Milk
According to EU Directive 2007/68/EC the addition of bovine milk has to be labelled. For the detection of bovine milk in foodstuffs, sensitive detection systems are required. Approximately 80% of bovine milk proteins are caseins. β-Lactoglobulin, the major allergen of whey, represents a further 10% of the total protein. Bovine milk is one of the most important allergenic food ingredients, especially for children. Very low amounts of bovine milk can cause allergic reactions, which may lead to anaphylactic shock in severe cases. Because of this, milk allergic persons must strictly avoid the consumption of milk or foods containing milk. In particular, the risk of hidden milk proteins in foods such as sausage, cookies, ready meals or beverages represent a critical problem for milk allergic persons.

Short instructions

Perform extraction for finished product, rinse water or swab.

Transfer 12 drops of extract to incubation vial.

Shake incubation vial vigorously by hand for 15 seconds.

Incubate for 5 minutes at room temperature.

Insert test strip into the solution and incubate for 5 minutes. Read result immediately.

Performance Characteristics:

**LOD:**
1 ppm Milk protein* (Finished product & rinse water testing)
1 µg/25cm² Milk protein** (Swab testing)

* LOD was determined in extraction solution
** LOD was calculated
Sample preparation – Finished Products and Rinse Water

1. **Homogenize** the sample (i.e. blend, crush, grind)
2. Add **0.2 mL** Rinse water or **0.2g** of sample (weigh with Balance or estimate by filling up one of the extraction tube caps) to the sample extraction tube
3. Fill Extraction Tube with **Extraction Buffer** to level shown below (blue arrow)
4. Close tube with tube cap, and shake vigorously by hand for **1 minute**.
5. Remove cap from the Extraction Tube and replace with dropper tip. And transfer **12 drops** (**400µl**) to an incubation vial.

Proceed to the Assay Section (page 3) to complete your test

Sample preparation – Swab Testing

1. Fill extraction tube with **Extraction Buffer** to level shown below (blue arrow), take a swab and wet the end by dipping into the buffer
2. Wipe an area of **5cm x 5cm** using side to side movements, rotating the swab tip as you go (we recommend the “cross-hatch” swabbing technique indicated below)
3. Place the swab into the extraction tube. Carefully break off the end at the pre-scored point.
4. Close the tube with a cap and shake vigorously for **1 minute**
5. Remove cap from the Extraction Tube and replace with dropper tip. And transfer **12 drops** (**400µl**) to an incubation vial.

Proceed to the Assay Section (page 3) to complete your test
Assay Procedure in detail

1. Shake Incubation Vial vigorously by hand for **15 seconds** (ensuring liquid comes in contact with the lid of the vial) then leave to stand at room temperature for **5 minutes**.

2. Open the container of AgraStrips®, remove the necessary number of strips and close the tube. Open the Incubation Vial and insert the bottom end of test strip into the vial.

3. Remove the test strip from the Incubation Vial **after 5 minutes** and read the result immediately.

Interpretation of Results

**Negative Test**

![Negative Test Image]

**Positive Test**

![Positive Test Image]

One single purple line in the central part of the test = negative result

Two purple lines in the result zone = positive result. The sample contains allergen higher than the cut-off level and further investigations should be performed.

No control line appears = invalid result, regardless of whether the test line appears. In the case of an invalid result, please repeat the procedure with a new strip. If the problem persists, please contact Romer Labs® before continuing further.

**Important advice for the proper execution of the test:**

- It is important to **read the results immediately after the 5 minute incubate step** since the AgraStrip® test system has been validated extensively and shows reliable results after that exact time. Longer incubation times can lead to the development of false positive results.

- The AgraStrip® Allergen lateral flow tests are for the **detection of trace amounts of allergens** in a low ppm range. If the sample contains more than 1% (10000ppm) allergen, the test will come up negative.
Performance Characteristics in Detail

Limit of detection: 1 ppm Milk protein (Finished product & rinse water testing)
1 µg/25cm² Milk protein (Swab testing)

Range of detection: 1 – 10000 ppm Milk protein
3 – 30000 ppm Skimmed milk powder

pH range: Performing the assay in a pH range of 6-8 will lead to reliable results. Highly acidic samples can lead to false positive results whereas in an alkaline milieu there is the tendency to false negative results.

Materials Supplied with Kit:

- 1 Tube containing 10 AgraStrip® Milk Strips
- 1 Dropper Bottle (green label) containing 35mL Extraction Buffer
- 10 incubation vials
- 10 Extraction Tubes
- 10 Tube Caps
- 10 Extraction Tube Dropper Tips
- 10 Breakpoint Swabs
- 1 Tube Holder

Materials required but not supplied for solid sample preparation

- Blender or Crusher or Blade
Technical and Background Information

The AgraStrip® Milk Test Kit is a lateral flow assay for the detection of Milk content in food, rinse waters and environmental swab samples.

Milk Allergy
According to EU Directive 2007/68/EC the addition of bovine milk has to be labelled. For the detection of bovine milk in foodstuffs, sensitive detection systems are required. Approximately 80% of bovine milk proteins are caseins. β-Lactoglobulin, the major allergen of whey, represents a further 10% of the total protein. Bovine milk is one of the most important allergenic food ingredients, especially for children. Very low amounts of bovine milk can cause allergic reactions, which may lead to anaphylactic shock in severe cases. Because of this, milk allergic persons must strictly avoid the consumption of milk or foods containing milk. In particular, the risk of hidden milk proteins in foods such as sausage, cookies, ready meals or beverages represent a critical problem for milk allergic persons.

Assay Principles
Immunological rapid test in lateral flow format for the detection of Milk in food, rinse waters and swab samples (environmental samples). The extracted sample is transferred to an incubation vial that contains specific ready-to-use antibodies. If the sample contains Milk, an antigen-antibody complex will form. This is subsequently detected by the test strip. The test is easy to use, fast and reliable.

Precautions

1. The product must be stored in its original package, between 15 and 25°C (room temperature). Do not use components beyond the expiration date indicated on the kit labels. Do not open the product until needed.
2. Test strips must be kept inside their original packaging, closed as tightly as possible. Do not freeze.
3. Adhere to the instructions for test procedures.
4. The components in this test kit have been quality control tested as a standard batch unit. Do not mix components from different lot numbers.

Sampling:
Consideration must be taken that the food may contain an uneven distribution of Milk (spot contamination). It is important to test a representative portion of food as only a small amount of material is tested with the AgraStrip® Total Milk test.

Detection:
The detection limit of the AgraStrip® Total Milk test is at the low ppm level but will vary depending on the food matrix being tested. To give reliable results each individual matrix should be validated before the kit is used routinely.

For further information regarding validation please contact Romer Labs.

Note:
Chocolate and flour samples may block the filter tip of the extraction tube. This can be avoided by transferring the extract directly from the extraction tube to the reaction vial using a pipette or by hand to a level just under the 0.5ml graduation of the reaction vial.
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