

AllergenControl™

m-Gluten Residue Environmental Surface Test

Product Code: PA-E43

Directions For Use

Introduction

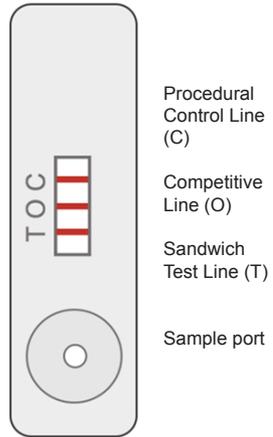
Gluten is a composite protein found in cereal grains such as wheat, barley, and rye. Adverse immune responses to ingested gluten are relatively common and manifest as debilitating symptoms including celiac disease. Accordingly, numerous countries require that foods labeled “gluten-free” certify gluten content as less than 20 ppm (mg/kg). The AllergenControl™ m-Gluten Residue Kit was developed to reliably detect gluten residues on surfaces and equipment down to 0.25 µg protein/swab in ~45 minutes.

Intended Use

This test kit is designed for use in the qualitative determination of gluten residues obtained from sampling surfaces. The test is intended for laboratory use only and should only be performed by trained personnel.

Assay Principle

The AllergenControl™ m-Gluten Residue Lateral Flow Test Kit features monoclonal antibodies directed against gluten proteins configured in both sandwich and competitive format. To operate the kit, the sample is first subjected to a short extraction step. The sample extract is mixed with a buffer then applied to the lateral flow device sample port, where it is allowed to migrate across the reagent zone thus enabling visualization of the Sandwich Test Line (**T**) and Competitive Test Line (**O**) results. In addition, the reagent zone includes a Procedural Control Line (**C**) to minimize the potential for false negative outcomes.



Performance Characteristics

Limit of Detection: 0.25 µg protein/swab

Sample Extraction Time: 20 minutes

Test Operation Time: 15-20 minutes

Cross-Reactivity: Cross-reactivity was not detected in extracts from lima bean, mung bean, pea, lupin, kidney bean, lentil, chick pea, poppy, pumpkin, banana, apple, chicken, sesame, sunflower, peanut, almond, Brazil nut, macadamia, pine nut, walnut, hazelnut, cashew, pistachio, and soy.

Kit Components

m-Gluten Residue Lateral Flow Devices (LFDs) (25)

Reagent E Concentrate (90 mL)

Reagent B (30 mL)

m-Gluten LFD Running Buffer (30 mL)

100 µL Disposable Pipettes (25)

Environmental Swabs (25)

Disposable Extraction Tubes (50)

Also Required (but not supplied)

Vortex

Pipettor and tips (p100 and p1000)

Water bath incubator (70°C)

Timer

Polypropylene tubes appropriate for Reagent EB

Centrifuge

Calibrated Lateral Flow Device or Strip Reader (optional)

190 Proof or 95% Ethanol

Protocol

A. Reagent Preparation

Gluten Extraction Buffer (Reagent EB)

To prepare reagent EB, follow these steps:

1. To each bottle of Reagent E Concentrate (90 mL), add 180 mL of 190 proof or 95% ethanol. Mix gently. Label as “Reagent E” with the kit lot number and kit expiration date, and store at 2-8°C (36-46°F) until ready for sample extraction.
2. Prepare Reagent EB just before sample extraction. Calculate the volume of reagent needed based on the number of samples, i.e. 10 mL per gram solid or per mL liquid sample. Once the volume required has been calculated, add 1 part of Reagent B to 9 parts of Reagent E from step 1.

B. Sample Preparation

Sample Collection

Before starting, ensure that the test components have been brought to room temperature (18-25°C).

1. Select unused swabs and tubes and label accordingly.
2. Add 1 mL of Reagent EB to a Disposable Extraction Tube.
3. Collect surface sample using one of the following methods
 - A. For dry surfaces:** Select a new swab and moisten with ~ 100 µL Reagent EB. Define a 10 x 10 cm² (or 4 x 4 inch²) surface area. Swab the defined surface using a rolling crosshatch technique.
 - B. For wet surfaces:** Select a new swab, do not moisten swab prior to use. Define a 10 x 10 cm² (or 4 x 4 inch²) surface area. Swab the defined surface using a rolling crosshatch technique.

Sample Extraction

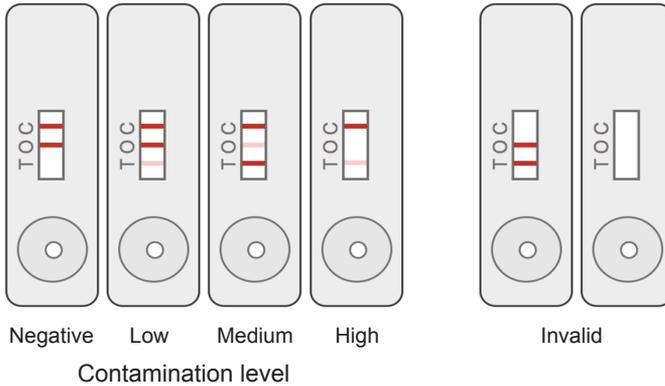
1. Place the swab tip in the Disposable Extraction Tube with 1mL of Reagent EB from Sample Collection step 2 and snap off the stick portion of the swab so that the tip remains in the tube.
2. Cap and close the tube and vortex for 15 seconds.
3. Extract for 20 minutes at 70°C using a hot water bath with periodic shaking for 1 min every 5 minutes.
4. Allow the extract to cool on ice for 3 - 5 minutes.
5. Centrifuge at 2,000 x g for 10 minutes.

C. Operating the LFD

1. Prior to starting, ensure that the test components (running buffers, sample extracts, LFDs) are at room temperature.
2. Unwrap the LFD and place on a clean, flat surface.
3. In a Disposable Extraction Tube, mix 100 μ L of the aqueous portion of the sample extract with 900 μ L of m-Gluten LFD running buffer.
4. Cap and vortex for 30 seconds.
5. Add 100 μ L of the solution from step 3 to the sample port.
6. Start the timer. The test is read at 15-20 minutes and assessed either visually or by using a calibrated Lateral Flow Device or Strip Reader.
7. For archiving purposes, the housing can be opened and the sample pad portion can be clipped off the test strip. Please note however, that as the strip dries, artifacts may form that can obscure test results.

Interpretation of the Test

The reagent zone contains 3 distinct print lines that must be considered in a coordinated manner when interpreting the test lines. These lines include the Sandwich Test Line (**T**), the Competitive Test Line (**O**), and the Control Line (**C**).



The Sandwich Test Line (**T**) will become clearly visible at the LOD value defined for the kit and continue to strengthen in intensity with increasing target analyte concentration up to a point where it will then start to fade and eventually disappear at high analyte levels. The Competitive Test Line (**O**) will be intense if the sample is negative for the target analyte and fade with increasing amount of target analyte, disappearing completely at high analyte levels before the Sandwich Test Line does. This feature allows the operator to distinguish between samples with none or low levels of target analyte and those with high levels. The Competitive Test Line also enables detection of target analyte that is highly hydrolyzed and poorly detected by the Sandwich Test Line. Failure of the Procedural Control Line (**C**) to appear denotes an invalid test, requiring repeat testing.

Kit Storage and Stability

Store at 2-25°C (35-77°F). Do not freeze. The kit is stable until the expiration date indicated on the box if stored as indicated.

Limitations of the Test

For all assays based on antibody platforms, there are certain conditions that alter the ability of the antibodies to detect the target analyte. In such instances, the test may not yield accurate results. Such factors must be considered in the interpretation of the results. Not all sample surfaces or conditions may be suitable for use with this assay, thus validation should be performed in advance to verify suitability. Environmental samples are used as a general indication of allergens for monitoring purposes and cannot be used for quantification.

Precautions

For Laboratory use only, not intended for human diagnostic use. The test should be performed by trained personnel as part of an Allergen Control plan. Operation of the test should be performed using Good Laboratory Practices and using personal protective equipment including gloves, lab coat, and safety glasses. Strict adherence to the assay protocol is mandatory to ensure proper operation of the test kit. Do not use expired reagents. Do not mix kit components with other kits or kit lot numbers. To limit contamination, do not reuse plastic components and avoid creating aerosols or aspirating when pipetting.

It is recommended to validate samples for use with this kit prior to testing actual samples. Questions regarding suitability of samples and strip readers recommended for use in recording test results should be addressed to customer support. SDS information can be obtained from your distributor or by emailing: tech@microbiologique.com.

Customer Support

For additional information on using this test kit, please contact:

1.888.998.4115 (USA & Canada)
+ 1.206.525.0412- (International)
Email: tech@microbiologique.com

Disclaimer

MICROBIOLOGIQUE, INC. (MICROBIO) MAKES NO CLAIMS, REPRESENTATIONS OR WARRANTIES INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, EITHER EXPRESSED OR IMPLIED, RELATED TO THE PERFORMANCE OF THIS PRODUCT. BUYER'S SOLE REMEDY FOR DEFECTIVE MATERIALS IS REPLACEMENT. IN NO EVENT SHALL MICROBIO BE LIABLE FOR ANY DIRECT, INDIRECT, PUNITIVE, INCIDENTAL, SPECIAL CONSEQUENTIAL DAMAGES OF ANY NATURE WHATSOEVER OR EXPENSES ARISING OUT OF OR CONNECTED WITH THE USE OR MISUSE OF THIS PRODUCT.

Manufactured by Microbiologique, Inc
8315 Lake City Way NE
Seattle, WA 98115
USA