

Biotest HYCON Systems

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New Validation of the Compressed Gas Adapter in combination with Agar Strips TC- γ

An initial validation of the RCS Compressed Gas Adapter was performed prior to the product launch in 2005. This test confirmed that the use of the RCS Compressed Gas Adapter with TCI- γ Agar Strips had no significant influence on recovery rate. In order to continually ensure the high quality standards of our products, an additional study was performed under different test conditions.

The study aim and result is that agar strips that are inoculated and exposed to the pressures and potential drying effects of compressed gas have a recovery rate comparable to agar strips that have not been exposed to compressed gas.

Test procedure:

In a variation to the first validation (see HYCON Newsletter No. 59, July 2005) fresh instead of pre-dried agar strips were used in the current testing.

The agar strips were first inoculated with microorganisms and then treated with compressed gas to demonstrate that the use of the Compressed Gas Adapter doesn't lead to dry out of the microorganisms collected at the beginning of an air sampling procedure. Agar strips of an identical lot were inoculated with 10-100 CFU of different test strains (in the 2005 validation the strains were collected on the agar strips by active air sampling after pre-drying by collection of 1000 L of sterile compressed air).



Next, one set of the agar strips was exposed to 1000 L of sterile compressed gas collected by the RCS High Flow with attached Compressed Gas Adapter, while a second set was directly incubated after half an hour. The agar strips not exposed to compressed gas were the reference strips.

A manometer operated in parallel with the RCS High Flow was used during the complete sampling time to verify a constant pressure. To make sure that the agar strips were not contaminated by potential microorganisms in the compressed gas, the microbial concentration of the gas was analyzed. For this test 1000 L of the same compressed gas was collected over fresh agar strips at the beginning, the middle and the end of the air sampling. The values were < 5cfu / 1000 L and comply with the acceptance criteria of the test protocol.

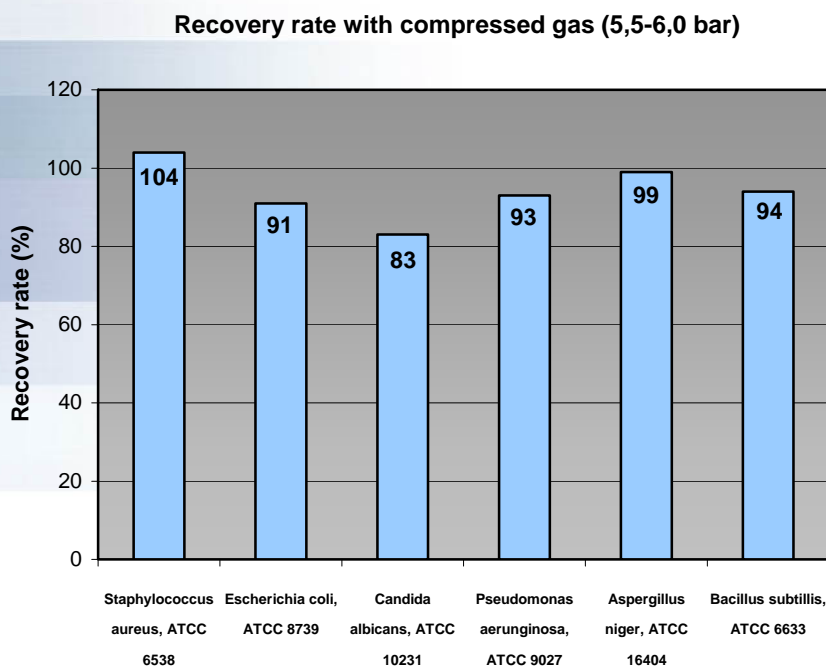
Test Strains

Staphylococcus aureus, ATCC 6538
Escherichia coli, ATCC 8739
Candida albicans, ATCC 10231
Pseudomonas aeruginosa, ATCC 9027
Aspergillus niger, ATCC 16404
Bacillus subtilis, ATCC 6633

The recovery rate of the TC- γ Agar Strips under test must be 50% to 150% as prescribed by the test protocol.

Test results:

The following graph shows the results in recovery rate of the agar strips exposed to compressed gas as compared to the reference agar strips:



Interpretation of the test results:

The measured recovery rates are between 83% and 104%, which means they are within the allowable range. These values are comparable with the recovery rates of the validation in 2005.

The results show that even microorganisms that are collected at the beginning of the sampling with the Compressed Gas Adapter will grow and be detected. The dehydration of the agar strips during sampling of compressed gas is in a range that has no demonstrable significant effect on the results of microbial air sampling.



Biotest RCS Compressed Gas Adapter
(Art. Nr. 940 720)
in combination with an RCS High Flow Microbial Air Sampler used for examination of microbiological quality of compressed gases