

Alexeter IAQ-Pro *Stachybotrys* Test™ Specifications

Description and Intended Use:

The *Guardian Reader™*, *Defender TSR™* and *BioCapture 650™* are all designed to accept all Alexeter IAQ-Pro *Stachybotrys* test strips. Alexeter IAQ-Pro test strips are intended to screen environmental samples for molds. A positive test result indicates the presence of the antigen at or above the detectable concentration (threshold), which is also listed below. THESE TESTS ARE NOT INTENDED FOR MEDICAL OR DIAGNOSTIC USE.

Principles of Operation:

The Alexeter IAQ-Pro *Stachybotrys* test strip is a lateral-flow immunochromatographic device that uses two antibodies in combination to specifically detect the antigen in solution. One of the specific antibodies is labeled with a colloidal gold derivative. When sufficient antigen is present, the colloidal gold label provides a reddish-brown colored line that is visualized after accumulating in the test sample region on the device.

When a sample is added to the Alexeter IAQ-Pro *Stachybotrys* test strip, the sample begins to mix with the colloidal gold-labeled antibody and simultaneously moves along the strip membrane by capillary action. In the sample region of the test strip, if the antigen is present, the second specific antibody captures the colloidal gold-labeled antibody and bound antigen, forming a colored line or band in the sample (left side) window of the test strip. As an internal control, a second band visualized in the control (right side) window of the test strip is an indication that the test strip functioned properly. Two bands or colored lines are required for a positive result determination.

Storage:

All Alexeter IAQ-Pro *Stachybotrys* test strips should be stored at room temperature (15°-30°C).

Shelf Life:

All Alexeter IAQ-Pro *Stachybotrys* test strips can be used confidently until the expiration date printed on each foil package.

Sensitivity:

Alexeter IAQ-Pro *Stachybotrys* test strips display varying sensitivity levels to different *Stachybotrys* species types. Note that due to the unpredictable nature of environmental preparations, actual test sensitivity can vary for a given sample. In general, The IAQ-Pro *Stachybotrys* test is sensitive to mold species listed at or above 1x10⁵ mold spores per milliliter of sample. Since the test reacts against many different mold species, a positive result may be an indication that the aggregate number of spores of different types exceeds the sensitivity level for the test. This test does not differentiate between the various species listed.

Specificity:

The Alexeter IAQ-Pro *Stachybotrys* test strips have been tested against other mold species, toxic substances and potential environmental interferants.

The Alexeter IAQ-Pro™ *Stachybotrys* test strip has been shown to detect the following spore species:

Stachybotrys

chartarum
echinata

Examples of typical results of the IAQ-Pro *Stachybotrys* as read in the Guardian Reader follows. Threshold Sample Values (SV) for a positive result can vary with each batch but typically is set between 0.10 and 0.014.

Species	Conc. (spores/ml)	Reader Sample Value (SV)
<i>S. chartarum</i>	10 ⁶	0.1045
"	10 ⁵	0.0146
"	10 ⁴	0.0036
"	10 ³	0.0026
<i>S. echinata</i>	10 ⁶	0.1063
"	10 ⁵	0.0147
"	10 ⁴	0.0012
"	10 ³	0.0009

The Alexeter IAQ-Pro™ *Asp/Pen* test strip has been shown NOT to detect the following mold species:

<i>A. fumigatus</i>	<i>P. brevicompactum</i>
<i>A. niger</i>	<i>C. Cladosporioides</i>

Alexeter IAQ-Pro *Stachybotrys* test strips are manufactured and distributed by Alexeter Technologies, LLC, Wheeling, IL

NOTE: As with all screening tests, results from the any Alexeter IAQ-Pro *Stachybotrys* test strip should be confirmed by a qualified reference laboratory.