Product 8479

Questions? Call 800/234-5333

CUSTOMER SERVICE

Neogen Customer Assistance and Technical Services can be reached by using the contact information below. Training on this product, and 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 website 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/HT-2 toxins, fumonisin, histamine

• E. coli 0157:H7, Salmonella, Listeria, Listeria monocytogenes, Campylobacter, Staphylococcus aureus

Sanitation

ATP, yeast and mold, total plate count, generic E. coli and total coliforms, protein residues

Almonds, crustaceans, eggs, gliadin, hazelnut, lupine, milk, mustard, peanuts, sesame, soy,

Genetic modification

CP4 (Roundup Ready®)

Ruminant by-products

Meat and bone meal, feed



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Read instructions carefully before starting test

Reveal 3-D Total Milk Allergen Test

INTRODUCTION

The Reveal 3-D Total Milk Allergen Test is uniquely designed with three lines of detection and can be used virtually anywhere to screen environmental swabs, rinses and liquid products (e.g., juices, soy milk and sorbet) for the presence of milk (casein or whey). Its 3-D technology ensures greater reliability

with screening than ever before.

INTENDED USE

The Reveal 3-D Total Milk Allergen Test is intended for use only in an industrial food manufacturing/preparation context. Because of the problems of adequate sampling and extraction of milk, it is not suitable for the testing of foods to be consumed in the home or in a restaurant by allergic individuals. The test detects significant (low parts per million, or ppm) levels of milk in clean-in-place rinses, liquid products and environmental swabs.

DETECTION LIMIT

The test uses highly specific antibodies to detect milk. Milk residues can be detected from various surfaces using the provided environmental swabs or from rinses and liquid products (e.g., juices, soy milk and sorbet).

Utilizing the environmental swabs supplied, levels of 20 µg/100 cm² of milk (casein or whey) on surfaces can be detected.

When analyzing rinses or liquid products, milk residues are detectable at a level of 5-10 ppm. The presence of cleaners and sanitizers can affect limit of detection (LOD) in rinses.

TEST PERFORMANCE

The Reveal 3-D Total Milk Allergen Test has undergone rigorous validation to evaluate the specificity, sensitivity, robustness and intra- and inter-batch variability of the test method on rinses, liquid products and environmental swabs.

SAMPLE COMPATIBILITY

The Reveal 3-D Total Milk Allergen Test is designed to detect milk on environmental surfaces and in liquids. Although every effort has been made to validate as many variables as possible, there are some sample types that are not suitable for testing.

The validation of certain food ingredients may be applicable for the Reveal 3-D test format. However, it is recommended that a more broadly inclusive test method, such as Alert® or Veratox® Total Milk Allergen, be used for food ingredients. Existing commodity validations should be revalidated when suppliers or the manufacturing process has been changed. Please contact a Neogen representative or distributor for additional details.

MATERIALS PROVIDED

The Reveal 3-D Total Milk Allergen Test kit (Neogen item 8479) includes:

- An instruction leaflet
- 2. One sealed foil pouch, containing 10 Reveal 3-D Total Milk Test devices
- 3. Ten sachets containing 4 mL of Extraction Buffer Type 8
- 4. Ten sample tubes and caps
- 5. Ten individually packaged, sterile swabs and break-off tips

SAMPLING TECHNIQUE

1. Clean-in-place rinse water and liquid products

As only a small amount of material is required for the Reveal 3-D Total Milk Allergen Test, it is important to test a representative portion of the liquid.

2. Environmental swabbing

The swabs supplied are intended to be used for the collection of environmental samples from which the presence of milk residues can be tested. This method can be used to validate the adequacy of cleaning and/or to identify problem areas (e.g., unwanted buildup of milk residue in processing equipment).

PRECAUTIONS

- For environmental testing in an industrial food manufacturing/preparation, or labeling enforcement context only.
- 2. Do not use any part of the test beyond the expiry date.
- 3. Do not open the foil pouch until just before use.
- 4. Ensure the foil pouch is sealed tightly after removal of device.
- 5. Always store the kit between 2–8°C (35–46°F). Avoid freezing.
- 6. Bring kit to room temperature (18–30°C) (64–86°F) prior to use.

TEST STORAGE / SAMPLE STABILITY

Store the Reveal 3-D Total Milk Allergen Test kit between 2–8°C (35–46°F), and use within the expiry date stated on the outer label. Extracted samples should be tested within **3 hours** of extraction.

LIMITATIONS

A negative test from a surface or liquid sample cannot exclude the possibility that the food contains milk residue since it may be distributed unevenly on the surface or rinse and may be below the limit of detection of the test.

The Reveal 3-D Total Milk Allergen Test is qualitative and should only be used as a preliminary screen for the presence of milk residue. The validity of results obtained should be viewed in conjunction with data from a quantitative assay, such as Veratox for Total Milk Allergen.

LIQUID SAMPLING

Remove the following and allow to equilibrate at room temperature before use (20–30 minutes out of refrigerator):

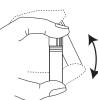
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- 1. 1 sample tube and cap
- 2. 1 Type 8 Extraction Buffer sachet
- 3. 1 Reveal 3-D Total Milk Test device (in foil pouch)
- Carefully tear/cut off the top of the Type 8 buffer sachet and add the entire contents to the sample tube.
- Add 1 mL of sample to the sample tube. If a pipette is unavailable, 1 mL may be crudely estimated by half-filling a white sample tube cap. NOTE: Test results will be less accurate.
- 3. Secure the white cap and shake for 1 minute.





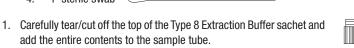


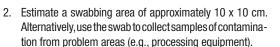


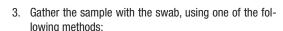
SWAB SAMPLING

Remove the following and allow to equilibrate at room temperature before use (20–30 minutes out of refrigerator):

- 1. 1 sample tube and cap
- 2. 1 Type 8 Extraction Buffer sachet
- 3. 1 Reveal 3-D Total Milk Allergen Test device (in foil pouch)
- 4. 1 sterile swab





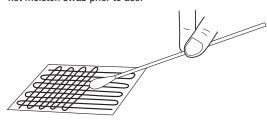


For dry surfaces: Remove a sterile swab from the packaging and wet with extraction buffer

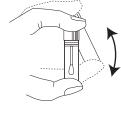


in the sample tube. Swab a 10×10 cm area using a crosshatch technique revolving the swab on the surface. Repeat this swabbing procedure using movements at right angles to those used in the first swabbing.

For wet surfaces: Remove a sterile swab from the packaging and swab a 10 x 10 cm area by using a crosshatch technique revolving the swab on the surface. Repeat this swabbing procedure using movements at right angles to those used in the first swabbing. Do not moisten swab prior to use.

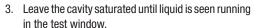


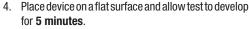
- 4. Return the swab to the extraction buffer in the sample tube and carefully break off the moistened end at the prescored mark so that it remains in the tube.
- Secure the cap of the sample tube, taking care to ensure that the stem does not prevent the tube from being properly sealed. Shake for 1 minute.



SAMPLE TESTING

- Remove the lid and fill it with the liquid from the tube. Any froth should remain in the tube.
- Dip the head of the Reveal 3-D device into the liquid in the lid. Ensure that the cavity is saturated with the liquid.





NOTE: It is essential to place the device flat on a level surface as soon as the liquid has entered the test window to stimulate flow through the device.



READING RESULTS

Liquid will flow into the test window. Read the result **5 minutes** after dipping.

Negative result

No line at position T (test): Level of milk undetectable. (See **Limitations** section.)



Negative

Positive result

Any intensity of line at position T (test): Level of milk above detection limit.



Positive

High result

No line is visible at position 0 (overload) and a line is faintly visible or absent at position T: Sample is overloaded with milk.





Invalid results

If no line appears at position C (control), then the test may be invalid.

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