Alternately, test strips can be interpreted using the AbraScan test strip reader (PN 475025B) or with the RapidScan test strip reader (PN 475035 with strip cassette 475032)., which provides objective determination of line intensities for consistent interpretation of results as well as a digital photographic record of all test strips,

Importance of Patulin Determination

Patulin [4-hydroxy-4H-furo[3.2c]pyran-2(6H)-one] is a toxic polyketide lactone metabolite produced mainly by numerous *Penicillium*, *Aspergillus*, and *Byssochlamys* fungal species. Although it can occur in infected fruits, grains, and other foods, the main route of patulin exposure is ingesting infected apples and some of its derivatives, such as juices and compotes. The Joint FAO/WHO (Food and Agriculture Organization of the United Nations/World Health Organization) Committee of Experts on Food Additives (JECFA) established in 1995 a provisional maximum tolerable daily intake (PMTDI) for patulin of 0.4 µg/kg (ppb) of body weight/day. Based on this recommendation, the European Union has established maximum allowed patulin levels of 50 µg/kg (ppb) for juices, 25 µg/kg (ppb) for solid apples, and 10 µg/kg (ppb) for foodstuffs for children's consumption.

Performance Data

Test sensitivity: The ABRAXIS® Patulin Strip Test will detect Patulin in 1X Sample Diluent from 0.08 ppb to 0.90 ppb. At this level, the test line exhibits moderate intensity. At levels greater than 0.90 ppb, the test line is very faint or invisible.

Additional Analysis

Positive samples can be confirmed by ELISA, HPLC, or other conventional methods if necessary.

The monoclonal antibody and test line Patulin conjugate included in the ABRAXIS® Patulin Strip test have a patent license agreement (Patent Application WO 2021/165557 A1) with Agencia Estatal Consejo Superior de Investigaciones Científicas (CSIC) and Universitat de Valencia, Estudi General (UVEG).

References

F. Rubio, T. Glaze, and G. Yearwood, ELISA test kit for the quantitation of Patulin in juices, cider and purees. Affidia -The Journal of Food Diagnostics. Vol 3, N 2, 2021, 68-75.

General Limited Warranty: Gold Standard Diagnostics warrants the products manufactured by the Company, against defects and workmanship when used in accordance with the applicable instructions for a period not to extend beyond the product's printed expiration date. **Gold Standard Diagnostics makes no other warranty, expressed or implied. There is no warranty of merchantability or fitness for a particular purpose.**

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Version: 03

ABRAXIS® Patulin Strip Test

Immunochromatographic Strip Test for the Detection of Patulin in Food Samples

Product No. 500130 (5 Test), 500135 (20 Test)

1. General Description

The ABRAXIS® Patulin Strip Test is a rapid immunochromatographic test designed solely for use in the qualitative screening of Patulin in food samples. A sample extraction is necessary for food samples such as applesauce, apple juice/cider, pear puree, and pear juice. Please see the Gold Standard Diagnostics website for the appropriate technical bulletin and/or matrix validation guidelines for these and other matrices of interest. The ABRAXIS® Patulin Strip Test provides only preliminary qualitative test results. Positive samples can be confirmed by ELISA, HPLC, or other conventional methods if necessary.

2. Safety Instructions

Consult state, local, and federal regulations for properly disposing of all reagents. All samples and reagents used in this test are not for consumption. Please do not eat or drink samples used in preparation, testing, or after contact with any reagents. 10X Sample Diluent contains 0.05% sodium azide as a preservative. Sodium azide may react with lead or copper plumbing to produce metal azides which might cause explosion. To prevent azide accumulation in plumbing, flush with copious amounts of water immediately after disposal.

3. Storage and Stability

The ABRAXIS® Patulin Strip Kit should be stored between 2-30°C. The test strips, vials, assay buffer, and samples to be analyzed should be at room temperature before use. Reagents may be used until the last day of the month as indicated by the expiration date on the box.

4. Test Principle

The test is based on the recognition of Patulin by specific antibodies. The sample to be tested is derivatized and then added to the conical test vial containing specific antibodies for Patulin labeled with colloidal gold. The Patulin conjugate on the membrane strip competes for antibody binding sites with the Patulin that may be present in the sample. A control line, produced by a different antibody/antigen reaction, is also present on the membrane strip. The control line is not influenced by the presence or absence of Patulin in the sample and, therefore, should be present in all reactions.

In the absence of Patulin in the sample, the colloidal gold-labeled antibody complex moves with the sample by capillary action to react with the immobilized Patulin conjugate. An antibody-antigen reaction forms a visible line in the 'test' area. The formation of two visible lines of similar intensity indicates a negative test result, meaning the test did not detect Patulin at or below the established cut-off point for the test. If Patulin is present in the sample, it competes with the immobilized Patulin conjugate in the test area for the antibody binding sites on the colloidal gold labeled complex. If a sufficient amount of Patulin is present, it will fill all of the available binding sites, thus preventing attachment of the labeled antibody to the Patulin conjugate, therefore preventing the development of a colored line. If a colored line is not visible in the test line region, or if the test line is lighter than the control line, Patulin is present at a detectable level (>0.08 µg/L (ppb) in buffer). Semi-quantitative results can be obtained by comparing the sample test strip appearance to the appearance of test strips from solutions of known Patulin concentrations (control/solutions).

5. Limitations of the ABRAXIS® Patulin Strip Test, Possible Test Interference

Numerous organic and inorganic compounds commonly found in samples have been tested and found not to interfere with this test. However, due to the high variability of compounds that might be found in samples, test interferences caused by matrix effects cannot be excluded entirely.

Mistakes in handling the test can also cause errors. Possible sources for such errors include inadequate storage conditions of the test strip, too long or too short incubation times, and extreme temperatures during the test performance (lower than 10°C or higher than 30°C).

This test is designed to be used with food samples. The ABRAXIS® Patulin Strip Test provides only a preliminary qualitative test result. To obtain a confirmed quantitative analytical result, use another, more quantitative analytical method, such as ELISA or instrumental analysis. Apply good judgment to any test result, particularly when preliminary positive results are observed.

6. Warnings and Precautions

The ABRAXIS® Patulin Strip Test is used to screen food samples (see Section D, Sample Collection and Handling). The test strips, vials, and samples should be allowed to reach room temperature before testing.

Before use, ensure that the product has not expired by verifying that the date of use is before the expiration date on the label. Test strips and conical test vials should be sealed in their original packaging with desiccant when not used. Exposure to humidity during storage may adversely impact their performance and give inaccurate results. After initial use in high humidity conditions, remaining kit components should be tightly closed with desiccant and refrigerated (2–8 °C) when unused. Conical test vials stored with indicating desiccant that has turned from blue to pink (indicating excessive exposure to moisture) should not be used for testing and should be discarded. Avoid cross-contamination of samples by using a new sample vial and disposable pipette for each sample. Use only the test strips, derivatization vials, and conical vials from one kit lot (do not mix with other lots), as they have been adjusted in combination. Use reasonable judgment when interpreting the test results.

- Results should be interpreted within 5-10 minutes after test completion.
- **Note**: Take precaution when retrieving strip from sealed bag to avoid twisting/bending the strip. This may damage the conjugate pad - membrane overlay and strip may not wick properly. The sample wicking and migration along the membrane is important to achieve strip's performance. Contact Technical Support for assistance.

Working Instructions

A. Reagents and Materials Provided

1. Patulin test strips in a desiccated sealed bag
2. Derivatization vials (dried)
3. Conical test vials (dried)
4. Exact Volume pipettes
5. Disposable graduated pipettes
6. 10X Sample Diluent (30 mL)
7. User's guide, flow chart, Interpretation guide, warranty
8. Tube holder

B. Additional Materials (not provided with the test kit)

1. Timer
2. Marking pen
3. Deionized water (diH_2O)
4. Heat block/tube incubator at 45°C
5. Serological pipettes or graduated cylinder
6. Vortex mixer/shaker and rotator
7. Analytical balance, 2 decimal places (range ± 0.05 grams)
8. Storage vials/bottles for sample collection/preparation
9. Large sized bottles (300 mL sized or larger)
10. Microcentrifuge and 2.0 mL microtubes

C. Test Preparation

1. Allow test strips, vials, and samples to reach room temperature before use.
2. To prepare 1X Sample Diluent, dilute the 10X Sample Diluent at a ratio of 1:10. If using the entire bottle (30 mL), add 270 mL of deionized water to 30 mL of 10X Sample Diluent into a large-sized clean bottle.
3. Remove the required number of conical test vials from the package. The remaining conical test vials are stored in a tightly closed container with desiccant.
4. Samples **must** be derivatized before each analysis (see Section F, Testing of Samples). Failure to derivatize samples will cause inaccurate results.

D. Sample Collection and Handling

Food samples must undergo appropriate sample preparation procedures before analysis to obtain accurate results. **Derivatized samples are only good within 24 hours.**

Apple Cider/Apple Juice/Pear Juice

1. Measure 0.5 mL of sample into a 15 mL plastic centrifuge tube.
2. Add 4.5 mL of 1X Sample Diluent, and vortex thoroughly for 10 seconds.
3. Let the sample settle for >2 minutes.
4. Dilute supernatant 10-fold by adding 400 µL of supernatant to 3600 µL 1X Sample Diluent in vial. Vortex to mix. **Total dilution: 100-fold**

Apple/Pear Puree

1. Weigh 0.5 ± 0.05 grams of sample into a 15 mL plastic centrifuge tube.
2. Add 5.0 mL of 1X Sample Diluent and vortex thoroughly for 10 seconds. Mix using a rotator for 10 minutes.
3. Let the sample settle for >2 minutes.
4. Remove 2 mL of sample to a 2.0 mL microcentrifuge vial. Centrifuge for 5 min at 8,100Xg or 10,000 rpm in microcentrifuge.
5. Dilute supernatant 5-fold by adding 800 µL of supernatant to 3200 µL 1X Sample Diluent in vial. Vortex to mix. **Total dilution: 50-fold**

E. Controls

It is a good laboratory practice to use positive and negative controls to ensure proper test performance. Samples containing known quantities of Patulin (positive controls), and samples known to be free of Patulin (negative controls) should be analyzed with each lot of test strips to provide a reference for line intensities to be expected. Patulin controls (ABRAXIS® Patulin Control, PN 500140) can be purchased from Gold Standard Diagnostics.

F. Testing of Samples

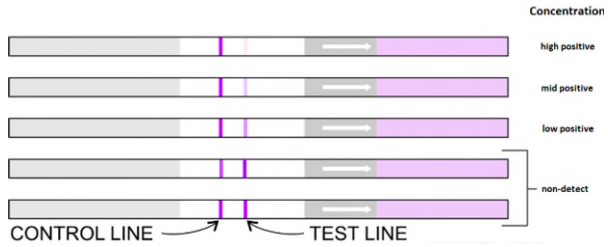
1. Label Derivatization Vials, Conical Test Vials, and disposable pipettes (provided in the kit, to be used for steps 2 and 4) for each test sample.
2. Using the appropriate **disposable graduated pipette** for each sample, draw the sample to the 1.0 mL mark of the pipette and **dispense the entire 1.0 mL** into the labeled Derivatization Vial.
3. Cap the vial and mix well by shaking/vortexing for 30 seconds. **Load the vial into a 45°C heat block and incubate for 45 minutes** to complete the sample derivatization. Remove the vial from the heat block and let the samples cool for at least 10 minutes.
4. Using a **new disposable exact volume transfer pipette** for each sample, **transfer 200 µL** of the derivatized sample to the appropriate labeled conical test vial (see pipette package for usage instructions).
5. Close the conical test vial and shake/vortex for 20-30 seconds. Examine the vial to **ensure all dried reagents are entirely dissolved** (dried reagents will dissolve, turning the sample purple).
6. **Incubate the conical test vial for 10 minutes** at room temperature.
7. **Insert the test strip** (arrows down) into the conical vial.
8. Allow the test to **develop for 10 minutes** at room temperature.
9. At the 10-minute mark, **remove the test strip**. Lay the strip flat and allow it to **continue developing for 10 minutes at room temperature**.
10. **Immediately** read the results as explained below in Section G, Interpretation of Results.

G. Interpretation of Results

Sample concentrations are determined by comparison of the intensity of the test line to the intensity of the control line on the same test strip. Although control line intensity may vary, a visible control line must be present for results to be considered valid. Test strips with a test line that is darker than or of equal intensity to the control line indicate a result that is below the limit of detection of the test. Test strips with a test line that is lighter than the control line indicate a low to moderate concentration result. Test strips with a very faint test line or no test line visible indicate a high concentration result. Please see the appropriate technical bulletin for the actual sample concentration ranges in various matrices. Results should be determined within 5-10 minutes after the strip test procedure is completed. Determination made using strips that have dried for more or less than the required time may be inaccurate, as line intensities may vary with drying time.

Control Line	***Test Line***	***Interpretation***
No control line present	No test line present	Invalid result
Control line present	Very faint or no test line present	High concentration
Control line present	Moderate intensity test line present	Low to moderate concentration

The appearance of test strips may also be compared to the illustration below to determine approximate sample concentration ranges. Please note that the illustration is intended for the demonstration of a test line to control line intensity only. Results should not be determined by comparing the intensity of test lines from test strips to the test line intensity of the illustration, as the overall intensity of test strips may vary slightly with different lots of reagents. To obtain semi-quantitative results, solutions of known Patulin concentration (control solutions) must be tested concurrently with samples. Sample test line intensities can then be compared with control solution test line intensities, yielding approximate sample concentrations. Do not use strips run previously to determine semi-quantitative sample concentrations, as test line intensities may vary once strips are completely dry.



Revision History:

Revision	Description	Date
03	Added note concerning handling of strip to avoid wicking problems	DRAFT
02	Updated component description	05/16/2025
01	Create new document	04/30/2025