

or other similar items, lay out a 3 foot by 6 foot sampling area.

3. Attach the Dust Sample Collector to the vacuum. Be sure the front and rear caps are removed, keep them in a safe place, as you will need them for shipment of the sample.
4. Turn on the vacuum and collect a dust sample from the area identified in step 2, for a total of 5 minutes.
5. After 5 minutes, turn off the vacuum.
6. Remove the Dust Sample Collector from the vacuum and place both the front and rear caps on, to contain the dust sample.
7. To submit samples for qPCR analysis, place the Dust Sample Collector in the qPCR FedEx mailer, along with the completed Chain of Custody Form, and send via FedEx for confirmatory testing.

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

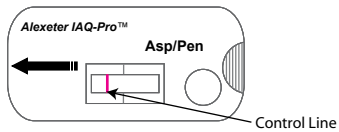


Figure 2: Negative Test Result
Control Line Only

Window. 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

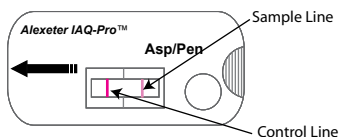


Figure 3: Positive Test Result
Control and Sample Line Present

sample line can be very faint. Evaluation in a Guardian Reader™ or the Defender TSR™, is strongly recommended.

Positive Result

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. Evaluation in a Guardian Reader™ or the Defender TSR™, is strongly recom-

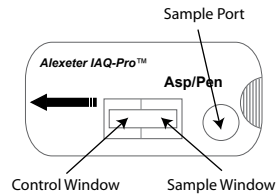


Figure 4: Invalid Result, no Control Line
and no Sample Line

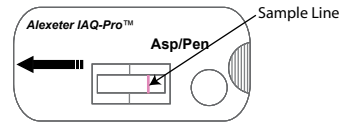


Figure 5: Invalid Result,
Sample Line Only

mended .

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).

LIMITATIONS OF THE PROCEDURE

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. If possible, a portion of the area not visibly contaminated with mold should be tested as a "negative control".

Alexeter's IAQ Pro Sample Collection Kit contains materials for pH testing, collecting additional samples and full instructions for use.

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.

IAQ1000v3-081908



IAQ-Pro® Mold Speciation Pack Aspergillus/Penicillium

Catalog Number: IAQ-1000

FOR THE RAPID QUALITATIVE AND
QUANTITATIVE IDENTIFICATION OF
Aspergillus and Penicillium Molds

INCLUDES QUANTITATIVE PCR
ANALYSIS VIA ENCLOSED MAILER

Features

- Radio Frequency Identification (RFID) technology built-in
 - One step test with built-in quality control check
- Read initial results in 15 minutes
 - 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

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.

CONTENTS

- 4 IAQ-Pro™ Asp/Pen Test strips
- 4 Alexeter Collection Swabs
- 1 Dust sample collector
- 1 Instructions for Use
- 1 Prepaid qPCR Mailer
- 1 Chain of Custody form

AVAILABLE ACCESSORIES

Alexeter's IAQ-Pro™ Sample Collection Kit: (contains pH test kit and additional collection materials)

ADDITIONAL EQUIPMENT AND MATERIALS REQUIRED

**Canister vacuum
Measuring Device (e.g. tape measure)**

**Timer
Masking Tape**

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.

The Alexeter IAQ-Pro™ Asp/Pen Mold Speciation Pack enables the user to test 4 samples on-site and submit one sample for qPCR confirmatory testing. Therefore, after performing the field tests you should re-sample an area which gave you positive results using the vacuum method for qPCR (ERMI) analysis. See the procedure below: "Dust (Vacuum) Samples".

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 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,

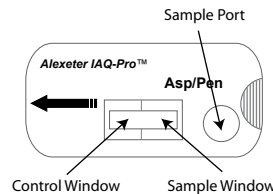


Figure 1: Alexeter IAQ-Pro™ Test Strip

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, unguis, versicolor.*

Neosartorya species: *fisheri.*

Paecilomyces species: *marquandii, variotii, viridis.*

Penicillium species: *aurantogriseum, brevicompactum, chyrosegenum, citrinum, corylophilum, expansum, glabrum, marquandii, roqueforti, spinulosum, variotii, 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 test kit.
2. Sample pH extremes may interfere with the performance of the test kit. Sample pH should be in the range of 6 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 printed 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 sus-**

pected 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.

Dust (Vacuum) Samples

ERMI Dust Sample Collection

Procedure: The following procedure follows the ERMI guidelines published by the US EPA. Note that local conditions may allow for a significantly smaller sampling area and sampling time so as not to clog the Dust Sample Collector.

1. Identify the area where sample is to be collected.
2. Using a tape measure and masking tape