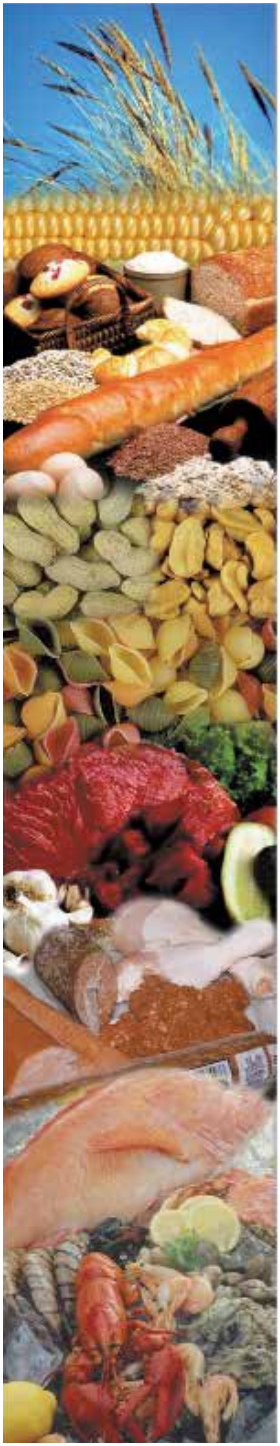


Micro biologique

AllergenControl™

Soy Residue
Environmental Surface Test

Product Code: PA-E11

Directions For Use

Introduction

Soy, a member of the legume family, is widely used in processed foods. However, allergy to soy is relatively common and can manifest as severe allergic reactions. For this reason, numerous countries require that food labels clearly indicate soy content. To assist the food industry in establishing effective food safety practices, the rapid AllergenControl™ Soy Residue Kit has been developed to reliably detect soy residues on surfaces and equipment down to 0.1 µg protein/swab and 1 ppm protein/rinse water in ~25 minutes.

Intended Use

This test kit is designed for use in the qualitative determination of soy protein residues obtained from sampling environmental surfaces and/or rinse water. The test is intended for laboratory use only and should only be performed by trained personnel.

IFU-PA-E11 REV 2.0, 30 JAN 2017

Assay Principle

The AllergenControl™ Soy Residue Lateral Flow Test features polyclonal antibodies directed against soybean proteins configured in both sandwich and competitive format. To operate the kit, the surface is first sampled and then the sample is subjected to a short extraction step. The sample extract is then directly 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.

Procedural Control Line (C)

Competitive Line (O)

Sandwich Test Line (T)

Sample port

Performance Characteristics

Limit of Detection: 0.1 µg protein/swab
1 ppm protein/ rinse water sample
Sample Extraction Time: 1 minute or 15 minutes
Test Operation Time: 15 minutes
Cross-Reactivity: Cross-reactivity was detected in extracts from kidney bean.

Kit Components

Soy Residue Lateral Flow Devices (LFDs) (25)
LFD Buffer B (32 mL)
Disposable Extraction Tubes (25)
100 µL Disposable Pipettes (25)
Environmental Swabs (25)

Also Required (but not supplied)

Vortex
Pipettor and tips (p100 and p1000)
Water bath incubator (60°C or 95°C)
Timer
15mL centrifuge tube
Centrifuge
Calibrated Lateral Flow Device or Strip Reader (optional)
pH indicator and adjustment solutions (1 M NaOH or HCl)

Protocol - Swab testing

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 LFD Buffer B to a 2 mL 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 LFD Buffer B. Define a 10 x 10 cm^2 (or 4 x 4 $inch^2$) 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 cm^2 (or 4 x 4 $inch^2$) surface area. Swab the defined surface using a rolling crosshatch technique.

Sample Preparation

1. Place the swab tip in a labeled 2 mL Disposable Extraction Tube 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 the swab tip for 15 minutes at 60°C ***or*** 1 minute at 95°C (pre-heat buffer at 95°C) using a hot water bath. For the 95°C incubation period, **DO NOT EXCEED** 1 minute.
4. Allow the extract to cool on ice for 3 - 5 minutes.
5. Centrifuge at 2,000 x *g* for 10 minutes.

Operating the LFD

1. Unwrap the LFD and place on a clean, flat surface.
2. Using the 100 µL disposable pipette, add 100 µL of the aqueous portion of the extract to the sample port.
3. 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.
4. 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 the test results.

Protocol - Rinse water testing

Sample Collection

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

1. Perform equipment cleaning according to your allergen control plan.
2. Ensure that equipment is adequately rinsed to eliminate residual disinfectant.
3. Perform final rinse following your routine procedure. Mix rinse water sample thoroughly and collect rinse water sample into a 15-mL Falcon tube.
4. Vortex 30 seconds.
5. Check pH and adjust to pH 7.0-7.5 with NaOH or HCl.
6. Take 100 µL of rinse water and add to the Disposable Extraction Tube.

Sample Preparation

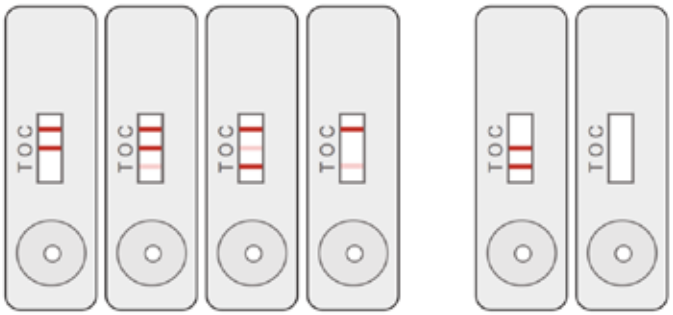
1. Add 900 µL of LFD Buffer B to the rinse water sample contained in the 2 mL Disposable Extraction Tube and mix by vortexing for 15 seconds.
2. Extract sample for 15 minutes at 60°C ***or*** 1 minute at 95°C (pre-heat buffer at 95°C) using a hot water bath. For the 95°C incubation period, **DO NOT EXCEED** 1 minute.
3. Allow the extract to cool on ice for 3 - 5 minutes.
4. Centrifuge at 2,000 x *g* for 10 minutes.

Operating the LFD

1. Unwrap the LFD and place on a clean, flat surface.
2. Using the 100 µL disposable pipette, add 100 µL of the aqueous portion of the extract to the sample port.
3. 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.
4. 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 the 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. In this instance, it is recommended that the sample extract be diluted 1/5 in LFD Buffer B and then retested using a new LFD.

Testing Swab Samples: The LFD will register a clear signal at the Sandwich Test Line (**T**) at an antigen concentration of 0.1 µg protein/swab. This value may vary with use of non-recommended swabs.

Testing Rinse Water Samples: In testing rinse samples, it is critical to ensure the rinse water does not contain any residual disinfectant, as many types of disinfectants can interfere with the assay and invalidate the test result. In interpretation of the results, the operator must consider both the surface area being tested as well as the rinse water volume. The LFD will register a clear signal at the Sandwich Test Line (**T**) at an antigen concentration of 1 ppm in the rinse water.

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

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