

Alexeter IAQ-Pro Asp/Pen® Test
 Expanded Data Results

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).

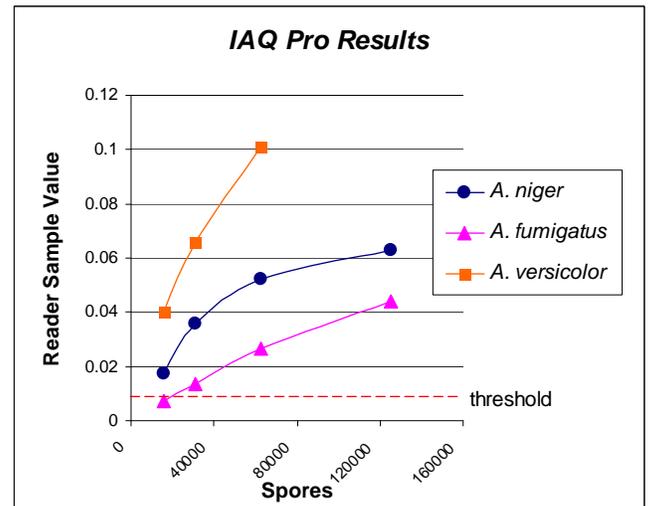
Shelf Life:

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 1x10⁵ 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.

The data below represent a reader results obtained for a series of dilutions for the fungal species indicated. Spores were grown on appropriate growth plates and spore fractions prepared according to *Haugland, et al. (2004)*¹.



Specificity:

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

Spore Fraction Specificity

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>fumigatus,</i> | <i>sclerotiorum,</i> |
| <i>nidulans,</i> | <i>sydowii,</i> |
| <i>niger</i> | <i>terreus,</i> |
| <i>ochraceus</i> | <i>unguis,</i> |
| | <i>versicolor</i> |

Chaetomium

- globusum*

Neosartorya

- fisheri,*

Paecilomyces

- | | |
|--------------------|------------------|
| <i>Marquandii,</i> | <i>variotii,</i> |
| <i>viridis</i> | |

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>crustosum,</i> | <i>viridis</i> |
| <i>expansum,</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>

Examples of Reader Values

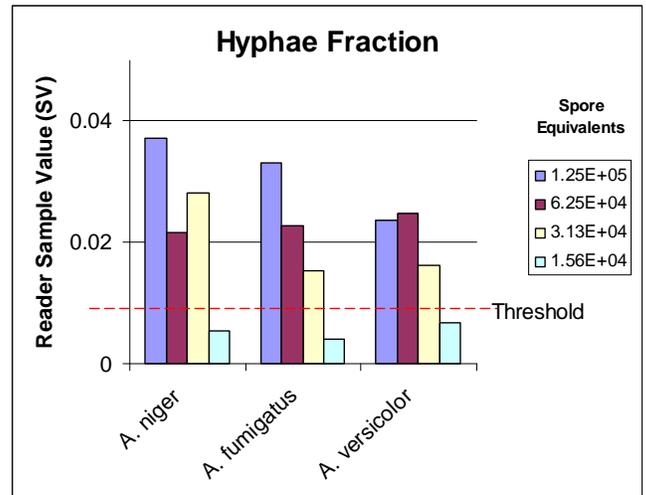
Sample Value (SV) reader results on various fungal preparations. Positive readings are obtained when SV values exceed a threshold level of 0.01 relative units.

Fungal Species	Sample Values
<i>Aspergillus flavus</i>	0.1653
<i>Aspergillus fumigatus</i>	0.1564
<i>Aspergillus niger</i>	0.3532
<i>Aspergillus ochraceus</i>	0.3953
<i>Aspergillus penicillioides</i>	0.2911
<i>Aspergillus sclerotium</i>	0.1797
<i>Aspergillus sydowii</i>	0.2967
<i>Aspergillus unguis</i>	0.2165
<i>Aspergillus ustus</i>	0.1791
<i>Aspergillus versicolor</i>	0.3722
<i>Chaetomium globosum</i>	0.2353
<i>Clad. cladosporoides type I</i>	0.0052
<i>Clad. cladosporoides type II</i>	0.002
<i>Clad. sphaerospermum</i>	0.0053
<i>Eurotium group</i>	0.0933
<i>Paecilomyces variotii</i>	0.1871
<i>Penicillium corylophilum</i>	0.3642
<i>Penicillium crustosum</i>	0.3089
<i>Penicillium purpurogenum</i>	0.0057
<i>Penicillium spinulosum</i>	0.1752
<i>Penicillium variable</i>	0.0051
<i>Scopulariopsis brevicaulis</i>	0.0031

Fungal Fraction Specificity

The Alexeter *IAQ Pro®* test recognizes both spore and conidia fractions prepared under standard conditions. Below, the indicated fungi fractions were prepared and collected as previously described¹. The hyphae (liquid supernatant) fraction from standard spore preparations

were diluted from the indicated spore equivalent fractions and tested on the *IAQ Pro* test. After 15 minutes, tests were analyzed in the Guardian reader. Sample Value (SV) results are shown for three different fungal hyphae at four different concentrations. Positive threshold is indicated at 0.01 SV.



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.

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 Test Specs 032008.

¹ Haugland RA, Varma M, Wymer LJ, and Vesper SJ, System. Appl. Microbiol. 27, 198 (2004).

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