

PRECAUTIONS

1. The test strips must remain sealed in the stay-dry tube before use.
2. Microwell strips should remain sealed in the foil pouch until needed. Remove wells from the foil pouch only after the samples are extracted and the test procedure is set to begin. Reseal foil pouch.
3. This kit is designed to detect trace amounts of milk residue. If samples are suspected to contain gross contamination (greater than 50%) of milk (casein or whey) samples should be diluted. Testing samples with a gross contamination of milk may result in a negative test result due to saturation of the antibody.
4. Samples to be tested for milk must be extracted separately from samples to be tested for other food allergens. Extraction additives are specifically designed for each food allergen.
5. This test kit's components (e.g., extraction reagents) may contain milk, egg, peanut and/or soy protein. If allergic to any of these compounds, use this product with caution.
6. The testing environment should be clean and dust-free.
7. Do not use kit components beyond expiration date.
8. Treat labware and test liquids (e.g., sample extract) as if they contain milk.
9. To avoid cross-contamination, use clean labware for each sample, and thoroughly wash all labware between samples.

PROCEDURAL NOTE

Extraction Solution: Prepare extraction solution by adding 1 foil pouch of extraction solvent, 10mM PBS, to 1 L distilled or deionized water. Swirl to mix thoroughly. Cover and store any unused portions refrigerated at 2-8°C (35-46°F). Extraction solution should be preheated to (60°C, 140°F) prior to sample extraction. Note: Discard unused portions of extraction solution when the test kit has been used completely.

SAMPLE PREPARATION AND EXTRACTION

Test samples should be collected according to accepted sampling techniques (if necessary, see Neogen's Food Allergen Handbook). Liquid food or CIP samples can be extracted by shaking or using a heated water bath extraction method. To extract food allergen residues from swabs, use the environmental swab extraction method in this section. For extracting solid food type samples contact Neogen's Technical Services Department.

Liquid or CIP sample extraction method

1. Prepare extraction solution as described in the procedural note.
2. Preheat the extraction solution to 60°C (140°F).
3. Obtain a representative sample.
4. Transfer 10 mL of liquid sample to be tested to a 250 mL disposable extraction bottle.
5. Add 1 level scoop of milk extraction additive to the bottle.
6. Pour 90 mL of the preheated (60°C, 140°F) extraction solution into

the bottle, cap and shake vigorously for 3 minutes. Alternative method: shake (150 rpm) in a water bath at 60°C (140°F) for 15 minutes.

7. The sample extract is now ready for testing.

Environmental swab extraction method

1. Prepare the extraction solution as described in the procedural note.
2. Prepare a working solution by combining 125 mL of the extraction solution, and 1 level scoop of milk extraction additive to a separate container and mix. Prepare a fresh working solution daily. **Note:** Prepare 125 mL of the working solution for every 25 environmental swabs to be tested.
3. Preheat the working solution to 60°C (140°F). Shake container to mix additive. **Note:** not all the additive will dissolve.
4. Gather the sample with a swab, using one of the following methods: **For dry surfaces:** Open a new swab and wet with extraction solution. Swab a 10 x 10 cm area by using a crosshatch technique. (Do not use working solution to moisten swabs.) **For wet surfaces:** Open a new swab and swab a 10 x 10 cm area by using a crosshatch technique. Do not moisten swab prior to use. Return the swab to its original tube once sampling is complete. Remember to label each tube.
5. Remove the swab from its tube, and add 5 mL of working solution at 60°C to the tube. Mix by placing the swab back into the tube and shaking for 2 minutes by hand (inverting tube), or for 30 seconds with a Vortex mixer.
6. Remove the swab from its tube.
7. The sample extract is now ready for testing.

TEST PROCEDURE

1. Remove 1 reagent well for each sample being tested.
2. Add 100 µL of the sample diluent to each reagent well and swirl gently by hand for approximately 30 seconds to rehydrate.
3. Using a new tip for each, add 100 µL of sample extract to the rehydrated microwell and pipette the sample up and down 3 times to mix.
4. Immediately insert the lateral flow device into the microwell containing the diluent/sample mix (1 device per well) and allow the test to run for **5 minutes** at room temperature.
5. **PROMPTLY** after the 5 minutes, remove the device from the microwell and interpret results against a white background or with Neogen's Reveal AccuScan Reader.

INTERPRETATION OF RESULTS

Positive results: If a line forms in the test zone and another line forms in the control zone within 5 minutes (2 lines total), the sample is positive. A positive sample may be determined as soon as 2 lines are visible on the strip. If there is no line in the control zone, the test is invalid and the sample should be retested with another strip.

Negative results: If after the full 5 minutes there is no visible line in the test zone, but a visible line in the control zone, the sample is negative. If there is no line in the control zone, the test is invalid and the sample should be retested with another strip.

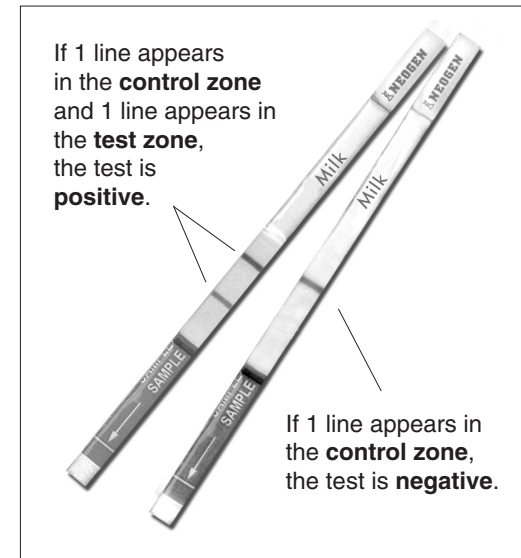
Notes:

- Observations should be made between 5 and 6 minutes. Observations after 6 minutes may be inaccurate due to over-development of the device.
- The strips can be read using Neogen's Reveal AccuScan Reader*. This eliminates subjectivity by interpreting and storing sample results.
- Positives can be confirmed by Neogen's quantitative Veratox for Total Milk Allergen*.

*Contact Neogen or visit www.neogen.com for more information on these products.

PERFORMANCE CHARACTERISTICS

Reveal for Total Milk Allergen is designed to screen for milk residue at 5 ppm. At this concentration level, the user should expect to see a positive line in the test zone and a line in the control zone. Matrix effects may impact the intensity of the line in the test zone. See **PRECAUTIONS** section, step 3, regarding highly contaminated samples.



CUSTOMER SERVICE

Neogen Customer Assistance and Technical Service can be reached between 8 a.m. and 6 p.m. Eastern Time by calling 800/234-5333 or 517/372-9200 and asking for a Neogen sales representative or Technical Services. Assistance is available on a 24-hour basis by calling 800/867-0308. Training on equipment use for all Neogen test kits, is available.

MSDS INFORMATION AVAILABLE

Material safety data sheets (MSDS) are available for this test kit, and all of Neogen's test kits, on Neogen's Web site at www.neogen.com, or by calling Neogen at 800/234-5333 or 517/372-9200.

WARRANTY

Neogen Corporation makes no warranty of any kind, either expressed or implied, except that the materials from which its products are made are of standard quality. If any materials are defective, Neogen will provide a replacement of the product. Buyer assumes all risk and liability resulting from the use of this product. There is no warranty of merchantability of this product, or of the fitness of the product for any purpose. Neogen shall not be liable for any damages, including special or consequential damage, or expense arising directly or indirectly from the use of this product.

TESTING KITS AVAILABLE FROM NEOGEN
Natural Toxins

- Aflatoxin, DON, Ochratoxin, Zearalenone, T-2 Toxin, Fumonisin, Histamine

Foodborne Bacteria

- *E. coli* O157:H7, *Salmonella*, *Listeria*, *Listeria monocytogenes*, *Campylobacter*, *Staphylococcus aureus*

Sanitation

- ATP, Yeast and Mold, Total Plate Count, Generic *E. coli* and Total Coliforms, Protein Residues

Food Allergens

- Peanuts, Milk, Eggs, Almonds, Gluten, Soy Flour, Hazelnut

Genetic Modification

- CP4 (Roundup Ready®)

Ruminant By-products

- Meat and Bone Meal, Feed



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Read instructions carefully before starting test

Reveal[®] for Total Milk Allergen

TOTAL MILK ALLERGEN

Food allergens are proteins in food that can create an immune response in sensitive individuals. Once ingested, food allergens can cause a number of reactions, ranging in severity from hives and itching to anaphylaxis. Anaphylaxis is a severe allergic reaction, involving vomiting, diarrhea, difficulty breathing, swelling of the mouth and tongue, and a rapid drop in blood pressure.

An estimated 3.5 to 4 percent of adults, and 6 to 8 percent of children, are sensitive in some degree to food allergens. More than 12 million people in the United States alone are thought to have a food allergy.

Food manufacturers protect those with food allergies by clearly labeling their products with a list of ingredients. Testing for the presence of milk components ensures food manufacturers that an unlabeled — and potentially dangerous — ingredient did not make its way into a food product.

INTENDED USE

Reveal for Total Milk Allergen is intended for the qualitative analysis of milk residue (casein or whey) in liquid products (e.g., juices and sorbet), clean-in-place rinses, and on environmental surfaces.

INTENDED USER

This test kit is designed for use by quality control personnel and others familiar with foods and surfaces possibly contaminated by milk or milk products. Since technique is very important, operators should be trained by a Neogen representative or someone who has successfully completed the Neogen training.

ASSAY PRINCIPLES

Reveal for Total Milk Allergen is a two part lateral flow immunochromatographic assay. The first part of the assay consists of a detector reagent well, which contains antibodies specific for milk residue conjugated to colored particles. This reagent is rehydrated with a supplied sample diluent, and sample is added to the reagent well. If milk residue is present in the sample, it will be bound by the antibody-particle complex.

The second part of the assay consists of an immunochromatographic device used for the detection of milk residue. This device is inserted into the sample/reagent well. The milk-antibody-particle complex is then wicked onto a membrane which contains a zone of antibody specific for milk residue. This zone captures the complex allowing the particles to concentrate and form a visible line. If no milk is present, no line will form. The membrane also contains a control zone where an immune complex present in the reagent zone is captured by an antibody, forming a visible line. The control line will always form regardless of the presence of milk, ensuring the strip is working properly.

STORAGE REQUIREMENTS

Store kit components at room temperature (18-30°C, 64-86°F) to assure full shelf life.

MATERIALS PROVIDED

1. 24 lateral flow milk test strips in a sealed stay-dry tube
2. 24 reagent wells in a foil pouch
3. 3 foil pouches of 10 mM PBS dry powder extraction solvent; each pouch contains enough powder to prepare 1 L of extraction solution
4. 1 bottle of sample diluent
5. 1 bottle of extraction additive
6. Plastic 1 g scoop to measure extraction additive

MATERIALS RECOMMENDED BUT NOT PROVIDED

1. Water bath, hot plate or equivalent heat source capable of maintaining 60°C ± 1° (140°F)
2. Thermometer
3. 1 L bottle to prepare extraction solution (Neogen item #9472)
4. Pipettor, 100 µL (Neogen item #9272, 9278 or 9276)
5. Pipette tips (Neogen item #9410, 9407)
6. Well holder (Neogen item #9402)
7. Waterproof marker
8. Distilled or deionized water
9. Timer (Neogen item #9426)
10. Graduated cylinder capable of measuring 5-100 mL (Neogen item #9368)
11. Allergen Extraction Kit (Neogen item #8429)
12. Allergen Environmental Swabbing Kit (Neogen item #84325)