



## Mold and Bacteria Testing Overview

TRI Air Testing, Inc. (TRI) offers a test for mold and bacteria in compressed air but it is not appropriate for all compressed air system end uses. The TRI mold and bacteria compressed air sampling and analytical testing procedures should be evaluated by a competent technical individual to determine if it is appropriate for your use to protect the safety of the employees and the integrity of the products being processed. TRI does not make recommendations or evaluate the appropriateness of the mold and bacteria test in meeting good manufacturing practices, cGMP.

We are providing the below description of the TRI mold and bacteria testing method to help you evaluate whether the test will meet your operation's cGMP needs.

- 1) The collection method used is a filter sample material of a polyvinylidene fluoride 0.22 micron pore size membrane. This filter does not contain growth nutrients. Mold or bacteria that require specific environmental conditions such as controlled temperature, humidity or nutrients may not stay viable until being cultured days after sample collection at the analytical laboratory.
- 2) TRI uses a contract analytical laboratory to perform the analysis. This lab is accredited by the American Industrial Hygiene Association (AIHA) to perform microbiological testing.
- 3) There is a negative control blank, from the same lot of prepared filter media that is processed by the analytical laboratory.
- 4) There is no positive control blank used in the test processes.
- 5) The analytical process dilutes the material collected in a 50 to 1 dilution factor. The detection limit of the blank control is 50 colony forming units (CFU). This means that if no colonies are found on the culture media the results are reported as <50 CFU.
- 6) Typically one cubic meter (M<sup>3</sup>) of air is passed through the test filter per instructions provided for sampling by TRI. This air volume along with the dilution factor results in a reporting limit of < 50 CFU/ M<sup>3</sup> if no CFUs are growing on the culture plates.
- 7) The culture media used for mold is 2% malt extract agar(MEA) and for bacteria is tryptic soy agar (TSA).
- 8) Lab test descriptions: Fungi-Genus identification and enumeration of culturable filamentous fungi; individual enumeration of yeast, speciation of prominent *Aspergillus*, *Cladosporium*, and *Stachybotrys*. Bacteria-Genus identification and enumeration of predominate three culturable bacteria (excluding *Legionella*); individual enumeration of yeast.
- 9) Normally test results are available in 14 to 21 days.

If you have further technical questions about our testing methodology please contact me directly.

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