

Alexeter IAQ-Pro Asp/Pen Test™ Specifications

Description and Intended Use:

The *Guardian Reader™*, *Defender TSR™* and *BioCapture 650™* are all designed to accept all Alexeter IAQ-Pro Asp/Pen test strips. Alexeter IAQ-Pro Asp/Pen 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 Asp/Pen 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 Asp/Pen 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 Asp/Pen test strips should be stored at room temperature (15°-30°C).

Shelf Life:

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

Sensitivity:

Alexeter IAQ-Pro Asp/Pen test strips display varying sensitivity levels to different mold 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 Asp/Pen test is sensitive to mold species listed in the range of 1×10^5 mold spores per milliliter of sample. Since the test reacts against many different mold spore types, 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 mold types listed.

Specificity:

The Alexeter IAQ-Pro Asp/Pen test strips have been tested against other numerous mold species, toxic substances and potential environmental interferants.

The Alexeter IAQ-Pro™ Asp/Pen test strip has been shown to detect the following species:

Aspergillus

<i>candidus,</i>	<i>penicilloides</i>
<i>flavipes,</i>	<i>restrictus,</i>
<i>flavus,</i>	<i>sclerotiorum,</i>
<i>fumigatus,</i>	<i>sydowii,</i>
<i>nidulans,</i>	<i>terreus,</i>
<i>niger,</i>	<i>ungus,</i>
<i>ochraceus,</i>	<i>versicolor,</i>

Neosartorya

fisheri,

Paecilomyces

marquandii,
variotii,
viridis,

Penicillium

<i>aurantogriseum,</i>	<i>glabrum,</i>
<i>brevicompactum</i>	<i>marquandii,</i>
<i>chyrosegenum,</i>	<i>roqueforti,</i>
<i>citrinum,</i>	<i>spinulosum,</i>
<i>corylophilum,</i>	<i>variotii,</i>
<i>expansum,</i>	<i>viridis</i>

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

<i>Alternaria alternata,</i>	<i>P. pupurogenum,</i>
<i>Epicoccum nigrum</i>	<i>P. variabile,</i>
<i>C. Cladosporioides I, II,</i>	<i>Scopularis brevicaulis</i>
<i>C. herbarum,</i>	<i>Mucor A,</i>
<i>C. sphaerospermum,</i>	<i>Mucor plumbeus</i>

Alexeter IAQ-Pro Asp/Pen 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 Asp/Pen test strip should be confirmed by a qualified reference laboratory.