Cleanroom Environmental Monitoring Report

Q3 Routine Microbiological and Particle Evaluation

Facility Location:	Apex Suite 4, Filling Line B	**Monitoring Period:**	August 1 – August 3, 2026
Cleanroom Class:	ISO Class 5 (Grade A) & ISO Class 7 (Grade C)	**Report Number:**	RP-EM-2026-0804
Operation State:	Operational (In-Operation)	**Inspector:**	Dr. Evelyn Thorne
Date of Issue:	August 4, 2026	**Status:**	⚠ ALERT

Executive Summary

This report summarizes the routine environmental monitoring (EM) results obtained for the Grade A filling zone (ISO Class 5) and the surrounding Grade C cleanroom background (ISO Class 7) at the Apex Suite 4 facility during the Q3 operational monitoring cycle. The assessment includes non-viable particle counts (0.5 µm and 5.0 µm fractions), active air microbiological sampling, passive settle plates, and surface contact plates for personnel and equipment. A total of twenty-four (24) locations were monitored. Overall compliance was high, with 23 of 24 points meeting all regulatory action limits. However, an Action Limit exceedance for 0.5 µm non-viable particles was observed at Location **L-A03** (Needle Assembly Bench) during mechanical setup on August 2. Active air and settle plate microbial counts remained within alert levels. This report outlines the data, describes the trend analysis, and documents the immediate corrective actions implemented.

1 Scope & Standards

Environmental monitoring was performed in compliance with the following standard operating procedures and international guidelines:

- **ISO 14644-1:2015** [2]: Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration.
- **EU GMP Annex 1 (2022 Revision)** [1]: Manufacture of Sterile Medicinal Products.
- **SOP-QC-MICRO-402**: Routine Environmental Monitoring of Aseptic Processing Areas.

The monitoring protocol is designed to ensure that air quality, surface cleanliness, and microbial levels are maintained within acceptable limits to mitigate product contamination risk during sterile filling.

2 Monitoring Methodology & Limits

The environmental monitoring program employs a combination of physical and microbiological assays.

2.1 Monitoring Protocols

- **Non-Viable Particles**: Measured using calibrated *Apex Particle Tracer Pro* optical counters. Probes were placed isokinetically at working height. Sampling volume was 1.0 m^3 (1000 L) per sample location.
- **Active Air (Viable)**: Conducted using Synapse MAS-100 samplers pulling 1000 L of air onto Tryptic Soy Agar (TSA) plates.
- **Settle Plates**: 90 mm TSA plates exposed to cleanroom air for a maximum of 4 hours under laminar flow hoods.
- **Contact Plates**: 55 mm RODAC plates containing TSA with lecithin and polysorbate 80, applied to surfaces with a standardized pressure for 10 seconds.

2.2 Regulatory Limits (EU GMP Annex 1)

The alert and action levels for cleanrooms under "In-Operation" state are defined in Table 1.

Table 1: Airborne Particle and Microbiological Limits (In-Operation)

Cleanroom Grade	Sampling Type	Particle Limits (per m^3)		Microbial Limits	
		$\geq 0.5\,\mu m$	$\geq 5.0\,\mu m$	Alert	Action
Grade A (ISO Class 5)	Non-Viable	3,520	29	–	–
	Active Air	–	–	1 CFU	> 1 CFU
	Settle Plate (4h)	–	–	1 CFU	> 1 CFU
Grade C (ISO Class 7)	Non-Viable	352,000	2,900	–	–
	Active Air	–	–	50 CFU	100 CFU
	Settle Plate (4h)	–	–	25 CFU	50 CFU

3 Monitoring Results

Measurements collected during the monitoring period are tabulated below. Table 2 outlines particle concentrations and microbial growth across high-risk locations.

Table 2: Non-Viable and Viable Monitoring Results (August 1–3, 2026)

ID	Location Description	Grade	Particles (m^3)		Active Air	Settle	Contact	Status
			$\geq 0.5\,\mu m$	$\geq 5.0\,\mu m$	(CFU)	(CFU)	(CFU)	
L-A01	Under Laminar Flow A	Grade A	280	0	0	0	0	COMPLIANT
L-A02	Filling Vessel Interface	Grade A	1,420	4	0	0	0	COMPLIANT
L-A03	Needle Assembly Bench	Grade A	**4,890***	18	0	0	1	ACTION
L-A04	Capping Station Bowl	Grade A	2,110	8	0	0	0	COMPLIANT
L-C01	Suite 4 Main Corridor	Grade C	142,500	840	12	8	4	COMPLIANT
L-C02	Material Entry Airlock	Grade C	210,400	1,120	18	14	9	COMPLIANT
L-C03	Personnel Gowning Room	Grade C	295,800	1,940	**52**†	18	15	ALERT
L-C04	Conveyor Exit Buffer	Grade C	84,200	410	6	3	2	COMPLIANT

* Exceeds Grade A Action Limit (3,520 particles/m^3). See Section 4 for investigation details.
† Exceeds Grade C Alert Limit (50 CFU/m^3).

3.1 Non-Viable Particle Trend Analysis

Trend analysis of Location **L-A03** (Needle Assembly Bench) shows a sudden spike in particle concentration during Shift 2 on August 2. Figure 1 represents the historical counts over the last 10 monitoring intervals.

4 Alert & Action Limit Exceedances

Two exceedances were documented during the current monitoring cycle. Table 3 provides a detail of these events, including target limits and immediate corrective actions.

4.1 Investigation Findings

Location L-A03 Exceedance (Action Limit): An investigation was opened under CAPA ref **CAPA-2026-088**. It was determined that the particle spike occurred during a mechanical tooling adjustment of the needle assembly. A technician used a standard tool kit that had not undergone complete dust-removal wipes. The mechanical friction of

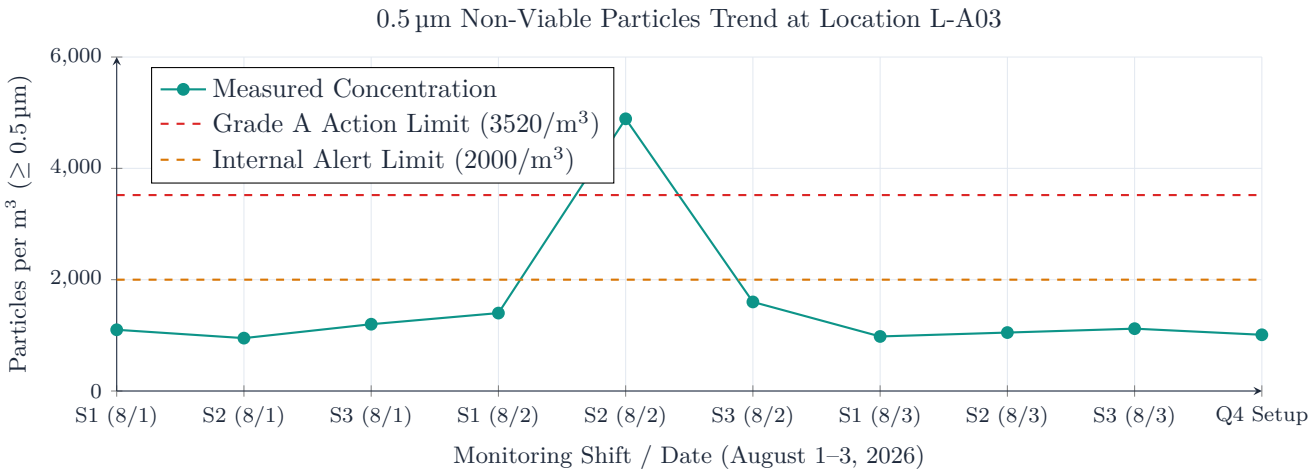

Figure 1: Historical non-viable particle concentrations (0.5 µm) at Location L-A03.

Table 3: Summary of Alert and Action Limit Exceedances

Date	Location	Grade	Parameter	Value	Limit	Immediate Action Taken
Aug 2	**L-A03**	Grade A	Non-Viable Particle ($\geq 0.5\,\mu m$)	4,890	3,520	Stopped line setup. Performed double sanitization cycle. Re-tested successfully before production.
Aug 2	**L-C03**	Grade C	Active Air Microbial (CFU)	52	50	Initiated cleaning of gowning locker units. Conducted personnel retraining on gowning hygiene.

the needle mount also generated localized particulates.

Microbiological results from active air and contact plates exposed concurrently at L-A03 showed zero growth (0 CFU), indicating that the particle excursion did not introduce microbial contamination. The filling line was not in production during this excursion; hence, no product was impacted.

Location L-C03 Exceedance (Alert Limit): The alert level of 52 CFU at the personnel gowning room was investigated. A slight increase in traffic during the shift crossover led to localized air turbulence. Plates showed common skin flora (*Micrococcus luteus*), indicating a minor gowning technique variance. Personnel on shift were retrained.

5 Conclusion & Recommendations

Based on the monitoring results, the following recommendations and certification decisions have been made.

Cleanroom Certification Status

Cleanroom Status: Approved with Qualification
With the exception of the resolved transient excursions at locations L-A03 and L-C03, all cleanroom environments in Apex Suite 4 were found to be operating within their established microbiological and physical states of control. The immediate corrective actions were successful, as demonstrated by the subsequent compliant re-testing. Production was permitted to proceed.

5.1 Recommendations

1. **Tooling Preparation Protocol**: Update SOP-QC-MICRO-402 to mandate that all mechanical adjustment tools used within Grade A/B zones undergo a specialized ultra-clean wipe down and particle screening prior to chamber entry.
2. **Gowning Air Flow Check**: Perform a diagnostic check on the HEPA filters in the Gowning Room (L-C03) to ensure appropriate air change rates are maintained during peak shift transitions.
3. **Sampling Frequency**: Maintain the current routine monitoring frequency, but increase particle verification at L-A03 to twice per shift for the next two weeks as a precautionary measure.

5.2 Sign-Off & Approval

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Date: August 4, 2026

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Date: August 4, 2026

References

[1] European Commission. The rules governing medicinal products in the european union - volume 4 - eu guidelines to good manufacturing practice - annex 1: Manufacture of sterile medicinal products. *EudraLex*, August 2022.

[2] International Organization for Standardization. Iso 14644-1:2015 - cleanrooms and associated controlled environments - part 1: Classification of air cleanliness by particle concentration. *ISO Standard*, 14644-1, 2015.