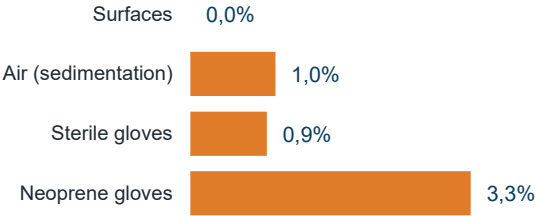


Tracking the source of contamination in an isolator : contribution of chemical indicators and swab sampling

1 BACKGROUND

Microbiological monitoring of isolators has been in place for 5 years — **2,190 samples collected in 2025.**

Positivity rate by sample type:



2 OBJECTIVES

A. Reorganization of sampling

Based on current recommendations and risk analysis.

B. Investigate the contamination source

Verify the homogeneous distribution of the sterilizing agent and the absence of contamination of incoming equipment.

3A RISK ANALYSIS

Criticality = Positivity freq. × Handling freq. × Severity

Positivity frequency
Based on data from 2025 **1–5**

Handling frequency
Number of contacts during preparation **1–5**

Severity for the preparation
Potential impact on the quality/safety of the final product **1–5**

3B SAMPLING REORGANIZATION

Sampling point	Criticality /125	Action
Neoprene gloves	60	↑
Sterile gloves	50	↑
Air (sedimentation)	50	↑
Exit door	16	↑
Entry door	15	↑
Flat surfaces	1	= or ↓

⚠ **insufficient frequencies**

4A CHEMICAL INDICATORS AND SWABBING

🔍 Verify the homogeneous distribution of the sterilizing agent and the absence of contamination of incoming equipment.

Period : 5-week study — 2 tests/week

Device: 1 chemical indicator per basket

Staff involved: Hygiene officer + 7 different pharmacy technicians

Sampling: Swabbing after each cycle (connectors, syringes, caps)

4B EFFECTIVENESS OF DECONTAMINATION CYCLES

ALL
positive chemical indicators: homogeneous diffusion of the sterilizing agent

0/60
positive swab samples: no contamination of incoming equipment detected

1
routine sample positive (sterile glove), collected on the same day as a test session

5 CONCLUSION

↑ Increase sampling of gloves, air by sedimentation, and doors

↓ Reduction or maintenance considered for historically compliant areas (flat surfaces)

🔍 **The contamination source does not appear to originate from incoming equipment**

✚ Microbiological sampling on sterilized equipment + chemical indicator = complementary monitoring to annual validation

PERSPECTIVES

📅 Pursue of microbiological monitoring according to the new schedule

🧤 Investigate the type of under-gloves to use

🔄 Rotation of cleaning/disinfection