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Application Note

Collection Efficiency Validation of the MAS-100 Eco® Microbial Air Sampler acc. to EN 17141

A side-by-side conformity comparison with an already qualified air sampler

EN 17141 (2020) describes the complex validation procedure of microbial air samplers, which should be performed by an external competent body, and stipulates that the supplier must demonstrate the collection efficiency of the microbial air sampler. [1] The method for validation of collection efficiency is in two parts: physical efficiency and the biological efficiency. Physical efficiency is a measure of an air sampler's ability to collect various particle sizes down to small particles of, for example, 1 µm diameter. It can be expressed by the d50 value, the particle diameter at which a minimum of 50% recovery is achieved. The biological efficiency, stated in percent recovery, describes the ability of the air sampler to capture organisms from the air gently so they remain viable.

The biological and physical efficiencies are influenced by the impaction speed. The speed must be high enough to collect small particles but low enough to maintain the viability of any microorganisms during impaction.

EN 17141 also describes an alternative, simpler laboratory method that allows on-site validation. This method is a side-by-side comparison against a membrane filtration method or an already qualified air sampler that has been validated to the more complex biological and physical efficiencies. The recovery rate of the air sampler to be validated needs to achieve a recovery rate of 100% ± 50% versus the qualified air sampler. In this study, the already qualified MAS-100 NT® air sampler served to validate the MAS-100 Eco® air sampler.

The MAS-100 NT® volumetric microbial air sampler has been validated according to ISO 14698, which is identical with complex validation method described in EN 17141, by a competent external body. Its certified biological efficiency is 83% and its measured d50 value less than 1 µm. [2]

The MAS-100 Eco® air sampler is based on the same impaction principle as MAS-100 NT® sampler, accelerating the air through a sieve plate (Andersen principle). The nominal d50 (calculated acc. EN 17141) of the MAS-100 Eco® sampler is 1.6 µm vs 1.1 µm for the MAS-100 NT® sampler.

To demonstrate the collection efficiency of MAS-100 Eco® sampler we performed a side-by-side comparison versus the qualified MAS-100 NT® air sampler. In this study, we document the collection efficiency at two different locations in a non-controlled environment, with higher contamination rates than typically in a cleanroom, but no homogenous distribution of the microorganisms. It is a requirement of EN 17141 to test at two different locations.

Method

The MAS-100 NT® and MAS-100 Eco® air samplers were positioned side by side (distance 1 meter) and at the same height (80 cm) at the locations A and B of the non-controlled environment. Ten parallel samples were taken at each location, and the positions (A/B) of the air samplers were switched after each run. The 10 samples per location were taken consecutively within one working day.

500 liters of air were collected per run, with a delay of 1 min to avoid negative influences of the technician's movement near the air sampler instruments. The agar plates were incubated for 48 hours, after which visible colonies were counted.

Article	Cat. No
MAS 100-Eco® air sampler	**1092270001**
MAS 100-NT® air sampler	**1091910001**
Tryptic Soy Agar + LTHTh – LI	**1.46002**

Table 1: Hardware and consumables used in this study.

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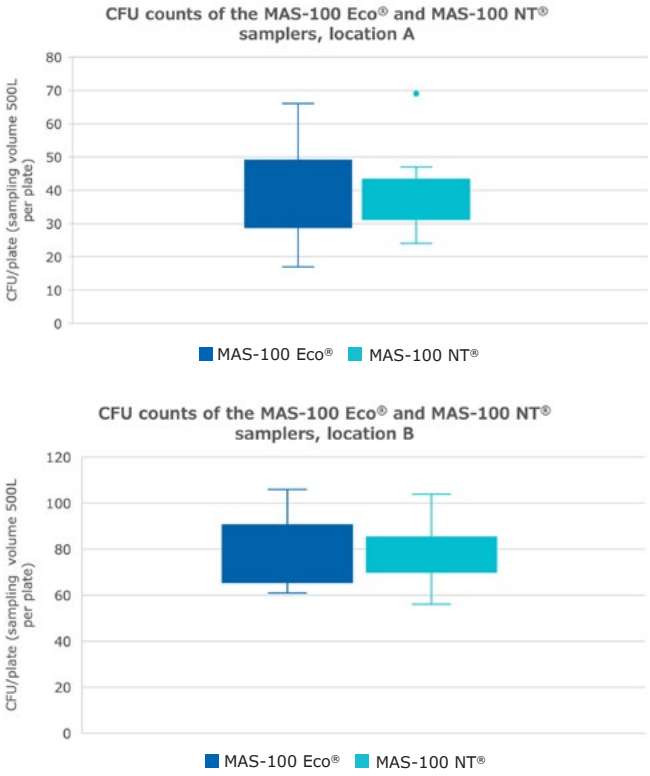
Results

Graphs 1 and 2 illustrate the documented CFU per plate and per location (A and B) including the feller correction calculation. Feller corrections are necessary for impaction air samplers with sieve plates to adjust for the statistical probability of two or more microorganisms entering the same inlet.

Recovery rates are calculated by setting the results of the qualified reference MAS-100 NT® sampler to 100 percent.

For both instruments, the average CFU count was the same for location A (39 CFU; recovery rate 100%). For location B, the recovery rate was 103 percent, with average CFU values of 79 for the MAS-100 Eco® and 76 for the MAS-100 NT® sampler.



Graph 1 and 2: Illustration of CFU per plate of all 10 runs per location of the MAS-100 Eco® and MAS-100 NT® air samplers.

Conclusion

EN 17141 describes an on-site validation method of air samplers whereby the sampler to be validated is compared side-by-side with an already qualified air sampler that has been validated to the more complex biological and physical efficiency method, which is also described in EN 17141. For such side-by-side validations, the acceptance criterion is 100% ± 50% recovery.

The MAS-100 NT® air sampler had been fully validated according to ISO 14698 requirements, which is identical with complex validation method described in EN 17141, at a competent external body. In this study, it was used to confirm EN 17414 requirements via an on-site validation of the MAS-100 Eco® air sampler instrument.

The test trials were performed at two different locations (10 runs per location) in a non-controlled environment, at which recovery rates of 100 % (Location A) and 103% (Location B) were determined.

The MAS-100 Eco® air sampler therefore fulfills the collection efficiency criterion of 100% ± 50% as required by EN 17414.

References

1. EN 17141 (2020): Cleanrooms and associated controlled environments – Biocontamination control.
2. Biological Efficiency Testing of MAS-100 NT® - Techniques described in ISO 14698-1: Report No. 14/013 E (2015) - (PHE Biosafety group in Porton Down)
3. Impact of the new EN 17141 on the ISO 14698 Validation of MAS-100® Air Samplers MK_AN6557EN Ver. 1.0 32802 11/2020

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