

# HARBEC Inc Ontario, NY

## Cleanroom Certification Report

PREPARED FOR



369 Route 104  
Ontario, NY 14519-8999

**Paul Scheible**  
Engineering Manager

**Main Cleanroom  
Gown Room**

**Room Design Classification  
ISO Class 8 @ 0.5 Microns  
Test Mode: At Rest and Operational**

**Test Date  
August 21<sup>st</sup> 2013**

Tests Performed By

R. **KRAFT**, Inc.  
129 Shorecliff Dr.  
Rochester, NY 14612  
(585) 621-6946

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# SUMMARY

R. **KRAFT**, Inc. was retained to perform certification of this new constructed softwall facility at the above address. An “As Built” certification was not performed because the softwall area was built around an existing piece of equipment. Certification of the “At Rest” and “Operational” modes was done consecutively on the same day. In an effort to minimize airborne particulate the HEPA filter integrity test was done after all other testing for both modes of testing.

The following information provided is indicative of the quality of the facility design, construction and performance as of the time and dates of each test procedure. R. **KRAFT**, Inc. makes no warranties concerning the continued safety, performance or operation of this facility past this time.

All instrument documentation of instruments utilized in the following tests is on file at our office. All Instruments utilized are calibrated within the last 12 months and are NIST traceable

## Tests Performed:

1. Air Velocity
2. HEPA Filter Integrity Test
3. Temperature and Relative Humidity Measurements
4. Room Pressurization
5. Particle Count

Temperature and Relative Humidity Readings are taken at the same location and elevation as the particle counts, when performed in accordance to purchase order.

# DEFINITIONS

**Unidirectional airflow:** Airflow having generally parallel streamlines, operating in a single direction, and with uniform velocity over its cross section; previously referred to as “Laminar” airflow. This is usually found in a raised floor application.

**Non-Unidirectional air flow:** Airflow which does not meet the definition of unidirectional air flow; previously referred to as “turbulent” or non-laminar airflow. This is found with side wall returns.

**AS-BUILT:** A cleanroom that is complete and ready for operation, with all services connected and functional, but without equipment or operating personnel in the facility

**AT-REST:** A cleanroom that is complete with all services functioning and with equipment installed and operable or operating, but without operating personnel in the facility.

**OPERATIONAL:** A cleanroom in normal operation, with all services functioning and with equipment and personnel, if applicable present and performing their normal work functions in the facility.

**CFM:** Cubic Feet per Minute

**FPM:** Feet per Minute

**Wg:** Inches of Water

**TEMP:** In Fahrenheit

**RH** in Percentage

# Industry Recommendations

*Recommended Air Changes/Hr\*.*

| Cleanliness Class |       | Recommended Air Changes/Hr |
|-------------------|-------|----------------------------|
| 100K              | ISO 8 | 5-48                       |
| 10K               | ISO 7 | 60-90                      |
| 1K                | ISO 6 | 150-240                    |
| 100               | ISO 5 | 240-480                    |
| 10                | ISO 4 | 300-540                    |

\* (n.d.) CRW News Update: Air Flow Rates. *Clean Room West Inc.* Retrieved January 28<sup>th</sup> 2005, from [http://www.cleanroomswest.com/news\\_air\\_velocity.asp](http://www.cleanroomswest.com/news_air_velocity.asp)

\* (n.d.) FS209E and ISO Cleanroom Standards. *Terra Universal.Com Critical Environmental Solutions.* Retrieved 11/15/2012, from <http://www.terrauniversal.com/cleanrooms/iso-classification-cleanroom-standards.php>

## Cleanroom Classifications Per ISO 14644-1

*Design Class High Limits:*

| 0.5 Microns  |             |       | 5.0 Microns  |             |         |
|--------------|-------------|-------|--------------|-------------|---------|
| Fed Std 209e | ISO 14644-1 |       | Fed Std 209e | ISO 14644-1 |         |
| 1            | 35          | ISO 3 | 0            |             | 0       |
| 10           | 352         | ISO 4 | 0            |             | 0       |
| 100          | 3,520       | ISO 5 | 0            |             | 29      |
| 1,000        | 35,200      | ISO 6 | 7            |             | 293     |
| 10,000       | 352,000     | ISO 7 | 70           |             | 2,930   |
| 100,000      | 3,520,000   | ISO 8 | 700          |             | 29,300  |
| N/A          | 35,200,000  | ISO 9 | N/A          |             | 293,000 |

## Pressurization

ISO 14644-4 – Sub Section A 5.3 Room Pressurization

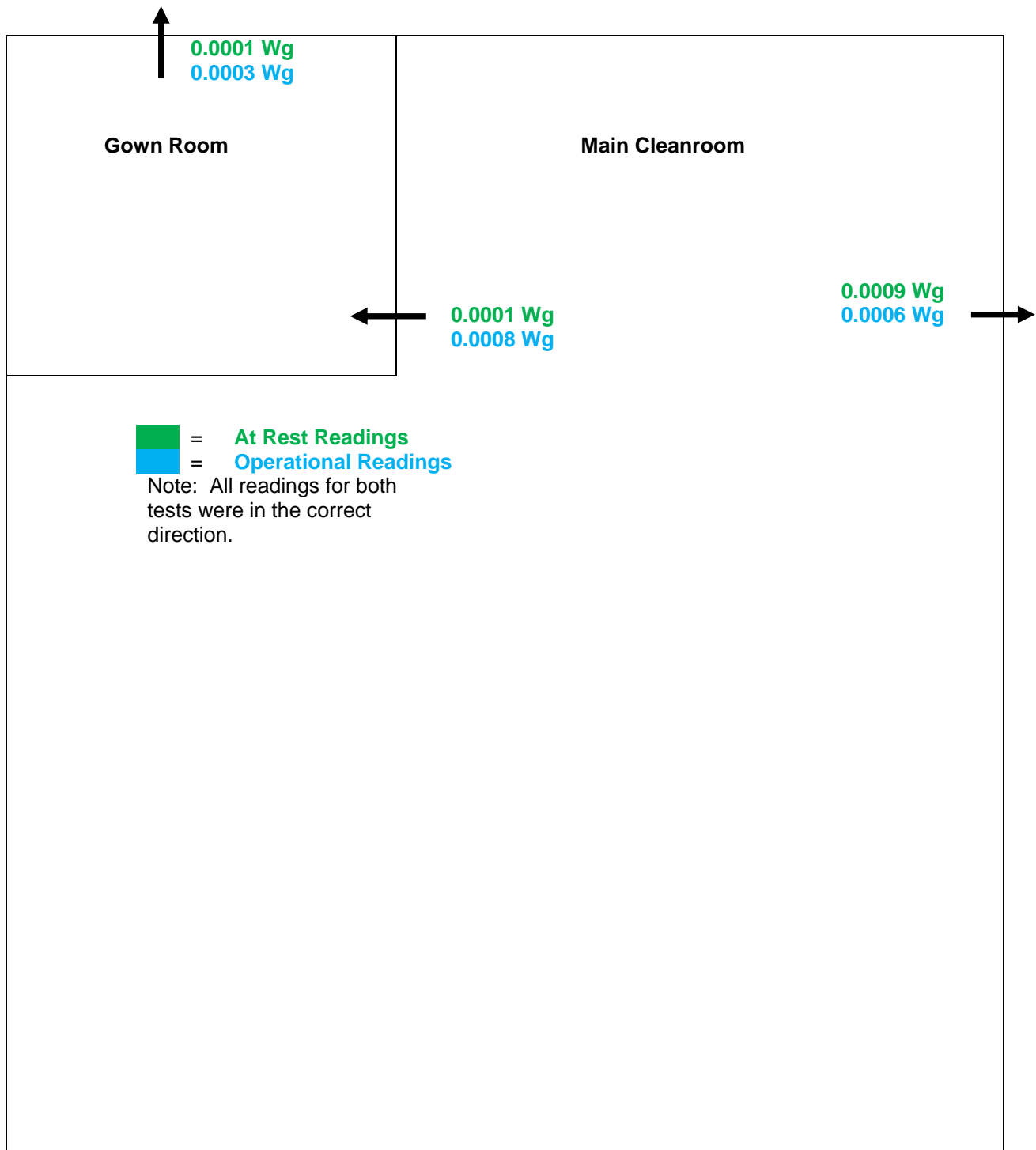
“The pressure differential between adjacent cleanrooms or clean zones of different cleanliness level should lie in the range of 5 Pa to 20 Pa, to allow doors to be opened and to avoid unintended cross-flows due to turbulence”

IEST 6.3 – Sub section 6.4 Room Pressurization

“As a general rule, a difference in pressure of 12 Pa or .05 in Water Column (Wg) between a cleanroom and an external environment is sufficient to prevent unwanted migration of airborne particles. A positive pressure differential of at least 5 Pa (.02 in Water Column (Wg) should be maintained between a space of more critical air cleanliness requirements and any adjacent space.”

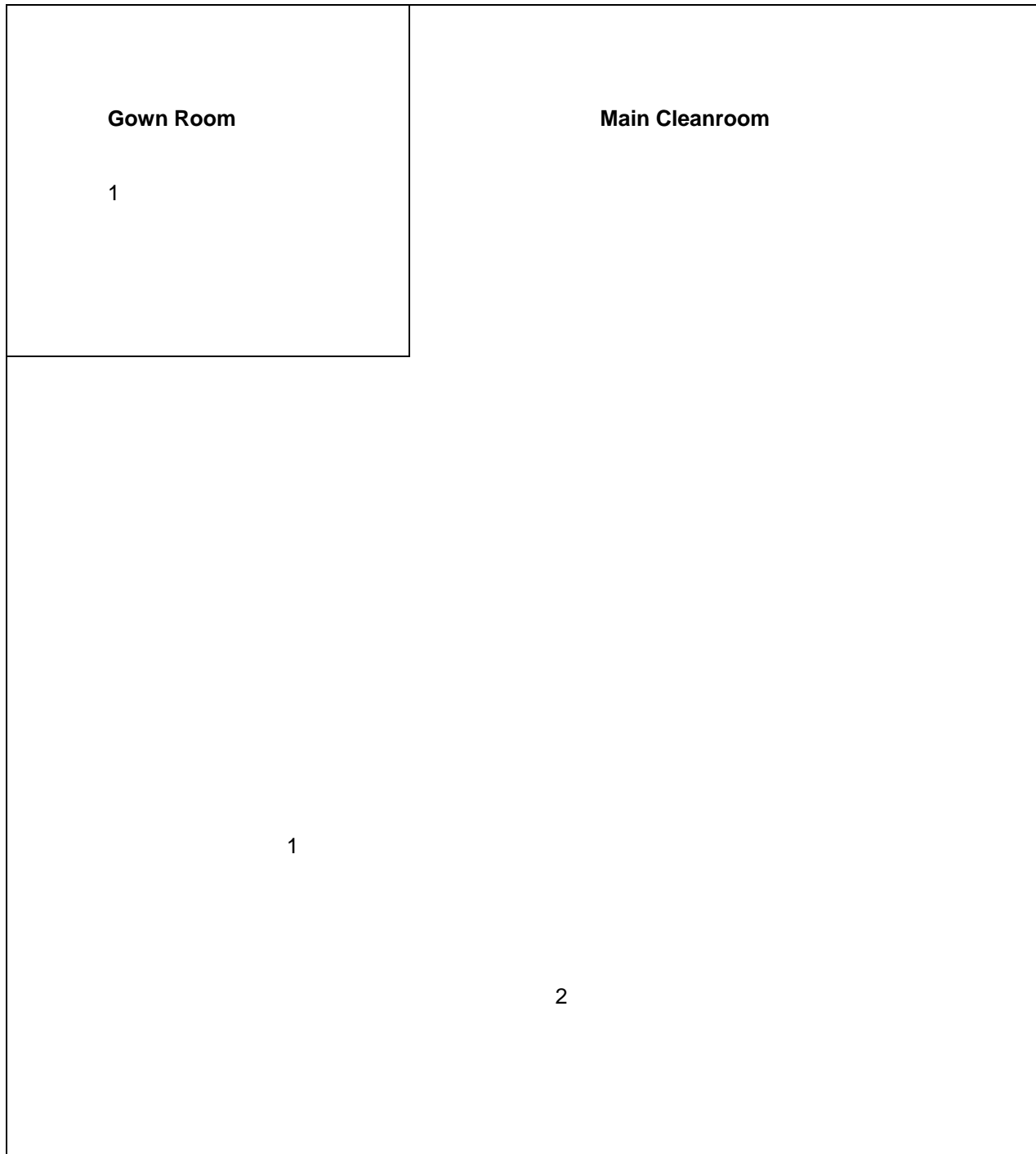
| <i>Conversion between Pascal and Inches of Water Column</i> |                             |                                      |
|---|-----------------------------|--------------------------------------|
| Pascal (Pa)   | Inches of Water Column (Wg) | Comments                             |
| 2.49  | 0.01                        |                                      |
| <b>4.98</b>   | <b>0.02</b>                 | <b>Between Spaces</b>                |
| 7.47  | 0.03                        |                                      |
| 9.96  | 0.04                        |                                      |
| <b>12.45</b>  | <b>0.05</b>                 | <b>Between Cleanroom and ambient</b> |

# PRESSURIZATION GRID MAP



# VELOCITY & UNIFORMITY TEST GRID MAP

See worksheet CR2 for details



# HEPA FILTER CHALLENGE

## PROCEDURE:

Each HEPA filter is scanned with an Aerosol Photometer by holding the probe not more than 1" away from the filter face. The probe is passed in slightly overlapping strokes across the filter face so that the entire face of the filter is scanned. Separate passes are made around the periphery of the filter, along the gasket seal, between the filter frame and housing, through which leakage might by-pass the filter media. The traverse rate shall be at a speed sufficient to insure accurate determination of the existence of a leak, but not more than a rate of 10 Linear feet per minute (LFPM).

Challenge Concentration/Filter: ~10ug/L (micrograms per liter)

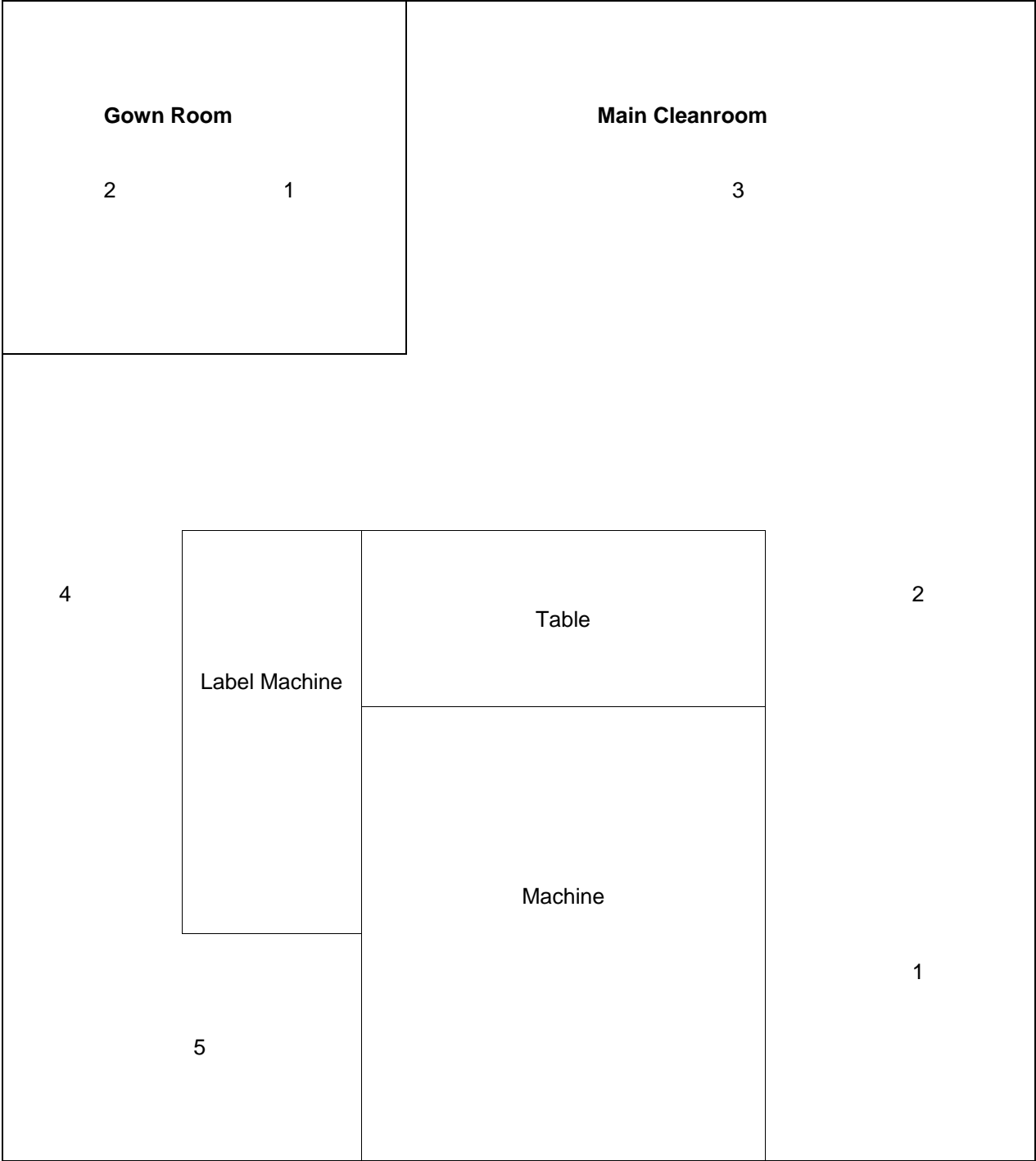
Scan Rate: 10 Linear Feet per Minute (LFPM)

Any point that reveals a penetration of 0.01% of the upstream level or greater is considered a leak.

TEST RESULTS: Leakage did not exceed 0.01% of the upstream challenge

# PARTICLE COUNT LOCATION GRID MAP

Test Elev: 42.5" Above floor level / Test at 0.5 Mircon  
See following sheet (CR 3) for each location's performance.





## INSTRUMENT CALIBRATION DATA

| <u>Test</u>                        | <u>Equipment</u>               | <u>Serial Number</u> | <u>Next Calibration Date</u> |
|------------------------------------|--------------------------------|----------------------|------------------------------|
| Air Velocity                       | Shortridge ADM 870             | MO5855               | 10/26/2013                   |
| Room Pressurization                | Shortridge ADM 870             | MO5855               | 10/26/2013                   |
| Filter Integrity Test              | ATI Digital Aerosol Photometer | 16502                | 2/14/2014                    |
| Particle Count for room compliance | Climet CI 500 EC               | 056735               | 6/6/2014                     |
| Temperature & Humidity             | Extech EA 20                   | 80113523             | 11/2/13                      |

*All certificates of calibration for above instruments are on file at our office.*

All instruments utilized were calibrated within the last 12 months, **traceable to NIST.**

Calibration Certificates of instruments utilized are on file in our office

All data pertaining to testing procedures are on file in our office.

All calibration documentation procedures pertaining to instruments utilized are on file at the respective manufacturer's sites.

End of Report

# DATA PACKAGE

Air Velocity Worksheet (CR 2)

**AIR VELOCITY READINGS**

Client: Harbec Inc  
Rm Loc: Ontario, NY

Test Date: 8/21/2013  
Last Test: N/A (New)

Instrument Utilized: Shortridge ADM With: **Vel Grid (X)** Hood ( )  
Shortridge operators manual -page 40 - section 6.5 (ADM 870 07/20/04)  
"Each reading represents 16 velocity points over a 14 x 14" Area (1.36 SF)"  
Air Velocity reading taken at 6" below filter face with velgrid

Calculations for Figuring Filter Free Area if Velgrid is used.

Measured Up ststream Challenge at .3 Micron:  
High Limit on Filter Scan:

N/A

Filter Size & Free Area Calculations:

| Size  | Width | Length | # Panels | Total Sq In | Free Area (Sq Ft) | Mfg     | Readings | CFM Rated |
|-------|-------|--------|----------|-------------|-------------------|---------|----------|-----------|
| 2 X 4 | 22.00 | 46.00  | 1        | 1012.0      | 7.03              | Unknown | 3        | Unknown   |

**Main Cleanroom - At Rest**

| Filter Number | FPM Reading 1 | FPM Reading 2 | FPM Reading 3 | FPM Reading Av | Filter Free Area | Filter Total CFM | Filter S/N                  | Filter Scan @ 0.3: Filter Peripheral  | Notes |
|---------------|---------------|---------------|---------------|----------------|------------------|------------------|-----------------------------|---|-------|
| 1             | 93            | 108           | 100           | 100            | 7.03             | 705.12           | Refer to Customers Grid Map | Due to testing the At Rest Mode and Operational Mode consecutively on the same day, the filters were scanned once at the end to avoid any contamination of the space. |       |
| 2             | 117           | 102           | 95            | 105            | 7.03             | 735.57           |                             |   |       |
| Rm Sq Ft      | Height        | Cu Ft         | Av FPM        | 103            | Total CFM        | 1441             |                             |   |       |
| 167.0         | 8.0           | 1336.0        |               |                |                  |                  |                             |   |       |

|  |              |              |
|--|--------------|--------------|
| Average Air Volume                                 | 720.35       | <b>CFM</b>   |
| Total Room Supply Air Volume in Cubic Feet per Min | 1440.69      | <b>CFM</b>   |
| Total Room Supply Volume in Cubic Feet Per Hour    | 86441.67     | <b>CFH</b>   |
| Total Room Volume in Square Feet                   | 167.0        | <b>SF</b>    |
| Total Room Volume in Cubic Feet                    | 1336.0       | <b>Cu Ft</b> |
| Total Air Changes per Hour                         | <b>64.70</b> | <b>AC/Hr</b> |

**Gown Room - At Rest**

| Filter Number | FPM Reading 1 | FPM Reading 2 | FPM Reading 3 | FPM Reading Av | Filter Free Area | Filter Total CFM | Filter S/N                  | Filter Scan @ 0.3: Filter Peripheral  | Notes |
|---------------|---------------|---------------|---------------|----------------|------------------|------------------|-----------------------------|---|-------|
| 1             | 106           | 131           | 97            | 111            | 7.03             | 782.43           | Refer to Customers Grid Map | Due to testing the At Rest Mode and Operational Mode consecutively on the same day, the filters were scanned once at the end to avoid any contamination of the space. |       |
| Rm Sq Ft      | Height        | Cu Ft         | Av FPM        | 111            | Total CFM        | 782              |                             |   |       |
| 25.0          | 8.0           | 200.0         |               |                |                  |                  |                             |   |       |

|  |               |              |
|--|---------------|--------------|
| Average Air Volume                                 | 782.43        | <b>CFM</b>   |
| Total Room Supply Air Volume in Cubic Feet per Min | 782.43        | <b>CFM</b>   |
| Total Room Supply Volume in Cubic Feet Per Hour    | 46945.56      | <b>CFH</b>   |
| Total Room Volume in Square Feet                   | 25.0          | <b>SF</b>    |
| Total Room Volume in Cubic Feet                    | 200.0         | <b>Cu Ft</b> |
| Total Air Changes per Hour                         | <b>234.73</b> | <b>AC/Hr</b> |

**Main Cleanroom - Operational**

| Filter Number | FPM Reading 1 | FPM Reading 2 | FPM Reading 3 | FPM Reading Av | Filter Free Area | Filter Total CFM | Filter S/N                  | Filter Scan @ 0.3: Filter Peripheral  | Notes |
|---------------|---------------|---------------|---------------|----------------|------------------|------------------|-----------------------------|---|-------|
| 1             | 89            | 97            | 91            | 92             | 7.03             | 648.90           | Refer to Customers Grid Map | HEPA filter integrity test done with DOP, not ambient challenge, see report for detail on page 7. |       |
| 2             | 119           | 99            | 106           | 108            | 7.03             | 759.00           |                             |   |       |
| Rm Sq Ft      | Height        | Cu Ft         | Av FPM        | 92             | Total CFM        | 1408             |                             |   |       |
| 167.0         | 8.0           | 1336.0        |               |                |                  |                  |                             |   |       |

|  |              |              |
|--|--------------|--------------|
| Average Air Volume                                 | 703.95       | <b>CFM</b>   |
| Total Room Supply Air Volume in Cubic Feet per Min | 1407.90      | <b>CFM</b>   |
| Total Room Supply Volume in Cubic Feet Per Hour    | 84473.89     | <b>CFH</b>   |
| Total Room Volume in Square Feet                   | 167.0        | <b>SF</b>    |
| Total Room Volume in Cubic Feet                    | 1336.0       | <b>Cu Ft</b> |
| Total Air Changes per Hour                         | <b>63.23</b> | <b>AC/Hr</b> |

**Gown Room - Operational**

| Filter Number                                      | FPM Reading 1 | FPM Reading 2 | FPM Reading 3 | FPM Reading Av | Filter Free Area | Filter Total CFM | Filter S/N                  | Filter Scan @ 0.3: Filter Peripheral  | Notes |
|--|---------------|---------------|---------------|----------------|------------------|------------------|-----------------------------|---|-------|
| 1  | 116           | 100           | 96            | 104            | 7.03             | 730.89           |                             |   |       |
|  |               |               |               |                |                  |                  | Refer to Customers Grid Map | HEPA filter integrity test done with DOP, not ambient challenge, see report for detail on page 7. |       |
| Rm Sq Ft   | Height        | Cu Ft         | Av FPM        | 104            | Total CFM        | 731              |                             |   |       |
| 25.0   | 8.0           | 200.0         |               |                |                  |                  |                             |   |       |
| Average Air Volume                                 |               |               |               |                |                  | 730.89           | <b>CFM</b>                  |   |       |
| Total Room Supply Air Volume in Cubic Feet per Min |               |               |               |                |                  | 730.89           | <b>CFM</b>                  |   |       |
| Total Room Supply Volume in Cubic Feet Per Hour    |               |               |               |                |                  | 43853.33         | <b>CFH</b>                  |   |       |
| Total Room Volume in Square Feet                   |               |               |               |                |                  | 25.0             | <b>SF</b>                   |   |       |
| Total Room Volume in Cubic Feet                    |               |               |               |                |                  | 200.0            | <b>Cu Ft</b>                |   |       |
| Total Air Changes per Hour                         |               |               |               |                |                  | <b>219.27</b>    | <b>AC/Hr</b>                |   |       |

**End Of Report**

# DATA PACKAGE

Particle Count, Temperature,  
Relative Humidity,  
Worksheet (CR 3)

### Particle Count Work Sheet

Client: Harbec Inc  
 Rm Loc: Ontario, NY  
 Design Class As Indicated in each Data Set  
 Test Doc: ISO 14644-1-1999-05-01 Cleanliness Classifications  
 IEST RP-CC006.3 Testing of cleanrooms

Test Date 8/21/2013  
 Last Tested: N/A (New)  
 Test Time 08:00 - 11:30  
 Test Elev 42.5" AFF  
 Test Mode As Indicated  
 Temp °F  
 Rel. Hum. %  
 Pressure Wg

**Micron Size for Compliance 0.5**  
 Micron Size for Alert Level 5

#### ROOM CLASSIFICATION HIGH LIMITS

| At 0.5 Microns |            | ISO Class | At 5.0 Microns |         |
|----------------|------------|-----------|----------------|---------|
| Cu Ft          | Cu M       |           | Cu Ft          | Cu M    |
| FED STD        | ISO        |           | FED STD        | ISO     |
| 1              | 35         | 3         | 0              | 0       |
| 10             | 352        | 4         | 0              | 0       |
| 100            | 3,520      | 5         | 0              | 29      |
| 1,000          | 35,200     | 6         | 7              | 293     |
| 10,000         | 352,000    | 7         | 70             | 2,930   |
| 100,000        | 3,520,000  | 8         | 700            | 29,300  |
| N/A            | 35,200,000 | 9         | N/A            | 293,000 |

**UCL FACTORS:**

| # Loc   | 2    | 3    | 4    | 5    | 6    | 7    | 8    | 9    | ≥10 |
|---------|------|------|------|------|------|------|------|------|-----|
| FS 209e | 6.31 | 2.92 | 2.35 | 2.13 | 2.02 | 1.94 | 1.90 | 1.86 | N/A |
| ISO     | 6.3  | 2.9  | 2.4  | 2.1  | 2.0  | 1.9  | 1.9  | 1.9  | N/A |

Testing was done in the indicated mode of operation for the specified room(s) listed below at 0.5 microns with a particle counter have a flow rate of One (1) CFM/28.3 Liters for a period of One (1) minute per sample - per location

A Zero count was performed on the particle counter, hose and isokinetic probe before any testing.

Determining of the number of sample locations required for particle counting.  
 Square Root of the Square Meters of room being tested

NOTE: INTERPRETATION OF PARTICLE COUNT RESULTS PER ISO 14644-1.1999.05.01 Section B.6.  
 B.6.1: "The clean zone is deemed to have meant the specified air cleanliness classification, if the averages of the particle concentrations **measured at each of the locations do not exceed the concentration limits.**"

Temp - RH - Sound - Light readings are done at the same location and elevation as the particle count.

#### PARTICLE COUNTING STANDARD DEVIATION WORKSHEET

##### Main Cleanroom - At Rest

| Square Feet | Room Height (Ft) | Square Meters | Locations Calculated | ISO 14644-1 Locations Required | Designed for ISO Class | Test Mode   |          |
|-------------|------------------|---------------|----------------------|--------------------------------|------------------------|-------------|----------|
| 167.00      | 8                | 15.5          | 3.94                 | 4                              | 8                      | At Rest     |          |
| Micron Size | 0.5              | 0.5           | 0.5                  | 0.5                            | 0.5                    |             |          |
| Loc #       | Reading 1        | Reading 2     | Reading 3            | Fed Std                        | ISO                    | Temperature | Humidity |
| 1           | 2143             | 1900          | 1820                 | 1954.3                         | <b>68792.5</b>         | 74.2        | 55.5     |
| 2           | 1138             | 1801          | 3590                 | 2176.3                         | <b>76606.9</b>         | 74.4        | 54.8     |
| 3           | 10284            | 10137         | 9420                 | 9947.0                         | <b>350134.4</b>        | 74.5        | 55.4     |
| 4           | 4672             | 4731          | 5485                 | 4962.7                         | <b>174685.9</b>        | 74.2        | 55.6     |
| 5           | 15295            | 14055         | 13466                | 14272.0                        | <b>502374.4</b>        | 74.4        | 55.2     |
|             |                  |               | Mean                 | <b>6662.5</b>                  | <b>234518.8</b>        | 74.3        | 55.3     |
|             |                  |               | Std Dev              | <b>5335.6</b>                  | <b>187813.0</b>        |             |          |
|             |                  |               | Std Error            | <b>2386.2</b>                  | <b>83992.5</b>         |             |          |
|             |                  |               | UCL                  | <b>2.35</b>                    | <b>2.4</b>             |             |          |
|             |                  |               | 95% UCL              | <b>12269.9</b>                 | <b>436100.9</b>        |             |          |

| Micron Size | 5         | 5         | 5         | 5       | 5     |
|-------------|-----------|-----------|-----------|---------|-------|
| Loc #       | Reading 1 | Reading 2 | Reading 3 | Fed Std | ISO   |
| 1           | 14        | 7         | 5         | 8.7     | 305.1 |
| 2           | 3         | 2         | 0         | 1.7     | 58.7  |
| 3           | 0         | 3         | 6         | 3.0     | 105.6 |
| 4           | 3         | 2         | 1         | 2.0     | 70.4  |
| 5           | 3         | 11        | 3         | 5.7     | 199.5 |
|             |           |           | Mean      | 4.2     | 147.8 |
|             |           |           | Std Dev   | 2.9     | 103.8 |
|             |           |           | Std Error | 1.3     | 46.4  |
|             |           |           | UCL       | 2.35    | 2.4   |
|             |           |           | 95% UCL   | 7.3     | 259.3 |

**Gown Room - At Rest**

| Square Feet | Room Height (Ft) | Square Meters | Locations Calculated | ISO 14644-1 Locations Required | Designed for ISO Class | Test Mode   |          |
|-------------|------------------|---------------|----------------------|--------------------------------|------------------------|-------------|----------|
| 25          | 8                | 2.3           | 1.52                 | 2                              | 8                      | At Rest     |          |
| Micron Size | 0.5              | 0.5           | 0.5                  | 0.5                            | 0.5                    | Temperature | Humidity |
| Loc #       | Reading 1        | Reading 2     | Reading 3            | Fed Std                        | ISO                    |             |          |
| 1           | 23622            | 22771         | 22999                | 23130.7                        | 814199.5               | 74.8        | 55.3     |
| 2           | 3201             | 2691          | 2835                 | 2909.0                         | 102396.8               | 74.1        | 54.2     |
|             |                  |               | Mean                 | 13019.8                        | 458298.1               | 74.5        | 54.8     |
|             |                  |               | Std Dev              | 14298.9                        | 503320.5               |             |          |
|             |                  |               | Std Error            | 10110.8                        | 355901.3               |             |          |
|             |                  |               | UCL                  | 6.31                           | 6.3                    |             |          |
|             |                  |               | 95% UCL              | 76819.2                        | 2700476.5              |             |          |

| Micron Size | 5         | 5         | 5         | 5       | 5     |
|-------------|-----------|-----------|-----------|---------|-------|
| Loc #       | Reading 1 | Reading 2 | Reading 3 | Fed Std | ISO   |
| 1           | 7         | 7         | 2         | 5.3     | 187.7 |
| 2           | 1         | 0         | 1         | 0.7     | 23.5  |
|             |           |           | Mean      | 3.0     | 105.6 |
|             |           |           | Std Dev   | 3.3     | 116.2 |
|             |           |           | Std Error | 2.3     | 82.1  |
|             |           |           | UCL       | 6.31    | 6.3   |
|             |           |           | 95% UCL   | 17.7    | 623.0 |

**Main Cleanroom - Operational**

| Square Feet | Room Height (Ft) | Square Meters | Locations Calculated | ISO 14644-1 Locations Required | Designed for ISO Class | Test Mode   |          |
|-------------|------------------|---------------|----------------------|--------------------------------|------------------------|-------------|----------|
| 167         | 8                | 15.5          | 3.94                 | 4                              | 8                      | Operational |          |
| Micron Size | 0.5              | 0.5           | 0.5                  | 0.5                            | 0.5                    | Temperature | Humidity |
| Loc #       | Reading 1        | Reading 2     | Reading 3            | Fed Std                        | ISO                    |             |          |
| 1           | 7597             | 7978          | 9615                 | 8396.7                         | 295562.7               | 75.8        | 55.1     |
| 2           | 7159             | 8097          | 8869                 | 8041.7                         | 283066.7               | 75.9        | 54.2     |
| 3           | 10950            | 10776         | 10365                | 10863.0                        | 382377.6               | 76.0        | 54.6     |
| 4           | 7407             | 5455          | 5860                 | 6431.0                         | 226371.2               | 75.8        | 55.3     |
| 5           | 4964             | 5437          | 5140                 | 5200.5                         | 183057.6               | 75.9        | 55.1     |
|             |                  |               | Mean                 | 7786.6                         | 274087.1               | 75.9        | 54.9     |
|             |                  |               | Std Dev              | 2146.3                         | 75551.0                |             |          |
|             |                  |               | Std Error            | 959.9                          | 33787.5                |             |          |
|             |                  |               | UCL                  | 2.35                           | 2.4                    |             |          |
|             |                  |               | 95% UCL              | 10042.3                        | 355177.0               |             |          |

| Micron Size | 5         | 5         | 5         | 5       | 5     |
|-------------|-----------|-----------|-----------|---------|-------|
| Loc #       | Reading 1 | Reading 2 | Reading 3 | Fed Std | ISO   |
| 1           | 23        | 22        | 10        | 18.3    | 645.3 |
| 2           | 7         | 7         | 3         | 5.7     | 199.5 |
| 3           | 15        | 0         | 8         | 7.7     | 269.9 |
| 4           | 13        | 6         | 12        | 10.3    | 363.7 |
| 5           | 5         | 3         | 4         | 4.0     | 140.8 |
|             |           |           | Mean      | 9.2     | 323.8 |
|             |           |           | Std Dev   | 5.6     | 198.0 |
|             |           |           | Std Error | 2.5     | 88.6  |
|             |           |           | UCL       | 2.35    | 2.4   |
|             |           |           | 95% UCL   | 15.1    | 536.4 |

**Gown Room - Operational**

| Square Feet | Room Height (Ft) | Square Meters | Locations Calculated | ISO 14644-1 Locations Required | Designed for ISO Class | Test Mode   |             |          |
|-------------|------------------|---------------|----------------------|--------------------------------|------------------------|-------------|-------------|----------|
| 25          | 8                | 2.3           | 1.52                 | 2                              | 8                      | Operational |             |          |
| Micron Size | 0.5              | 0.5           | 0.5                  | 0.5                            | 0.5                    |             | Temperature | Humidity |
| Loc #       | Reading 1        | Reading 2     | Reading 3            | Fed Std                        | ISO                    |             |             |          |
| 1           | 11192            | 10656         | 9738                 | 10528.7                        | 370609.1               |             | 75.8        | 54.8     |
| 2           | 1230             | 1194          | 1131                 | 1185.0                         | 41712.0                |             | 75.8        | 55.0     |
|             |                  |               | Mean                 | 5856.8                         | 206160.5               |             | 75.8        | 54.9     |
|             |                  |               | Std Dev              | 6607.0                         | 232565.3               |             |             |          |
|             |                  |               | Std Error            | 4671.8                         | 164448.5               |             |             |          |
|             |                  |               | UCL                  | 6.31                           | 6.3                    |             |             |          |
|             |                  |               | 95% UCL              | 35336.1                        | 1242186.3              |             |             |          |

| Micron Size | 5         | 5         | 5         | 5       | 5     |
|-------------|-----------|-----------|-----------|---------|-------|
| Loc #       | Reading 1 | Reading 2 | Reading 3 | Fed Std | ISO   |
| 1           | 10        | 5         | 4         | 6.3     | 222.9 |
| 2           | 1         | 4         | 0         | 1.7     | 58.7  |
|             |           |           | Mean      | 4.0     | 140.8 |
|             |           |           | Std Dev   | 3.3     | 116.2 |
|             |           |           | Std Error | 2.3     | 82.1  |
|             |           |           | UCL       | 6.31    | 6.3   |
|             |           |           | 95% UCL   | 18.7    | 658.2 |

**End Of Report**



# DATA PACKAGE

ISO/IEC 17025:2005 Accreditation  
Certificate for R Kraft, Inc



# PERRY JOHNSON LABORATORY ACCREDITATION, INC.

## Certificate of Accreditation

*Perry Johnson Laboratory Accreditation, Inc. has assessed the Laboratory of:*

***R. Kraft, Inc.***

***129 Shorecliff Drive, Rochester, NY 14612***

*(Hereinafter called the Organization) and hereby declares that Organization is accredited in accordance with the recognized International Standard:*

**ISO/IEC 17025:2005**

This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (as outlined by the joint ISO-ILAC-IAF Communiqué dated January 2009):

***Testing of Clean Room Facilities, Laminar Flow Devices***  
*(As detailed in the supplement)*

Accreditation claims for such testing and/or calibration services shall only be made from addresses referenced within this certificate. This Accreditation is granted subject to the system rules governing the Accreditation referred to above, and the Organization hereby covenants with the Accreditation body's duty to observe and comply with the said rules.

For PJLA:

| <i>Initial Accreditation Date:</i> | <i>Issue Date:</i> | <i>Accreditation No.:</i> | <i>Certificate No.:</i> |
|------------------------------------|--------------------|---------------------------|-------------------------|
| October, 2012                      | October, 2012      | 72004                     | L12-185                 |

Tracy Szerszen  
President/Operations Manager

Perry Johnson Laboratory  
Accreditation, Inc. (PJLA)  
755 W. Big Beaver, Suite 1325  
Troy, Michigan 48084

*The validity of this certificate is maintained through ongoing assessments based on a continuous accreditation cycle. The validity of this certificate should be confirmed through the PJLA website: [www.pjlab.com](http://www.pjlab.com)*



# Certificate of Accreditation: Supplement

## R. Kraft, Inc.

129 Shorecliff Drive, Rochester, NY 14612  
Ralph Kraft Phone: 585-621-6946

Accreditation is granted to the facility to perform the following testing:

| FIELD OF TEST | ITEMS, MATERIALS OR PRODUCTS TESTED    | SPECIFIC TESTS OR PROPERTIES MEASURED | SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED | RANGE (WHERE APPROPRIATE) AND DETECTION LIMIT |
|---------------|--|---------------------------------------|--|---|
| Environmental | Clean Room and Controlled Environments | Particulate                           | ISO 14644-1 & 2<br>IEST RP-CC006.3               | Up to 999 999 Particles                       |
|               |  | Air Velocity                          | IEST RP-CC006.3                                  | Up to 1 000 FPM                               |
|               |  | Temperature                           | IEST RP-CC006.3                                  | Up to 100 F                                   |
|               |  | Relative Humidity                     | IEST RP-CC006.3                                  | Up to 100 RH                                  |
|               |  | Sound                                 | IEST RP-CC006.3                                  | Up to 150 DbA                                 |
|               |  | Light                                 | IEST RP-CC006.3                                  | Up to 1 000 FC                                |
|               |  | Hepa Filter Integrity                 | IEST RP-CC021.1<br>IEST RP-CC006.3               | Up to 999 999 Particles                       |
|               |  | Pressure Differential                 | ISO 14644-4<br>IEST RP-CC006.3                   | Up to 10 WG                                   |
|               | Laminar Flow and Clean Air Devices     | Particulate                           | ISO 14644-1 & 2<br>IEST RP-CC002.3               | Up to 999 999 Particles                       |
|               |  | Air Velocity                          | IEST RP-CC002.3                                  | Up to 1 000 FPM                               |
|               |  | Sound                                 | IEST RP-CC002.3                                  | Up to 150 DbA                                 |
|               |  | Light                                 | IEST RP-CC002.3                                  | Up to 1 000 FC                                |
|               |  | Hepa Filter Integrity                 | IEST RP-CC021.1<br>IEST RP-CC002.3               | Up to 999 999 Particles                       |
|               |  | Pressure Differential                 | ISO 14644-4<br>IEST RP-CC002.3                   | Up to 10 WG                                   |

# **DATA PACKAGE**

Certification Certificate

# CERTIFICATE OF COMPLIANCE

For  
**HARBEC Inc**  
At  
**369 Route 104**  
**Ontario, NY**

R. **KRAFT**, Inc. certifies that the air handling system supplying this cleanroom at this facility has been tested under the requirements of IEST RP CC 6.3 (Testing Cleanrooms)

And that the air system for this cleanroom has met ISO 14644-1-1999.05.10 guidelines to qualify for the following cleanliness classification of:

| Area           | ISO Design | ISO Achieved | Test Mode             |
|----------------|------------|--------------|-----------------------|
| Main Cleanroom | 8          | 8            | "At-Rest" @ 0.5 $\mu$ |
| Gown Room      | 8          | 8            | "At-Rest" @ 0.5 $\mu$ |

DATE OF INSPECTION: 08/21/13

NEXT DUE DATE: 08/21/14

REPORT NUMBER: H 130821

Authorized By: *C. Davis/R. Kraft* Certification Technicians

R. **KRAFT**, Inc. [www.cleanroomservices.com](http://www.cleanroomservices.com) (585) 621-6946  
"Product Gets 1<sup>st</sup> Air"®

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And that the air system for this cleanroom has met ISO 14644-1-1999.05.10 guidelines to qualify for the following cleanliness classification of:

| Area           | ISO Design | ISO Achieved | Test Mode                 |
|----------------|------------|--------------|---------------------------|
| Main Cleanroom | 8          | 8            | “Operational” @ 0.5 $\mu$ |
| Gown Room      | 8          | 8            | “Operational” @ 0.5 $\mu$ |

DATE OF INSPECTION: 08/21/13

NEXT DUE DATE: 08/21/14

REPORT NUMBER: H 130821

Authorized By: *C. Davis/R. Kraft* Certification Technicians

R. **KRAFT**, Inc. [www.cleanroomservices.com](http://www.cleanroomservices.com) (585) 621-6946  
“Product Gets 1<sup>st</sup> Air”®

# DATA PACKAGE

Customer Survey

# R. KRAFT, Inc. Customer Survey

In our continuing effort to better serve YOU, we need your feed back.

Please either Fax or Email back to R.KRAFT, Inc. (Fax: 1-585-621-2778)  
(Email: [clnrmsrvs@AOL.com](mailto:clnrmsrvs@AOL.com))

Customer Name:

Customer Address:

Recent Test Date:

We would like to get your opinion about the service you recently received from our firm.  
Please respond by place an **X** below the item that reflects your opinion

| <b><u>Thank You</u></b> in advance for your time.                                   | 1<br>Strongly<br>Disagree | 2<br>Somewhat<br>Disagree | 3<br>Agree | 4<br>Strongly<br>Agee |
|---|---------------------------|---------------------------|------------|-----------------------|
| Is it easy to do business with our firm?  |                           |                           |            |                       |
| The response time to your request met your expectations?                            |                           |                           |            |                       |
| The certification was performed to your satisfaction?                               |                           |                           |            |                       |
| The Certification test report was understandable?                                   |                           |                           |            |                       |
| Technician took time to discuss any recommended enhancements prior to exiting site? |                           |                           |            |                       |
| Would you recommend RKI to others for cleanroom certification                       | Yes                       | Neutral                   | No         |                       |

Addition questions

1) What have we done that added value to your operation?

2) How can we make it easier for you to do business with us?

3) How can we make the certification report better for you?

Additional Comments:

Signature of person submitting this survey (optional): \_\_\_\_\_ Date:

**Notes:**