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THE CORRECT METHOD FOR MICROBIAL CONTINUOUS MONITORING IN GRADE A

The GMP Annex 1 at the Chapter n.9 says:
"9.24 Continuous viable air monitoring in grade A (e.g.:air sampling or settle plates) should be undertaken for the full duration of critical processing, including equipment (aseptic set-up) assembly and critical processing". The active air sampler and the settle plate methods are quite different and give result quite different in term of cfu. A simple test can confirm this fact. It is here reported an example.

TEST 1

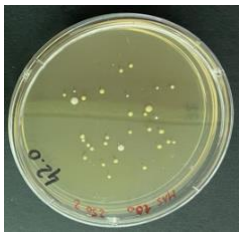
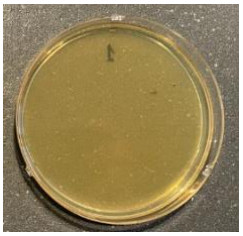
	PLATE 1 AIRBIO TRIO HEAD 1	PLATE 4 SETTLE 1h	PLATE 1 AIRBIO HEAD 1 26 cfu	PLATE 4 SETTLE 1h 1 cfu
SAMPLING TIME	AIRBIO HEAD 1 100 L/M (6.000 LT - 1h) CFU	SETTLE (1 h)c FU		
START SAMPLING 10:00 SAMPLING TIME : 1h	26	1		

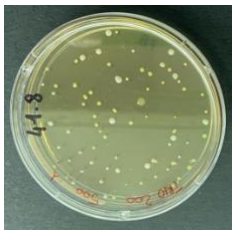
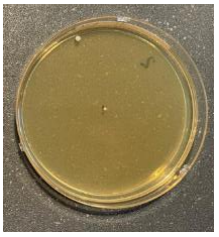
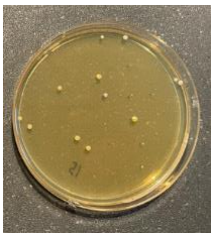
	PLATE 2 AIRBIO TRIO HEAD 2	PLATE 5 SETTLE 1h	PLATE 2 AIRBIO HEAD 2 55 cfu	PLATE 5 SETTLE 1h 2 cfu
SAMPLING TIME	AIRBIO HEAD 2 100 L/M (6.000 LT - 1h) CFU	SETTLE (1 h) CFU		
START SAMPLING 11:00 SAMPLING TIME : 1h	55	2		

	PLATE 3 AIRBIO TRIO HEAD 3	PLATE 6 SETTLE 1h	PLATE 1 AIRBIO HEAD 3 81 cfu	PLATE 6 SETTLE 1h 15 cfu
SAMPLING TIME	AIRBIO HEAD 1 100 L/M (6.000 LT - 1h) CFU	SETTLE (1 h) CFU		
START SAMPLING 12:00 SAMPLING TIME : 1h	81	15		

SAMPLING TIME	PLATE 1+2+3 AIRBIO H1+H2+H3	PLATE 4/5/6 SETTLE H1+H2+H3	% DIFFERENCE CFU
3 h	**Cfu 162**	**Cfu 18**	**-89%**

RESULTS TEST 1:
The total number of cfu collected in 3 hours of continuous sampling was 162 colonies for active air sampling versus 18 colonies for passive sampling (settle) (the difference is 89%). These results confirm that the two methods give an enormous difference in terms of credits and, for a real evaluation, active sampling should be adopted.

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TEST 2

	PLATE 1+2+3 AIRBIO H1+H2+H3	PLATE 7 SETTLE 3h	
	START SAMPLING 9:00- 11:00	START SAMPLING 9:00- 11:00	
SAMPLING TIME	AIRBIO HEAD 1 100 L/M (6.000 LT - 1h)	SETTLE (1 h)	% DIFFERENCE CFU
3 h	**Cfu 162**	**Cfu 23**	**-86%**

	
AIR BIO TRIO the portable active air sampler	TRIO SETTLE Floorsupport for passive air sampling

RESULTS TEST 2:

The total number of cfu collected in 3 hours of continuous sampling was 162 colonies for active air sampling (with three different plates) versus 23 colonies for passive (settling) sampling (with a single plate) (the difference is 86%). These results confirm that the two methods give a huge difference in terms of credits and, for a real evaluation, active sampling should be adopted.

JUST FEW BASIC CONCEPTS

Active and Settle sampling are two different way to collect micro-organisms from the air. The active air sampler indicates the number of micro-organisms present in a specific air volume (normally 1 cubic meter =1000 litres of air), whereas the settle sampling reports the number of micro-organisms that are simply deposited onto a surface.

The air sampling in a closed environment (e.g.: isolator, Grade A) is not influenced by the presence of the people, but the situation is quite different where the operators are involved because their moving produces an inconstant fallen down of the micro-organisms on the open agar plate.

It is therefore necessary a specific CCS to decide which is the sampling method to adopt. It is certainly clear that the active air sampling is the more efficient system.

Another point to consider is that the settle method cannot be validated.

CONCLUSION

The reported tests show clearly the difference between active and settle methods. The settle method has a number of cfu that is 86/89% less in comparison with the active method. This means that the reported data must be taken in consideration during the CCS.