

Positive Results

The test is positive if two colored lines appear: one colored line in the Sample Window (nearest the sample port) and one in the Control Window (away from the sample port) of the test strip (see Fig. 3). Evaluation in a Guardian Reader System™ or the Defender TSR System™, is strongly recommended.

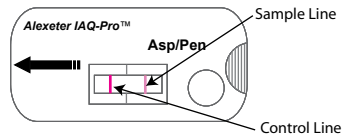


Figure 3: Positive Test Result
Control and Sample Line Present

Caution: If you are reading the test strip visually, the Sample Line may appear to be very lightly colored, considerably less intense than the Control Line. Any visible line in the Sample Window indicates a positive result.

Invalid Results

If the sample fails to run completely across the test strip, the result is invalid. The test is invalid if no colored line appears in the Control Window (away from sample port), even if a colored line appears in the Sample Window (nearest the sample port). See Fig. 4 and 5:

LIMITATIONS OF THE PROCEDURE

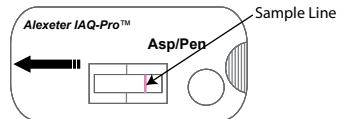


Figure 5: Invalid Result,
Sample Line Only

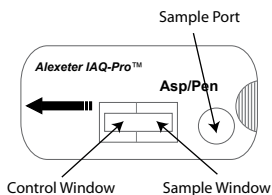


Figure 4: Invalid Result, no Control Line
and no Sample Line

Negative results may occur when levels of specific antigens (mold) are below the detectable concentration level (sensitivity) of the test.

Positive results can be obtained in the absence of the target antigens (mold) if cross-reacting substances are present.

Also note that some materials, specifically chemicals which cause significant pH changes, acid or alkaline, may yield positive results. Detergent powders and drain cleaners are examples.

IAQ Pro pH Test Strips are available separately from Alexeter (Catalog # IAQ-3100).

This test provides a presumptive result for the presence or absence of *Aspergillus* and/or *Penicillium* molds.

A certified laboratory must confirm all results before a definitive determination is made.
IAQ2000v3-071108



IAQ-Pro® Rapid Field Tests Aspergillus/Penicillium

Catalog Number: IAQ-2000

FOR THE RAPID QUALITATIVE
IDENTIFICATION OF
Aspergillus and *Penicillium* Molds

Features

- Radio Frequency Identification (RFID) technology built-in
- One step test with built-in quality control check
- Read results in 15 minutes
- Greater than 99% accuracy
- Room Temperature Storage

For Environmental Testing Only!!!
NOT FOR DIAGNOSTIC USE

Store at 40°F to 86°F (15° to 30°C)

For technical assistance, call toll-free:

877-591-5571

AS WITH ALL SCREENING DEVICES,
RESULTS MUST BE CONFIRMED BY A
CERTIFIED LABORATORY BEFORE ANY
OFFICIAL DETERMINATION IS MADE

A Product of:
Alexeter Technologies, LLC
830 Seton Court, Ste. 6
Wheeling, IL 60090 USA

www.alexeter.com

**Please read all instructions before
using these tests.**

™ Guardian Reader, Defender TSR, and IAQ-Pro are trademarks of Alexeter Technologies, LLC.

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AVAILABLE ACCESSORIES

IAQ-Pro™ Sample Collection Kit IAQ Pro Speciation Pack IAQ Pro pH Test Kit

INTENDED USE

Alexeter's IAQ-Pro™ Asp/Pen Test strip is a hand-held lateral flow immunoassay device for the identification of *Aspergillus* and *Penicillium* mold species (antigens). It is intended for use in the field for performing rapid screening of potential mold-containing samples collected from the environment. The Alexeter IAQ-Pro™ Test strip is NOT a diagnostic device.

SUMMARY AND EXPLANATION

The Alexeter IAQ-Pro™ Test strip employs unique antibodies for the preliminary identification of *Aspergillus* and *Penicillium* mold species. These same proven methods have

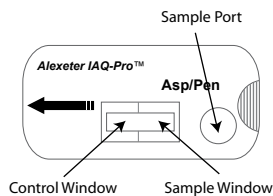


Figure 1: Alexeter IAQ-Pro™ Test Strip

been employed for several decades in the medical diagnostic's industry.

After an unknown material is dispersed in IAQ-Pro™ Sample Buffer and applied to the Asp/Pen test strip, reactive components bind to specific agents present to form colored lines on the test strip. The presence of a single colored line in the Control Window (see Fig. 2) of the test strip indicates a negative result. The presence of a second colored line in the Sample Window of the test strip indicates a positive result (see Fig. 3). A control line always forms in the Control Window of the test strip to indicate the test has run properly.

PRINCIPLE OF THE TEST

The Alexeter IAQ-Pro™ Test strip is a lateral-flow immunochromatographic device that uses antibodies in combination to specifically detect the antigen (in this case, *Aspergillus* and/or *Penicillium*) in solution. Antigen-specific antibodies are labeled with a colloidal gold derivative.

When a sample is added to the Sample Port of the Alexeter IAQ-Pro™ Asp/Pen Test strip, (see Fig. 1) the sample mixes with the colloidal gold-labeled antibodies and then moves along the strip membrane via capillary action. In the Sample Window of the test strip, if the antigen is present, a second antigen-specific antibody captures the colloidal gold-labeled antibody and bound antigen, forming a colored line in the Sample Window, nearest the sample port. This is the sample line. As an assay control, a second line must always form in the Control Window. This control line is an indication that the test strip functioned properly. The test is invalid if the control line does not appear. Two colored lines are required for a positive result determination. Note that the sample line may not always be visible to the naked eye and that evaluation using a *Guardian Reader™* or *Defender TSR™* is strongly recommended.

The Alexeter IAQ-Pro™ Asp/Pen Test strip can detect the following species:

***Aspergillus* species:** *candidus*, *flavipes*, *flavus*, *fumigatus*, *nidulans*, *niger*, *ochraceus*, *penicilloides*, *restrictus*, *sclerotiorum*, *sydowii*, *terreus*, *ungus*, *versicolor*.

***Neosartorya* species:** *fisheri*.

***Paecilomyces* species:** *marquandii*, *variottii*, *viridis*.

***Penicillium* species:** *aurantogriseum*, *brevicompactum*, *chyrosegenum*, *citrinum*, *corylophilum*, *expansum*, *glabrum*, *marquandii*, *roquefortii*, *spinulosum*, *variottii*, *viridis*.

PRECAUTIONS

1. Prepare all samples using the IAQ-Pro™ Sample Buffer. Alexeter's IAQ-Pro™ Test strips are intended to be used only with the buffer solutions provided in the Alexeter Collection Swab or in the IAQ Pro Sample Collection Kit.
2. Sample pH extremes may interfere with the performance of the test kit. Sample pH

should be in the range of 4 to 10.

3. This device is for environmental use only.
4. The test device should be discarded in a proper container after testing.
5. The test device should not be used beyond the expiration date on the foil package.
6. The test device should remain in the sealed pouch until ready for use. Do not use if pouch is torn or punctured.
7. Evaluate the test strip after 15 minutes of elapsed time and no longer than 30 minutes of elapsed time.

STORAGE AND STABILITY

The test kit is to be stored at room temperature 40°F to 86°F (15° to 30°C) for the duration of its shelf life. The test device must remain sealed in the pouch until ready for use.

ALEXETER IAQ-Pro™ Asp/Pen TESTING PROCEDURE

Swab Samples

1. When ready to sample, grasp the Alexeter Collection Swab in both hands and gently separate the liquid-filled bulb end from the swab sleeve, exposing the polyester swab.
2. **Mold colonies:** If the sample is an obvious mold colony, gently swab the suspect area until mold is visible on the swab tip. Be sure to sample a representative area of at least several square centimeters.
3. **Dust, particulates, and areas of suspected contamination not readily visible:** Gently swab the area until material is visible on the swab tip. Be sure to sample a representative area of at least several square centimeters.
4. After collection, firmly insert the swab back into the swab sleeve.
5. Use an indelible marker to label the Alexeter Collection Swab with the sample location, i.e., basement west, etc.

Preparing the Sample

1. After collecting your sample(s), you are ready to begin testing.
2. Ensure that the swab is firmly inserted into the sleeve.
3. Bend the liquid-filled bulb until the blue extension snaps, releasing the rinse buffer onto the swab tip in the sleeve.
4. Shake the Alexeter Collection Swab for 10 seconds to enhance the rinsing process.
5. Add the sample to the test strip using the directions below:

Running the Test

1. Open the foil pouch of an Alexeter IAQ Pro Asp/Pen test strip and place it on a flat, level surface.
2. Twist off the white cap the bottom of the Alexeter Collection Swab.
3. Add the sample to the IAQ Pro ASP/Pen test strip by gently squeezing the sides of the swab sleeve, placing 5 drops into the sample port of the test strip.
4. Record the time when the sample was added, preferably by writing it on the test strip.
5. Evaluate the test strip after 15 minutes have elapsed, using The Guardian Reader System™ or the Defender TSR System™. See the relevant Operating Manual for instructions.

INTERPRETATION OF RESULTS

Alexeter's IAQ-Pro™ Asp/Pen test strips provide accurate, presumptive results in 15 minutes.

Visually inspect your test strip after 15 minutes have elapsed. One or two colored lines should be present.

Negative Results

The test is presumed to be negative when a single colored line appears in the Control Window (see Fig. 2). A negative result (antigen not detected) is obtained when the antigen is either not present, or is present below detectable limits. The visual appearance of one (control) line may still be a positive result as the sample line can be very faint. Evaluation in a *Guardian Reader System™* or the *Defender TSR System™*, is strongly recommended.

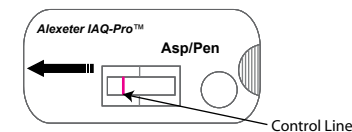


Figure 2: Negative Test Result
Control Line Only