AllergenControl™

Soy Residue Food Sampling Test

Product Code: PA-F11

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 in food down to 1.0 ppm in ~25 minutes.

Intended Use
This test kit is designed for use in the qualitative determination of soy protein residues obtained from sampling foods (solids, powders, and liquids). The test is intended for laboratory use only and should only be performed by trained personnel.
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 sample is first 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.

Performance Characteristics

Limit of Detection*: 1.0 µg protein/g or 1 ppm
Sample Extraction Time: 1 minute or 15 minutes
Test Operation Time: 15 minutes
Cross-Reactivity: Cross-reactivity was detected in extracts from kidney bean.
* matrix-free determination

Kit Components

Casein Residue Lateral Flow Devices (LFDs) (25)
LFD Buffer B (300 mL)
100 µL Disposable Pipettes (25)

Also Required (but not supplied)

Grinding or milling device (for solid samples)
Vortex
Pipettor and tips (p100 and p1000)
Water bath incubator (60°C or 95°C)
15 mL polypropylene tubes
Balance
Timer
Centrifuge
Calibrated Lateral Flow Device or Strip Reader (optional)
pH indicator and adjustment solutions (1 M NaOH or HCl)
Protocol - Solid or Powder Samples

Sample Collection

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

1. The sample must first be milled, ground, or otherwise reduced to a fine particle size such that it is fully homogeneous.
2. Weigh out 1.0 g of the sample into a 15 mL polypropylene tube and add 10 mL of the LFD Buffer B. Other amounts may be used as long as the 1+10 sample proportion is maintained.

Sample Preparation

1. Cap and vortex for 30 seconds.
2. Check pH and adjust to 7.0 - 7.5 with 1 M NaOH or HCl.
3. Extract for 15 minutes at 60°C with periodic shaking every 5 minutes *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 - Liquid Samples

Sample Collection

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

For liquid samples, place 1 mL of the sample into a suitable test tube or other container and add 9 mL of LFD Buffer B Other amounts may be used as long as the 1+9 proportion is maintained.

Sample Preparation

1. Cap and vortex for 30 seconds.
2. Check pH and adjust to 7.0 - 7.5 with NaOH or HCl.
3. Extract for 15 minutes at 60°C with periodic shaking every 5 minutes *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.
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.
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 food matrices may be suitable for use with this assay, thus validation should be performed in advance to verify suitability. Testing using the LFD can be 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

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