

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 800/234-5333. 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 Food Safety test kits, 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 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

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

- Almonds, Crustaceans, Eggs, Gliadin, Hazelnut, Lupine, Milk, Mustard, Peanuts, Sesame, Soy, Walnut

Genetic Modification

- CP4 (Roundup Ready®)

Ruminant By-products

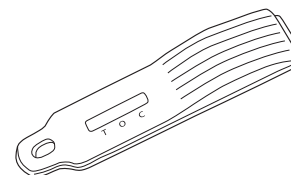
- Meat and Bone Meal, Feed

Read instructions carefully before starting test

Reveal 3-D Gluten Test

INTRODUCTION AND INTENDED USE

The Reveal® 3-D Gluten Test is uniquely designed with 3 lines of detection and can be used virtually anywhere to screen environmental swabs and rinses for the presence of significant levels of gluten. The test's 3-D technology ensures greater reliability with screening than ever before.

**DETECTION LIMIT**

The test uses a monoclonal antibody that demonstrates reactivity to both the toxic fractions of the gluten molecule namely gliadin and glutenin.

The LOD of the test should be determined for the sample(s) being tested by comparison to the Gluten Assay, contact Neogen or your distributor for details. The detection limit may, with care, be increased or decreased by optimizing the sample weight to extraction solution ratio. Utilizing the environmental swabs supplied levels of 80 µg/ 100 cm² of gluten extract can be detected.

When analyzing rinses, gluten residues are detectable at a level of 5-10 ppm. The presence of cleaners or sanitizers can affect LOD in rinses.

CROSS REACTIVITY

In addition to common bread wheat, the antibody used detects durum wheat, rye and to a lesser extent, barley.

The Reveal 3-D Gluten Test is specific for the above cereals and will not detect oats, rice or maize.

A panel of potential cross reactants was assessed. No cross reactants were detected except brown linseed, although gluten contamination cannot be ruled out.

TEST PERFORMANCE

The Reveal 3-D Gluten Test has undergone rigorous validation to evaluate the specificity, sensitivity, robustness and intra- and inter-batch variability of the test method on rinses and environmental swabs. A Customer Validation Report is available on request.

SAMPLE COMPATIBILITY

The Reveal 3-D Gluten Test is designed to detect gluten most effectively on environmental surfaces and in rinses. While every effort has been made to validate as many variables as possible, there are some sample types that are not suitable for testing.

Further information is available in the Reveal 3-D Gluten Customer Validation Report, available on request.

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, like Alert or Veratox Gliadin, be used for food ingredients. Existing commodity validations should be revalidated when suppliers or the manufacturing process has been changed. Please contact your Neogen representative or distributor for additional details.

REAGENTS AND MATERIALS

The pack contains the following:

1. An instruction leaflet
2. A sealed foil pouch, containing 10 green Reveal 3-D Gluten Test devices
3. Ten sachets containing 1 mL of Extraction Buffer Type 4
4. Ten sachets containing 3 mL of Extraction Buffer Type 5
5. Ten sample tubes and caps
6. Ten individually packaged, sterile swabs with break-off tips

SAMPLING TECHNIQUE**1. Clean-in-Place Rinse Water**

As only a small sample of material is required for the Reveal 3-D Gluten 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 gluten can be tested. This method can be used to validate the adequacy of cleaning and/or to identify problem areas, e.g. ineffective removal of gluten from processing equipment.

3. Food Samples

Contact your Neogen representative or distributor for additional details.



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e-mail: foodsafety@neogen.com • www.neogen.com

PRECAUTIONS

1. 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 foil bag is tightly sealed after removal of a device.
5. Always store the kit between 2–8°C (35–46°F); avoid freezing.

TEST STORAGE / SAMPLE STABILITY

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

LIMITATIONS

A negative test from a surface or rinse cannot exclude the possibility that the food or swabbed surface has gluten present since it may be distributed unevenly on the surface or in the rinse and may be below the limit of detection of the test.

In-house validation should be performed to ensure that the swabbing procedure can detect residual gluten at the desired levels.

The Reveal 3-D Gluten Test is **QUALITATIVE** and should only be used as a preliminary screen for gluten content.

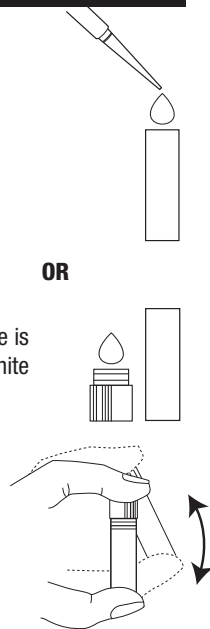
RINSE SAMPLING

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

- 1 x sample tube
- 1 x "Type 4" buffer sachet
- 1 x "Type 5" buffer sachet
- 1 x Reveal 3-D Gluten Test device (in foil pouch)

1. Carefully tear/cut off the top of the "Type 4" buffer sachet and add the entire contents to the sample tube.
2. Add the 0.25 mL (250 µL) sample to the sample tube. If a pipette is unavailable, 0.25 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 one minute.
4. Add the contents of the "Type 5" buffer sachet and again shake for one minute.

OR



PROCEED TO SAMPLE TESTING

SWAB SAMPLING

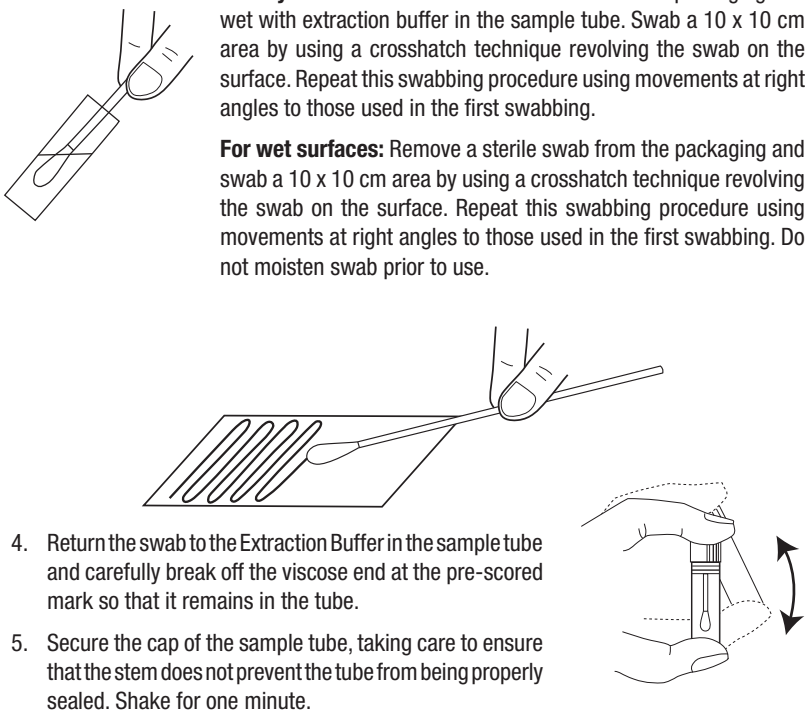
Remove the following and allow to equilibrate at room temperature before use (20–30 minutes out of refrigerator):

- 1 x sample tube
- 1 x "Type 5" buffer sachet
- 1 x Reveal 3-D Gluten Test device (in foil pouch)
- 1 x sterile swab

1. Carefully tear/cut off the top of the "Type 5" buffer sachet and add the entire contents to the sample tube.
2. Estimate a swabbing area of approx. 10 cm x 10 cm. Alternatively use the swab to collect samples of contamination from problem areas e.g. of processing equipment.
3. Gather the sample with the swab, using one of the following methods:

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

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.



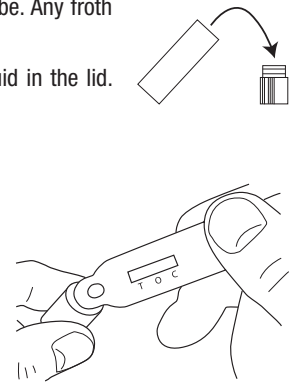
4. Return the swab to the Extraction Buffer in the sample tube and carefully break off the viscose end at the pre-scored mark so that it remains in the tube.
5. Secure the cap of the sample tube, taking care to ensure that the stem does not prevent the tube from being properly sealed. Shake for one minute.

PROCEED TO SAMPLE TESTING

SAMPLE TESTING

1. Remove the lid and fill it with the liquid from the tube. Any froth should remain in the tube.
2. Dip the head of the Reveal 3-D device into the liquid in the lid. Ensure that the cavity is saturated with the liquid.
3. Leave the cavity saturated until you see the liquid running in the test window.
4. Place device on a flat surface and allow test to develop for 5 minutes.

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.



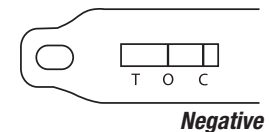
GO TO READING RESULTS

READING RESULTS

Liquid will flow into the test window; read the result **FIVE MINUTES** after dipping. If distinct lines are **NOT** visible at positions O and C, refer to numbers 3 or 4 below.

1. NEGATIVE Result

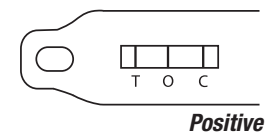
No line at position T (test): Level of Gluten undetectable. (See LIMITATIONS section).



Negative

2. POSITIVE Result

Any intensity of line at position T (test): level of Gluten above detection limit.



Positive

3. HIGH Results

No line is visible at position O (overload) and a line is faintly visible or absent at position T: **sample is OVERLOADED with Gluten.**



4. INVALID Results

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