



AllergenControl™

Total Milk Residue Food Sampling Test

Product Code: PA-F24

Directions For Use

Introduction

Allergies to cow milk are one of the most common food allergies. For this reason, numerous countries require that food labels clearly indicate milk content. The milk allergens of major clinical significance are casein and beta-lactoglobulin (β -LG). Frequently, they are added separately during food manufacturing. Accordingly, testing for milk contamination should include testing for both residue types. To assist the food industry in establishing effective food safety practices, the rapid AllergenControlTM Total Milk Residue Test Kit was developed to feliably detect both casein and β -LG residues down to 0.1 ppm in food in ~25 minutes.

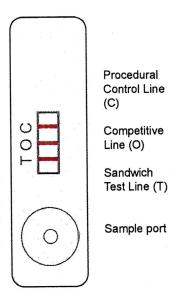
Intended Use

This test kit is designed for use in the qualitative determination of total milk 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.

IFU-PA-F24 REV 2.0

Assay Principle

The AllergenControlTM Total Milk Residue Lateral Flow Test features polyclonal antibodies directed against casein and β-LG 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.



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Performance Characteristics

Limit of Detection*: 0.1 µg protein/g or 0.1 ppm protein

Sample Extraction Time: 1 minute or 15 minutes

Test Operation Time: 15 minutes

Cross-Reactivity: Cross-reactivity was detected in extracts from pea, lentil,

kidney bean, sunflower.

* matrix-free determination

Kit Components

Total Milk 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

Scale or balance (precise to 0.1 g)

pH indicator and adjustment solutions (1 M NaOH or HCl)

Timer

Centrifuge

Calibrated Lateral Flow Device or Strip Reader (optional)

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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.
- 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 μ L disposable pipette, add 100 μ L 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.
- 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.

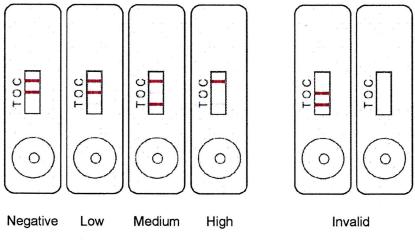
Operating the LFD

- 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 visually or by using either 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.

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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**).



Contamination level

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. If 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. This kit demonstrates reduced detection of β -LG residues that have unedrgone extensive thermal processing.

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 suitablility 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.

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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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