59.8) | 139.5~140.5 (59.7~60.3) |  |  |

| P | PRESSURE VERIFICATION |                     |                                    |   | EM V-110           | Unit: inH <sub>2</sub> O ( Pa ) |                                  |  |
|---|-----------------------|---------------------|------------------------------------|---|--------------------|---------------------------------|----------------------------------|--|
| # | STANDARD              | MEASURED            | ALLOWABLE RANGE                    | # | STANDARD           | MEASURED                        | ALLOWABLE RANGE                  |  |
| ı | -4.074<br>(-1014.4)   | -4.083<br>(-1016.7) | -4.120~-4.028<br>(-1025.8~-1003.0) | 3 | 8.062 (2007.4)     | 8.049 (2004.2)                  | 7.976~8.148 (1986.1~2028.8)      |  |
| 2 | 2.104 (523.9)         | 2.088 (519.9)       | 2.078~2.130 (517.4~530.4)          | 4 | 14.024<br>(3492.0) | 14.001<br>(3486.2)              | 13.879~14.169<br>(3455.8~3528.1) |  |

| HUMIDITY AS FOUND |          |          |                 | Syst | гем Н-102 | Unit: %RH |                 |  |
|-------------------|----------|----------|-----------------|------|-----------|-----------|-----------------|--|
| #                 | STANDARD | MEASURED | ALLOWABLE RANGE | #    | STANDARD  | MEASURED  | ALLOWABLE RANGE |  |
| 1                 | 10.0     | 9.9      | 7.0~13.0        | 4    | 70.0      | 70.1      | 67.0~73.0       |  |
| 2                 | 30.0     | 29.6     | 27.0~33.0       | 5    | 90.0      | 91.0      | 87.0~93.0       |  |
| 3                 | 50.0     | 49.9     | 47.0~53.0       |      |           |           |                 |  |

TSI does hereby certify that the above described instrument conforms to the original manufacturer's specification (not applicable to As Found data) and has been calibrated using standards whose accuracies are traceable to the United States National Institute of Standards and Technology (NIST) or has been verified with respect to instrumentation, whose accuracy is naceable to NIST, or is derived from accepted values of physical constants. TSI's calibration system is registered to ISO-9001.2008 and meets the requirements of ISO 10012.2003.

| Measurement Variable | System ID | Last Cal. | Cal. Due | Measurement Variable | System ID | Last Cal. | Cal. Due |
|----------------------|-----------|-----------|----------|----------------------|-----------|-----------|----------|
| DC Voltage           | E001658   | 07-13-12  | 01-13-14 | Temperature          | E004402   | 05-23-13  | 11-23-13 |
| Pressure             | E001719   | 06-06-13  | 12-06-13 | Pressure             | E001721   | 06-06-13  | 12-06-13 |
| Barometric Pressure  | E001992   | 04-04-13  | 04-04-14 | Velocity             | E004603   | 09-19-12  | 09-19-17 |
| Temperature          | E001800   | 07-10-13  | 01-10-14 | Temperature          | E001799   | 07-10-13  | 01-10-14 |
| Humidity             | E003539   | 08-21-13  | 08-21-14 |                      |           |           |          |

VERIFIED

September 13, 2013

DATE

DOC D CERT\_DEF ...T

SI P/N 2300157



Report for:

Marie Garza Superior Laboratory Services Inc. 1710 Preston Ave Ste A Pasadena, TX 77503

Regarding: Project: Empower Pharmacy; Air Viable Samples

EMĹ ID: 1168730

Approved by:

Dates of Analysis:

USP 797-Bacteria Air: 02-10-2014

Technical Manager Fernando Fernandez

Service SOPs: USP 797-Bacteria Air (2081)

All samples were received in acceptable condition unless noted in the Report Comments portion in the body of the report. Due to the nature of the analyses performed, field blank correction of results is not applied. The results relate only to the items tested.

EMLab P&K ("the Company") shall have no liability to the client or the client's customer with respect to decisions or recommendations made, actions taken or courses of conduct implemented by either the client or the client's customer as a result of or based upon the Test Results. In no event shall the Company be liable to the client with respect to the Test Results except for the Company's own willful misconduct or gross negligence nor shall the Company be liable for incidental or consequential damages or lost profits or revenues to the fullest extent such liability may be disclaimed by law, even if the Company has been advised of the possibility of such damages, lost profits or lost revenues. In no event shall the Company's liability with respect to the Test Results exceed the amount paid to the Company by the client therefor.

1501 West Knudsen Drive, Phoenix, AZ 85027 (800) 651-4802 Fax (623) 780-7695 www.emlab.com

Client: Superior Laboratory Services Inc.

C/O: Marie Garza

Re: Empower Pharmacy; Air Viable Samples

Date of Sampling: 01-31-2014 Date of Receipt: 02-07-2014 Date of Report: 02-10-2014

# USP <797> Bacteria Air Total Plate Count

| Location:              | 1 ISO Class 8:<br>Ante Room<br>TSA |         | Clear     | 3 ISO Class 7:<br>Clean Room<br>TSA |           | 5 ISO Class 5:<br>Clean Bench<br>(Left) TSA |           | 7 ISO Class 5:<br>Clean Bench<br>(Right) TSA |           | 9:<br>Control TSA |  |
|------------------------|------------------------------------|---------|-----------|-------------------------------------|-----------|---|-----------|--|-----------|-------------------|--|
| Comments (see below)   | N                                  | None    |           | None                                |           | None  |           | None   |           | Vone              |  |
| Lab ID-Version‡:       | 5289326-1                          |         | 5289328-1 |                                     | 5289330-1 |   | 5289332-1 |  | 5289334-1 |                   |  |
|                        | raw ct.                            | cfu*/m³ | raw ct.   | cfu*/m³                             | raw ct.   | cfu*/m³                                     | raw ct.   | cfu*/m³                                      | raw ct.   | cfu*/m³           |  |
| §Total bacteria        | ND                                 | < 2     | ND        | < 2                                 | ND        | < 1   | ND        | < 1  | ND        | N/A               |  |
| Positive Hole          |                                    | 400     |           | 400                                 |           | 400   |           | 400  |           | 0                 |  |
| Sample Volume (liters) |                                    | 600     |           | 600                                 |           | 1,200                                       |           | 1,200  |           | 0                 |  |

<sup>\*</sup>cfu = colony forming units

ND = none detected

Samples were incubated at  $35^{\circ}$  C  $\pm 2^{\circ}$  C for a period of 2 - 3 days.

#### **Comments:**

Compliance with USP <797> requires that any colony forming units detected on a volumetric air plate from an ISO 5, 7, or 8 area must be identified to at least the genus level. $\dagger$ 

#### Recommended Action Levels for Viable Particles in Air†

| ISO Class | Active Airborne (cfu/m³) |
|-----------|--------------------------|
| 5         | > 1                      |
| 7         | > 10                     |
| 8         | > 100                    |

†The United States Pharmacopeial Convention. <797> Pharmaceutical Compounding - Sterile Preparations. *Revision Bulletin*. 2008, p. 26.

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Positive hole correction chart used for all calculations

 $<sup>\</sup>ddagger$  A "Version" indicated by -"x" after the Lab ID# with a value greater than 1 indicates a sample with amended data. The revision number is reflected by the value of "x".

<sup>§</sup> Total cfu/m³ has been rounded to two significant figures to reflect analytical precision.



Report for:

Marie Garza Superior Laboratory Services Inc. 1710 Preston Ave Ste A Pasadena, TX 77503

Regarding: Project: Empower Pharmacy; Air Viable Samples

EMĹ ID: 1168730

Approved by:

Dates of Analysis:

USP 797-Fungi Air: 02-14-2014

Technical Manager Fernando Fernandez

Service SOPs: USP 797-Fungi Air (2081)

All samples were received in acceptable condition unless noted in the Report Comments portion in the body of the report. Due to the nature of the analyses performed, field blank correction of results is not applied. The results relate only to the items tested.

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Client: Superior Laboratory Services Inc.

C/O: Marie Garza

Re: Empower Pharmacy; Air Viable Samples

Date of Sampling: 01-31-2014 Date of Receipt: 02-07-2014 Date of Report: 02-14-2014

# USP <797> Fungi Air Total Plate Count

| Location:              | 2 ISO Class 8:<br>Ante Room<br>MEA |         | 4 ISO Class 7:<br>Clean Room<br>MEA |         | 6 ISO Class 5:<br>Clean Bench<br>(Left) MEA |         | 8 ISO Class 5:<br>Clean Bench<br>(Right) MEA |         | 10:<br>Control MEA |         |
|------------------------|------------------------------------|---------|-------------------------------------|---------|---|---------|--|---------|--------------------|---------|
| Comments (see below)   | None                               |         | None                                |         | None  |         | None   |         | None               |         |
| Lab ID-Version‡:       | 5289327-1                          |         | 5289329-1                           |         | 5289331-1                                   |         | 5289333-1                                    |         | 5289335-1          |         |
|                        | raw ct.                            | cfu*/m³ | raw ct.                             | cfu*/m³ | raw ct.                                     | cfu*/m³ | raw ct.                                      | cfu*/m³ | raw ct.            | cfu*/m³ |
| §Total fungi           | ND                                 | < 2     | ND                                  | < 2     | ND  | < 1     | ND   | < 1     | ND                 | N/A     |
| Positive Hole          | 400                                |         | 400                                 |         | 400   |         | 400  |         | 0                  |         |
| Sample Volume (liters) | 600                                |         | 600                                 |         | 1,200                                       |         | 1,200  |         | 0                  |         |

<sup>\*</sup>cfu = colony forming units

Samples were incubated at  $28^{\circ}$  C  $\pm$   $2^{\circ}$  C for a period of 5 - 7 days.

#### **Comments:**

Compliance with USP <797> requires that any colony forming units detected on a volumetric air plate from an ISO 5, 7, or 8 area must be identified to at least the genus level. $\dagger$ 

#### Recommended Action Levels for Viable Particles in Air†

| ISO Class | Active Airborne (cfu/m³) |
|-----------|--------------------------|
| 5         | > 1                      |
| 7         | > 10                     |
| 8         | > 100                    |

†The United States Pharmacopeial Convention. <797> Pharmaceutical Compounding - Sterile Preparations. *Revision Bulletin*. 2008, p. 26.

Aerotech Laboratories, Inc EMLab ID: 1168730, Page 2 of 2

Positive hole correction chart used for all calculations

ND = none detected

 $<sup>\</sup>ddagger$  A "Version" indicated by -"x" after the Lab ID# with a value greater than 1 indicates a sample with amended data. The revision number is reflected by the value of "x".

<sup>§</sup> Total cfu/m³ has been rounded to two significant figures to reflect analytical precision.