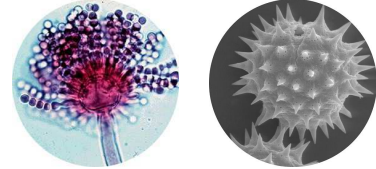




Airborne contamination detection in clean room

RNSA Laboratoire



Context

A cell culture laboratory working in clean room under microbiological safety cabinet was identifying pollens and molds spores into his cultures supernatant. Yet these contaminations were not detected by traditional air control methods of particular counting and microbiological control described in ISO 14644 and ISO 14698. Innovative methods for air sampling and analysis have been used to control the room air and determine the products non-quality causes.

Material

- Cyclonic air sampler Coriolis® μ
- Sterile membrane 0,2 μ m
- Optical microscope

Protocol

- 9 m³ of air sampling- 300 L/min – 3 x 10 min
- Sample filtration
- Membrane specific treatment (RNSA Laboratoire method)
- Observation of the whole sample
- Particles identification and counting

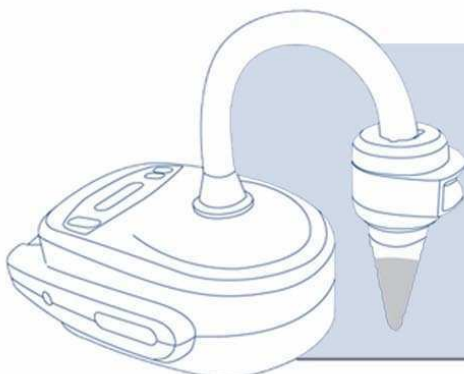
Results

- High and representative volume of air sampled
- Whole sample analysis
- Counting and identification of pollens and molds non detected by impaction on agar dishes: cultivable + non cultivable particles
- After aeraulics improvements, global decontamination and work procedures review
 → Microbiological acceptable level < 3 particles/m³ of air for each control point

	1 : 1 st trial set		2 : 2 nd trial set		Cell culture room		Airlock		Outside	
	1	2	1	2	1	2	1	2	1	2
Pollens										
Total pollens	98	63	121	37	324	180				
Particles/m ³ of air	11	7	13,4	4	36	20				
Molds										
Total molds	64	691	37	412	88	4052				
Particles/m ³ of air	7	77	4	46	10	450				



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Conclusion

Coriolis® μ combined with RNSA Laboratoire detection method allows to **identify airborne contaminants** non detected by traditional methods described within in force norms.

Corrective and preventive actions have thus been implemented to ensure clean rooms air and products quality.