

Biological efficiency of the MAS-100 NT® air sampler with TSA w. LTHThio sedi. ICR Settle Plates

ISO 14698-1 describes standard methods to measure biological contamination in cleanrooms and associated controlled environments. In areas that are used for manufacturing of safe pharmaceutical products, the control of biological contamination is mandatory. Part 1 of ISO 14698 specifies methods which can be used to monitor risk zones in cleanrooms or give information about sources of risks in the zones¹.

Annex A describes how to determine airborne biological contamination in sterile production. For active air sampling, impaction, impingement or filtration samplers are recommended devices.

Annex B gives guidance on how to validate air samplers. It is split into two parts, the physical and the

biological efficiency. For biological efficiency validation, the use of casein-peptone soymeal-peptone containing agar is recommended. As the validation depends on the types of microorganisms present, the formulation and quality of the culture medium also has an influence on the results.

MAS-100® air samplers are sieve impaction systems based on the Anderson impaction principle. They use 90–100 mm standard Petri dishes, are easy to handle and compact. They allow an appropriate suction flow rate, impact velocity and collection accuracy and efficacy.

Table 1. Physical and biological efficiency of the MAS-100® family (results derived from independent validation of MAS-100® family acc. ISO 14698 with TSA + LTHTh Cat. No. 146683)

Characteristics	Iso-MH (1)	Iso-MH (9)	Iso	NT	VF
Physical Efficiency for particle size of 0.8 µm	60.41	62.58	60.20	n/a	n/a
Physical Efficiency for particle size of 1.0 µm	n/a	n/a	n/a	78.77	84.18
Physical Efficiency for particle size of 1.3 µm	71.68	82.60	76.91	84.10	85.81
Physical Efficiency for particle size of 2.2 µm	96.90	91.54	91.96	91.76	94.22
Physical Efficiency for particle size 5.4-6 µm	99.04	93.27	90.24	92.65	99.65
Biological Efficiency	76.74	73.74	78.08	82.62	76.78

We offer a variety of TSA – ICR formulations with and without neutralizers. **Table 2** lists the ICR articles used in this application note MAS-100 instruments manufactured by MBV AG, Switzerland, www.mbv.ch, MBV. Air. Nothing else.

Materials and Methods

Table 2. TSA ICR test plates for air sampling

Cat. No.	Product Name	Format
146786*	TSA+LTHThio sedi- ICR	Ready-to-Use**
146683*	TSA+LTHTh sedi- ICRplus	Lockable, Ready-to-Use

*available in 20 and 120 pack sizes;

**media with a lower concentration of sodium thiosulfate compared to 146683

Tryptic Soy Agar + LTHThio sedi. – ICR and + LTHTh - ICRplus in 90 mm settle plates are designed for the determination of the total aerobic microbial count in active or passive air monitoring as well as glove prints in **Isolators and Clean Rooms**.

In a test room, two MAS-100 NT® instruments (Ref. No. 109191) were placed on two tables. Each sampler was placed in this specific position for the whole trial (figure 1). Positions were chosen to achieve symmetry in the room with respect to walls, ventilation inlets/

outlets etc. and to ensure a good distance between the individual samplers.

Active air sampling was performed in a non-controlled environment with high human movement in order to detect a broad range of real airborne microorganisms and further to achieve higher microbial counts for comparison. Two independent test trials were performed on consecutive two days in the same place, on the same table and at the same time (in total 14 plates per agar type).

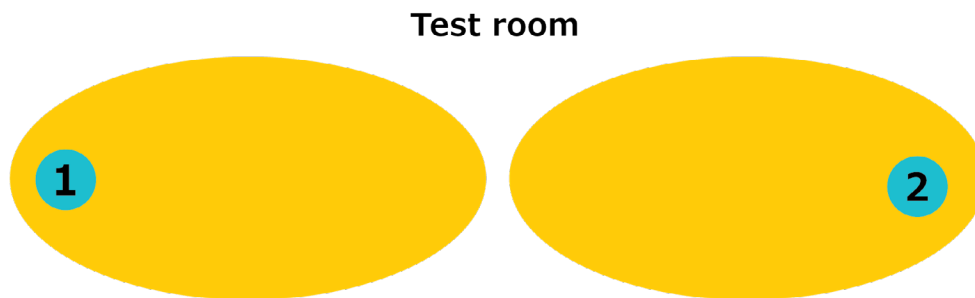


Figure 1. Sampling concept for active air sampling. Two MAS-100 NT® instruments were placed in different positions on two tables in an uncontrolled environment outside of cleanroom conditions
MAS-100 instruments manufactured by MBV AG, Switzerland, www.mbv.ch, MBV. Air. Nothing else.

For both test trials, agar plates were tested in a specific order (**table 3**). Before sampling of a 1000 liter volume every sampling step consisted of a three minutes delay. In case a reduced sampling volume of 500 liters (run 7 on day 1) or 250 Liter (run 7 on day 2) the final CFU measurements were scaled-up to a 1000 liter sampling volume.

After sampling, all plates were incubated for 2 days at 32.5 ± 2.5 °C. All lockable plates were incubated in the locked ("closed") position. After incubation, all visible colonies were counted and corrected by the Feller table.

Table 3. Order of sampling (day 1 and 2).
A and B stands for the different agar plates that were used.

	Position 1	Position 2
Run 1	A	B
Run 2	B	A
Run 3	A	B
Run 4	B	A
Run 5	A	B
Run 6	B	A
Run 7	A	B

Results and Conclusion

The single colony counts within this non-controlled environment varied between 33 and 97 CFU, whereby the two different ICR plate media formulations showed comparable recoveries, as shown in **figure 2**.

Comparison of CFU detected with two different ICR Media in MAS-100 NT®

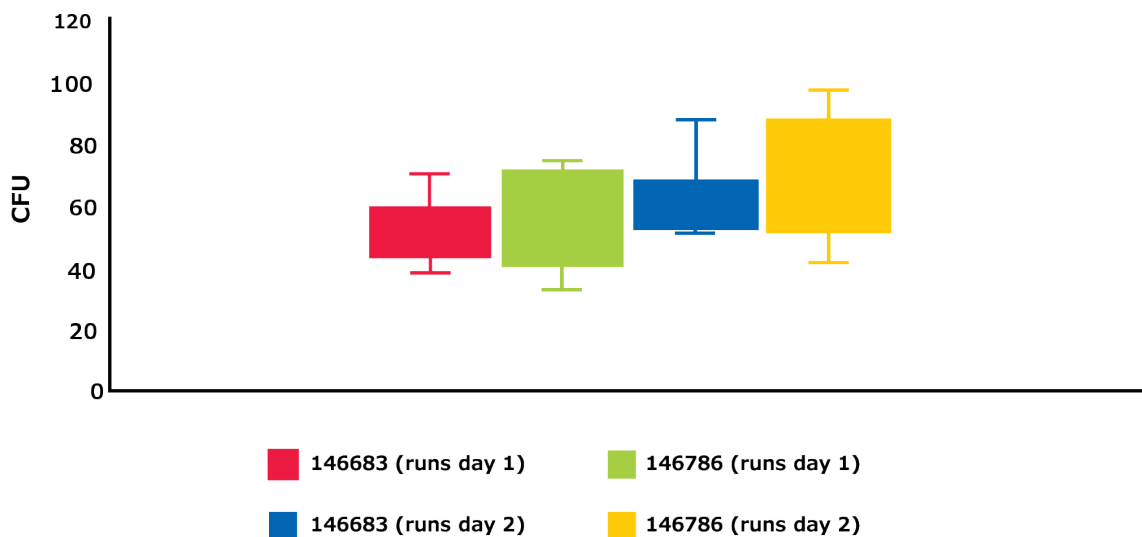


Figure 2. CFU/m³ recovered with MAS-100 NT® in a non-controlled environment on 2 consecutive days for the settle plates TSA w. LTHTh - ICR+ and TSA w. LTHThio sedi. - ICR

MAS-100 instruments manufactured by MBV AG, Switzerland, www.mbv.ch, MBV. Air. Nothing else.

The mean recovered CFU per 1 m³ for each medium are shown in **table 4** below.

Table 4. Average cfu/m³ out of 14 runs (7 runs per day)

Cat.No.	Product	Average recovery (cfu/m ³)
146786	TSA + LTHThio sedi. - ICR	57
146683	TSA + LTHTh - ICR plus	60

The results indicate that there was no significant difference between the recoveries obtained with the 2 different TSA media. It can be concluded that the biological efficiency, which was validated for the MAS-100 NT[®] instrument with the TSA w. LTHTh - ICR+ (Cat. No. 146683) settle plate, was also maintained when using TSA w. LTHThio sedi. -ICR (Cat. No. 146786) which contains a lower concentration of sodium thiosulfate.

Literature and further readings

1. ISO 14698-1(2003): Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods
2. Application Note: Active air sampling with Tryptic Soy Agar – ICR (Cat. No. 146001, 146050, 146069 and 146683)

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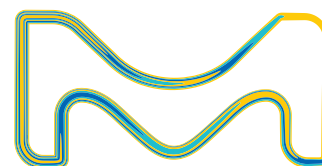


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