Scan Tool & Mold, Inc
Mold Making · Precision Molding · Design Engineering

2 Trefoil Drive Trumbull CT 06611

Ryan Dubey
Project Manager
PO # Q1000-120224

Certification Report

in accordance with:

ISO 14644-1:2015(E) Cleanrooms and associated controlled environments - Classification of air cleanliness by particle concentration
ISO 14644-3:2019(E) Cleanrooms and associated controlled environments - Test methods
IEST RP-CC006.3 Testing Cleanrooms

Room Name	ISO Class	Occupancy
Main Cleanroom	8	At-Rest

Test Date:
December 3, 2024

Tests Performed By

R. KRAFT, Inc
478 Manse Lane Rochester NY 14625
(585) 621-6946

Jeffrey Brooks
Sr. Certification Technician
December 3, 2024

APPROVED	
Customer Signature:	Date:

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Appendix

Summary

	Description	Main Cleanroom	ISO 8
1.0	Room Pressurization (Wg.) *Page(s) 1*	Cleanroom to Plant	+ 0.0184 wc
2.0	High Limit Particle Criteria Allowed per ISO 14644-1-2015 (E) per Room *Page(s) 2*	3,520,000 **@ 0.5 µm particles/m³**	
2.1	Maximum Particle Count Recorded / Room *Page(s) 5*	3,318,834 @ 0.5 µm particles/m³	
2.2	Room Pass or Fail *Page(s) 5*	PASS	
3.0	Average Room Temperature (°F) *Page(s) 3*	65.4	
	Average Room Humidity (RH %) *Page(s) 3*	23.9	
4.0	Recommended Air Change Rate Per Hr. (AC/Hr.) *Page(s) 4*	5 - 60	
4.1	Air Changes Per Hour (AC/Hr.) as recorded *Page(s) 15*	30	
5.0	HEPA Filter Integrity Test; Pg. 25	PASS	
6.0	NOTES	N/A	

NOTES & COMMENTS

N/A

SCOPE

R. KRAFT, INC. was retained to perform certification of the existing facility at the above address.

The following information provided is indictive 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 the facility past this time.

Documentation for all instruments utilized for the following test(s) are on file in our office(s). Instruments have been calibrated within one full calendar year and are NIST traceable.

Tests Performed:

- ☒ Room Pressurization(s)
- ☒ Particle Counts (non-viable)
- ☒ General (Non-Comprehensive) Temperature & Relative Humidity **Benchmark**
- ☐ General (Non-Comprehensive) Temperature & Relative Humidity Uniformity Analysis
- ☐ General (Non-Comprehensive) Temperature & Relative Humidity Test
- ☐ Comprehensive Temperature & Relative Humidity Test
- ☒ Air Velocity / Air Volume, Air Changes Per Hour (AC/Hr.)
- ☐ HEPA Uniformity (Laminar Flow vs. Turbulent) - Velocity / Volume Deviation must be 15% or less.
- ☒ HEPA Filter Integrity Test - with Atmospheric (Ambient) Challenge
- ☐ HEPA Filter Integrity Test - with Challenging Agent
- ☐ HEPA Filter Differential Pressure Test / Monitoring - HEPA Life Expectancy
- ☐ Differential Pressure Gage Calibration(s)
- ☐ Bench Certification(s) - Laminar Flow / Biological Safety Cabinet / Exhaust Hood(s)
- ☐ Misc./ Special Request(s) _____

Temperature & Relative Humidity Readings are taken at the same location and elevation as the particle counts, unless otherwise specified by purchase order.

HEPA Filter Integrity Test is performed only if directed by the purchase order, in the testing procedure also noted thereon.

DEFINITIONS and UNITS

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 Air Flow”. This is usually found in a raised floor application.

Non-Unidirectional airflow: Airflow which does not meet the definition of unidirectional airflow: previously referred to as “turbulent or non-laminar” airflow. This is found with low side wall air 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
Temp: Temperature (F°)
RH: Relative Humidity (%)
Wg: Inches of Water Gauge
wc: Inches of Water Column or Gauge

INDUSTRY RECOMMENDATIONS

Recommended Air Changes/Hr.*

Cleanliness Classifications		IEST Recommended Air Changes/Hr.	IEST Recommended Ceiling Coverage
New ISO Class	OLD Fed-Std-209E		
ISO Class 8	100,000	5-60	5-15%
ISO Class 7	10,000	60-150	15-25%
ISO Class 6	1,000	150-240	25-40%
ISO Class 5	100	240-600	35-70%
ISO Class 4	10	400-750	50-90%
ISO Class 3	1	500-750	60-100%
ISO Class 1 & 2		500-750	80-100%

**IEST RP-CC012.3 Considerations in Cleanroom Design Published 02/01/2015.*

ISO Classes of air cleanliness per ISO 14644-1

Cleanliness Classifications		Maximum Allowable Particle Concentration (particles / m3) @ 0.5 microns and greater.
New ISO Class	OLD Fed-Std-209E	
ISO Class 8	100,000	3,520,000
ISO Class 7	10,000	352,000
ISO Class 6	1,000	35,200
ISO Class 5	100	3,520
ISO Class 4	10	352*
ISO Class 3	1	35*
ISO Class 2		4*

** Cleanliness classifications for ISO Class 1-4 require different testing equipment and procedures, than less cleaner ISO Classes.*

PRESSURIZATION

ISO 14644-4 - Sub Section A.5.3 (Pressure Differential Concept)

"The pressure differential between adjacent cleanrooms or clean zones of different cleanliness level should lie typically 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 RP-CC006.3 - Sub Section 6.4 (Room pressurization test)

"As a general rule, a difference in pressure of 12Pa or 1.2mm (0.05 in.) water column (w.c. or 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 or 0.5 mm (0.02 in.) w.c. (Wg.) should be maintained between a space of more critical air cleanliness requirements and any adjacent space"

Conversion between Pascal and Inches of Water Column (Water Gauge)		
Pascal (Pa)	Inches of Water Column (w.c. or Wg)	Comments
2.49	0.01	
4.98	**0.02**	**Recommended between spaces**
7.47	0.03	
9.96	0.04	
12.45	**0.05**	**Recommended between Cleanroom and Ambient**

HEPA Filter Integrity Test Summary

Atmospheric (Ambient) Challenge Procedure (per ISO 14644-3):

Using the upstream ambient air as the challenging agent, 1710104 particles @ 0.3 microns were measured from the plant air.

Each HEPA filter is scanned with a light scattering particle counter 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 feet per minute (FPM).

HEPA filters where the scanned particle concentrate is *equal to or below* the 0.01% of the upstream challenge will be considered passing. Concentrations above 0.01% are considered to be a leak.

Overall Test Results:	**PASS**

For specific filter results, see the Appendix 'Air Velocity, Air Volume, Air Changes Per Hour & HEPA Filter Integrity Test Data'.

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Readings	Main Cleanroom
1st Reading @ .3µ	1691230
2nd Reading @ .3µ	1748904
3rd Reading @ .3µ	1690177
Average	***1710104***
0.01%	**172**
Maximum Scanned	41
Test Results	**PASS**

Notes: *N/A*

Instrument Calibration Data

Count	Test	Manufacturer / Model	Serial Number	Next Calibration Date	Notes
1	Room Pressurization (JB)	Evergreen / S-PVF-1	1900660	12/19/2024	N/A
2	Air Velocity (FPM) (JB)	Evergreen / S-PVF-1	1900660	12/19/2024	N/A
3	Particle Counts (JB)	Lighthouse / (4) Apex Z3	2304141001	04/11/2025	Locations 1-5
4	Temperature & Humidity (JB)	Lighthouse / (4) Apex Z3 (Probe)	12500329	04/11/2025	Locations 1-5
5	Particle Counts (RK)	Lighthouse / (2) Apex Z3	2006141012	09/03/2025	Locations 6-10
6	Temperature & Humidity (RK)	Lighthouse / (2) Apex Z3 (Probe)	12500083	09/03/2025	Locations 6-10

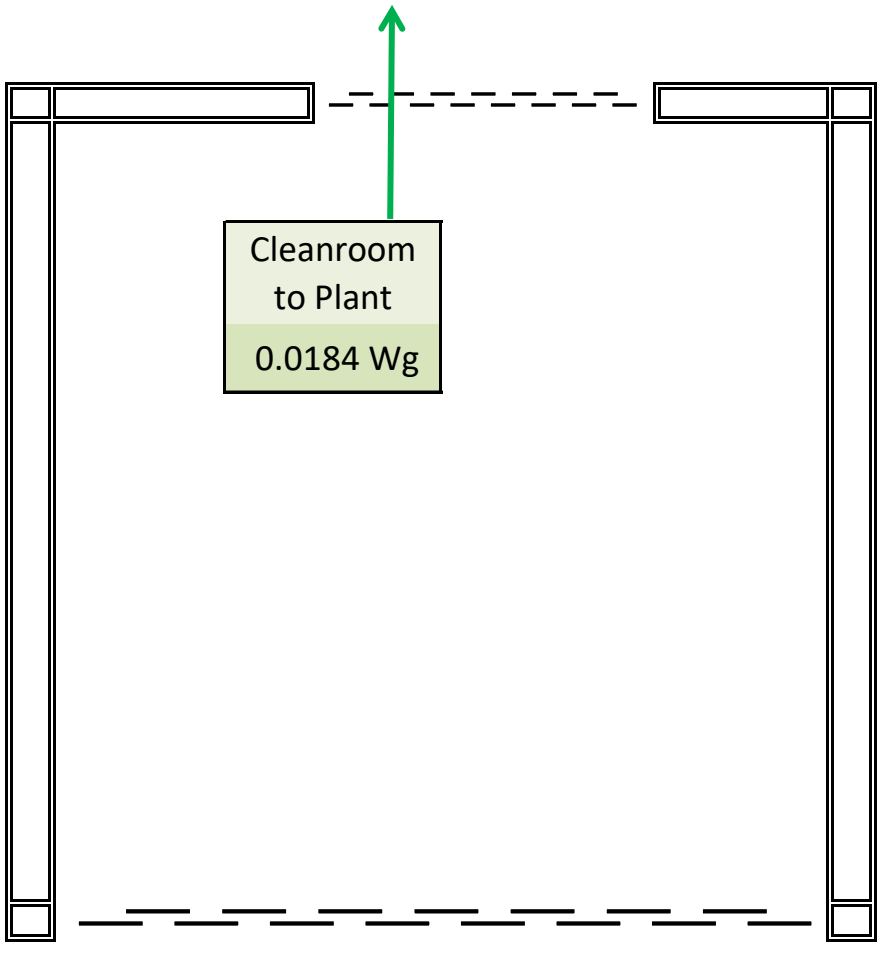
Copies of Equipment Calibration Certificates for all equipment used during testing, are available upon request.

All equipment used have been calibrated within the last 12 months, and are tracible to NIST.

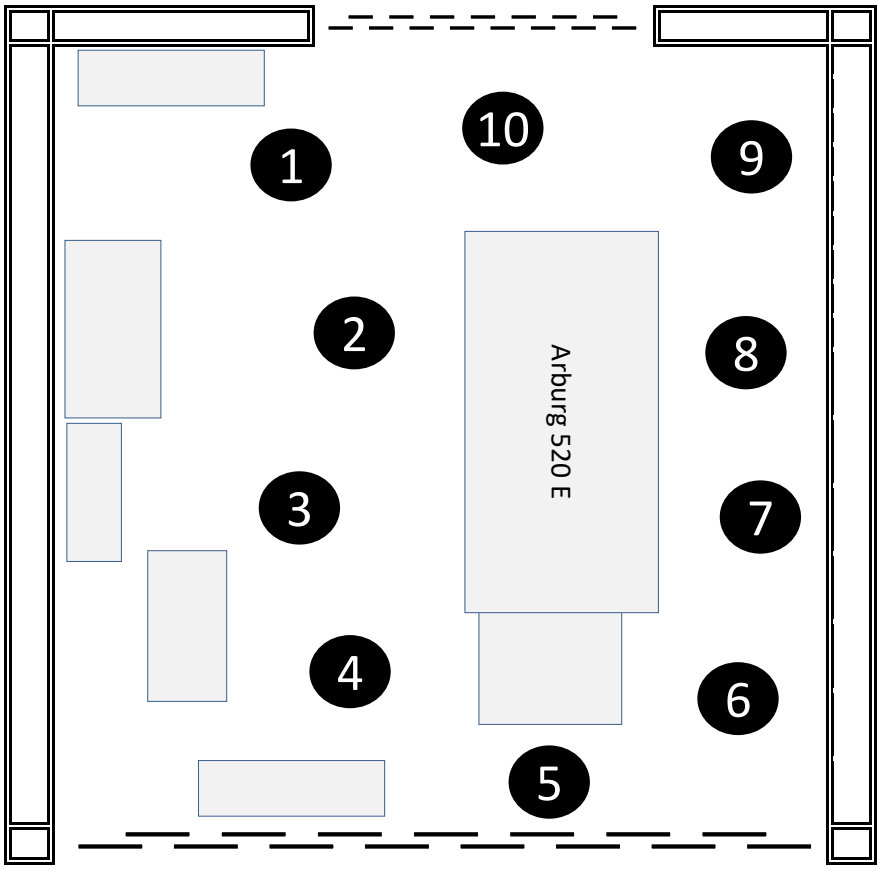
All data pertaining to testing is available upon request.

Calibration Date of "N/A" means apparatus does not need or require Calibration

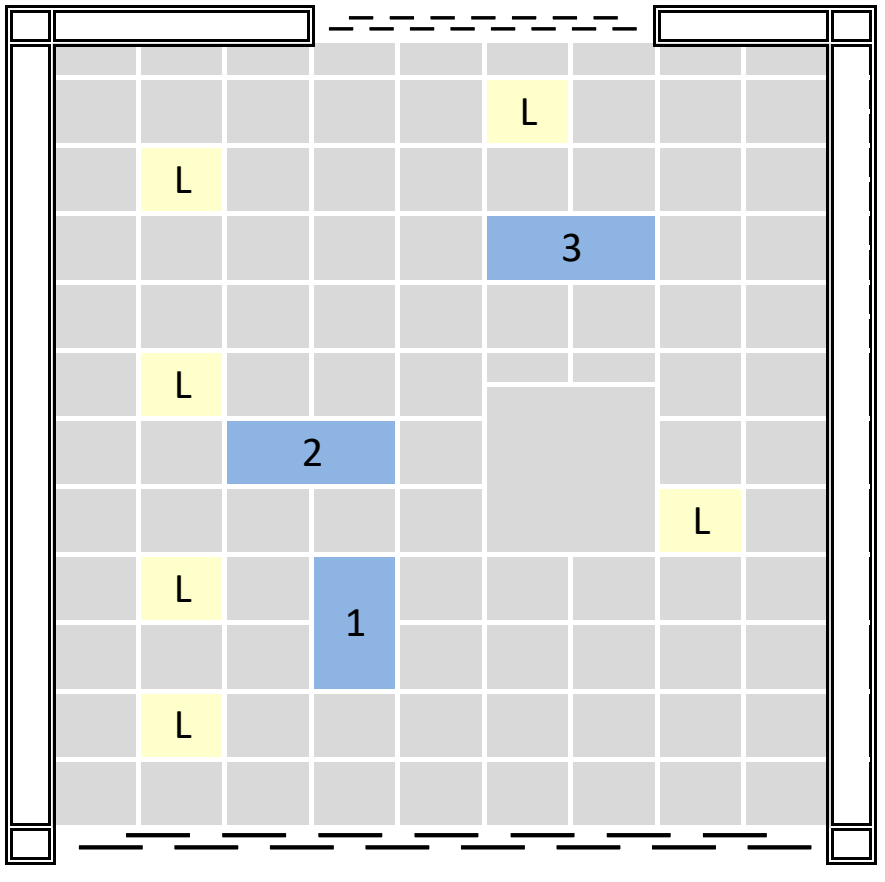
Room Pressurization Grid Map
(Not to Scale)



Particle Count, Temperature & Relative Humidity Sampling Location Grid Map
(Not to Scale)



Air Velocity, Air Volume, (HEPA Filter) Location Grid Map
(Not to Scale)



APPENDIX

Air Velocity, Air Volume, Air Changes Per Hour & HEPA Filter Integrity Test Data

Client:	Scan Tool & Mold, Inc.	**Test Date:**	**Last Test:**	**Next Test Date:**
	2 Trefoil Drive Trumbull CT 06611	12/03/2024	12/01/2023	12/03/2025
Contact:	Ryan Dubey; Project Manager		**Test Mode:**	
PO#	Q1000-120224		At-Rest	

Instrument Utilized: Evergreen S-PVF-1 with Velgrid [X]

Each single measurement represents the average of 16 separate velocity point readings over a 14" x 14" area (1.36 Sq. Ft.). Air Velocity readings taken at 6" below filter face.

HEPA Integrity Test Criteria	
Average Measured Upstream challenge at 0.3 micron:	*1,710,104*
Maximum Allowable Particles @ 0.01%	*172*

**Notes: See also; HEPA Filter Integrity Test Summary (Page 6).*

1

Main Cleanroom

of HEPA Filters 3 / ISO Class 8

The following Filter Size & Free area calculations, are used for Velgrid measurements:

Nominal Size (ft)	*Free Area Width (in)*	*Free Area Length (in)*	*# Panels*	*Free Area Total (sq. in)*	*Free Area (sq. ft)*	*Mfg.*	*Readings*	*CFM Rated*	*Notes:*
2 x 4	*22*	*46*	*1*	*1012.0*	*7.03*	*Unknown*	*3*	*Unknown*	*N/A*

		FPM Data							Filter Scan @ 0.3 micron	
									Passing ≤ 172	
Location #	**Notes**	**Reading 1**	**Reading 2**	**Reading 3**	**Average FPM Reading**	**Free Area (sq. ft)**	**Calculated CFM**	**S/N**	**Filter**	**Peripheral**
1	N/A	106	88	108	101	7.03	710	N/A	32	15
2	N/A	108	106	105	106	7.03	745	N/A	21	18
3	N/A	110	97	107	105	7.03	738	N/A	33	41
Average		**108**	**97**	**107**	**104**	**7.03**	**731**		**PASS**	**PASS**

Rm SF	Rm Hgt.	Cu Ft	Av FPM	Total CFM	AC/Hr.
403.0	11.0	4,433.0	104.0	2,193	30

Average Air Volume per filter	731	CFM
Total Room Supply Volume in Cubic Feet Per Minute	2,193	CFM
Total Room Supply Volume in Cubic Feet Per Hour	131,580	CFH
Total Room Volume in Square Feet	403	SF
Total Room Volume in Cubic Feet	4,433	Cu Ft
Total Air Changes per Hour	30	AC/Hr.

Notes: N/A

APPENDIX

Particle Count, Temperature & Relative Humidity

Client:	Scan Tool & Mold, Inc.	**Test Date:**	**Last Test:**	**Next Test Date:**
	2 Trefoil Drive, Trumbull CT 06611	12/03/2024	12/01/2023	12/03/2025
Contact:	Ryan Dubey			
	Project Manager		**Test Mode:**	At-Rest
PO#	Q1000-120224		**Test Elevation:**	42 Inches above finished floor

Instrument Utilized:	Lighthouse / Apex Z3
Test Documents:	ISO 14644-1-2015 (E) Cleanliness Classifications
	IEST-RP-CC006.3 Testing of Cleanrooms

Cleanroom Classification High Limits

	ISO Class	# of particles @ 0.5 µ
	3	35
	4	352
	5	3,520
	6	35,200
	7	352,000
X	**8**	**3,520,000**

Testing was done in the indicated mode of operation for the specified room(s) listed below, with a particle counter sampling 0.5 microns (or otherwise noted) at a flow rate of 28.3 Liters per minute (1 CFM) per sample. Each location was tested for 3 minutes yielding 3

A Zero count was performed on the particle counter, hose and isokinetic probe before testing began. Probe is positioned vertically unless otherwise noted and/or requested.

Determining the number of sample locations required for particle counting was done by measuring the room being tested and using the area in conjunction with Table A.1 in ISO 14644-1-1-2015(E).

Statistical Significance and Confidence Level: Using Table A.1 in ISO 14644-1-1-2015(E) , Section A.4.1; 'provides at least 95% level of confidence that at least 90% of the cleanroom or clean zone area does not exceed the class limits.'

NOTE: INTERPRETATION OF PARTICLE COUNT RESULTS PER ISO 14644-1-2015 (E) Section A.6.2.

NOTE: The Sample Locations represented on the Particle Count, Temperature & Relative Humidity Sampling Location Grid Map are not shown in the exact location but are a close proximity to where the sample is taken. Room details such as equipment, supplies, lights, product and other items being represented on any grid map are not a requirement of ISO 14644-1 or IEST RP-CC006.3 and are not intended to be exact, to scale, or in the exact locations within the room. All Grid Maps are simple diagrams, and as such are for

A.6.2.1 “The cleanroom or clean zone is deemed to have met the specified air cleanliness classification requirements if the averages of the particle concentrations measured at each sampling location does not exceed the concentration limits."

X The lowest particulate count recorded in each room tested is highlighted in Pale Green with black font.

X The highest particulate count recorded in each room tested, is highlighted in Bright Orange / Yellow with black font.

X Sampling location(s) that PASS cleanliness levels are highlighted in Bold Green with Bold White Font.

X Sampling location(s) that FAIL cleanliness levels are highlighted in Dark Red with Bold White Font.

Temperature & Relative Humidity

General Temperature Test:

This test should be measured at a minimum of one location for each temperature-controlled zone.

Each sensor should be placed at the designated location at work-level height.

Measurements should be performed as appropriate for the purpose of application.

Particle Count, Temperature & Relative Humidity Data

1

Main Cleanroom

Design Class	Square Feet	Square Meters	Required Locations	ISO Class Limit
8	403.0	37.4	10	3,520,000

Location #	Notes	Reading 1 @ 1 min / 28.3 L (1 cubic foot)	Reading 2 @ 1 min / 28.3 L (1 cubic foot)	Reading 3 @ 1 min / 28.3 L (1 cubic foot)	*Average 0.5 µm particles / 28.3 L (1 cubic foot)*	*Average 0.5 µm particles / m³ (1 cubic meter)*	ISO Class Limit	Pass or Fail	Temperature (°F)	Relative Humidity (%)	Temp & R.H. Time Stamp
1	N/A	55505	53636	47740	*52294*	1,847,845	3,520,000	PASS	55.8	34.7	08:09:17
2	N/A	36316	34196	26297	*32270*	1,140,283	3,520,000	PASS	62.1	26.6	08:12:35
3	N/A	30354	24018	13053	*22475*	794,170	3,520,000	PASS	63.7	24.1	08:15:53
4	N/A	15073	23973	24646	*21231*	750,212	3,520,000	PASS	66.7	21.8	08:19:11
5	N/A	48920	57638	65564	*57374*	2,027,350	3,520,000	PASS	68.0	21.8	08:22:29
6	N/A	65544	62082	50631	*59419*	2,099,611	3,520,000	PASS	61.1	34.1	08:10:59
7	N/A	41597	31717	30899	*34738*	1,227,491	3,520,000	PASS	65.3	22.2	08:14:17
8	N/A	33051	50583	38829	*40821*	1,442,438	3,520,000	PASS	68.6	19.3	08:17:35
9	N/A	64577	77712	94485	*78925*	2,788,869	3,520,000	PASS	70.7	17.6	08:20:53
10	N/A	99383	91675	90711	*93923*	3,318,834	3,520,000	PASS	71.7	17.2	08:24:11
Average		49032	50723	48286				PASS	65.4	23.9	

Maximum Particle Count @ 0.5 µm/ m³ as measured: ***3,318,834*** **Test Mode:** ***At-Rest*** ***ISO Class Achieved: 8***

Temperature Uniformity Summary

# of Readings	Start Time	End Time	Average Temperature (°F)	Temperature Std. Deviation	Temperature Std. Deviation %	Lowest Temperature (°F)	Highest Temperature (°F)
10	08:09:17	08:24:11	65.4	4.6	7.0%	**55.8**	**71.7**

Moisture Uniformity Summary

# of Readings	Start Time	End Time	Average Relative Humidity (%)	Relative Humidity Std. Deviation	Relative Humidity Std. Deviation %	Lowest Relative Humidity (%)	Highest Relative Humidity (%)
10	08:09:17	08:24:11	23.9	5.9	24.6%	**17.2**	**34.7**

*Note: N/A

ISO/IEC 17025:2017 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.

478 Manse Lane, Rochester, NY 14625

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

ISO/IEC 17025:2017

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 April 2017):

Mechanical (Environmental) Testing

(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:

Tracy Szerszen
President

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

Initial Accreditation Date:	*Issue Date:*	*Expiration Date:*
October 18, 2012	August 24, 2024	October 31, 2026

Accreditation No.:	*Certificate No.:*
72004	L24-654

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.pjlabs.com

Page 1 of 2

Certificate of Accreditation: Supplement

PJLA

R. Kraft, Inc.
478 Manse Lane, Rochester, NY 14625
Contact Name: Mr. Jeffrey Brooks Phone: 585-621-6946

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

FLEX CODE	FIELD OF TEST	ITEMS, MATERIALS, OR PRODUCTS TESTED	COMPONENT, CHARACTERISTIC, PARAMETER TESTED	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED
F1, F2	Mechanical (Environmental) [O]	Clean Room and Controlled Environments	Particulate	ISO 14644-1 & 2 IEST RP-CC006.3	Discrete-Particle Counter (DPC)
F1, F2			Air Velocity	IEST RP-CC006.3	Thermal Anemometer, Electronic Micromanometer with single or multipoint probe
F1, F2			Temperature		Digital Temperature Sensor/Meter
F1, F2			Relative Humidity		Digital Relative & Humidity (RH) Sensor/Meter
F1, F2			Sound		Sound-Level Meter
F1, F2			Light		Photoelectric Illumination Metering Device
F1, F2			HEPA Filter Integrity	IEST RP-CC021.5 IEST RP-CC006.3	Discrete-Particle Counter (DPC), Photometer, Aerosol Injection
F1, F2			Pressure Differential	ISO 14644-4 IEST RP-CC006.3	Electronic Micromanometer
F1, F2		Laminar Flow and Clean Air Devices	Particulate	ISO 14644-1 & 2 IEST RP-CC002.4	Discrete-Particle Counter (DPC)
F1, F2			Air Velocity	IEST RP-CC002.4	Thermal Anemometer, Electronic Micromanometer with single or multipoint probe
F1, F2			Sound		Sound-Level Meter
F1, F2			Light		Photoelectric Illumination Metering Device
F1, F2			HEPA Filter Integrity	IEST RP-CC034.5 IEST RP-CC002.4	Discrete-Particle Counter (DPC), Photometer, Aerosol Injection
F1, F2			Pressure Differential	ISO 14644-4 IEST RP-CC002.4	Electronic Micromanometer

1. The presence of a superscript O means that the laboratory performs testing of the indicated parameter onsite at customer locations.

2. Flex Code:
   F1-Introduction of the testing of a new item, material, matrix, or product for an accredited test method
   F2-Introduction of a new version of an accredited standard method (with no modifications)
   F3-Introduction of a new parameter/component/analyte to an accredited test method
   F4-Introduction of a new version or modifications of an accredited non-standard method
   F5-Introduction of a new method that is equivalent to an accredited method (using same technology or technique)

Certificate of Compliance

for

Scan Tool & Mold, Inc
Mold Making · Precision Molding · Design Engineering

2 Trefoil Drive, Trumbull CT 06611

R. KRAFT, Inc. certifies that the air handling system supplying this Cleanroom at this facility has been tested under the requirements of IEST RP CC0006.3 (Testing Cleanrooms) and that the air system has met ISO 14644-1:2015 (E) guidelines to qualify for the following cleanliness levels:

Room Name	ISO Class Design	ISO Class Achieved	Occupancy
Main Cleanroom	8	8	At-Rest

Date of Inspection: December 3, 2024

Next Due Date: December 3, 2025

Report # CR 241203

Authorized By: *Jeffrey Brooks* *Certification Technicians*

R. **KRAFT**, Inc. **"Product Gets First Air"** (585) 621-6946