

U.S. English

Product Number:
8505

Reveal[®] 3-D

for Gluten



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Introduction and Intended Use

The Reveal[®] 3-D for Gluten is uniquely designed with 3 lines of detection and can be used to screen foods, ingredients, environmental swabs, and rinses for the presence of gluten. The test's 3-D technology enables greater screening reliability than ever before.

In an AOAC Research Institute *Performance Tested Method*[™] (PTM) study, the Reveal 3-D for Gluten was found to be an effective method for the qualitative determination of the presence of gluten from wheat in environmental swabs from stainless steel and clean-in-place (CIP) rinse.

Limit of Detection (LOD)

Utilizing the environmental swabs supplied, levels of 5 µg/100 cm² of gluten can be detected.

When analyzing rinses and food samples, gluten residues are detectable at a level of 5 parts per million (ppm) gluten. The presence of cleaners or sanitizers can affect LOD in rinses.

Cross-reactivity

The antibody used in the test detects prolamins in wheat, rye, and barley. Reveal 3-D for Gluten is specific for the above cereals and will not detect oats or rice. The test was used to analyze a panel of potentially cross-reacting commodities including nuts, seeds, legumes, and grains. Of these, almond and sesame were found to cross-react with the test. In addition, corn cross-reacts with the food extraction method but does not cross-react when testing environmental samples (swabs and rinses). Further information is available in the Reveal 3-D for Gluten validation report, which is available on request.

Test Performance

Reveal 3-D for Gluten has undergone rigorous internal validation to evaluate the specificity, sensitivity, robustness, and intra- and inter-batch variability of the test method on foods, ingredients, rinses, and environmental swabs.

Sample Compatibility

Reveal 3-D for Gluten is designed to detect gluten on environmental surfaces, and in rinses and foods. Although every effort has been made to validate as many variables as possible, some food processes, such as heat processing or fermentation, will impact the detection of the allergen and there may be some sample types that are not suitable for testing.

Users should perform in-house, matrix-specific spike and recovery validation work to help confirm Reveal 3-D for Gluten results. The process will highlight any problematic matrices encountered. Please contact a Neogen[®] representative for additional details.

Materials Provided

The pack contains the following:

1. 1 sealed foil pouch, containing 10 green Reveal 3-D for Gluten devices
2. 1 bottle of swab wetting solution
3. 10 bottles containing 20 mL of extraction buffer
4. 10 individually packaged, sterile swabs with break-off tips

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Additional Materials

The extraction of food samples requires an additional extraction step and materials.

1. 3-D Gluten food buffer (item number 8503)
2. Tubes, 50 mL graduated polypropylene, pack of 25 (item number 9381)
3. 400 uL exact volume pipettes, bag of 25 (item number D2039)
4. Vortex (item number 9494)
5. Scale (item number 9427)

Sample Technique

1. CIP rinse water
As only a small sample of material is required for Reveal 3-D for Gluten, 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
Food sample extraction requires additional materials, listed above. As only a small sample of the material is required for Reveal 3-D for Gluten, it is important to test a representative portion of the food product or ingredient. Contact a Neogen representative or distributor for additional details.

Precautions

1. This test should be used in an industrial food manufacturing/preparation facility or labeling enforcement context only.
2. Do not use any part of the test beyond the expiration date.
3. Do not open the foil bag until just before use and ensure it is tightly sealed after removal of a device.
4. Always store the kit between 2–8°C (35–46°F). Do not freeze.
5. Bring the kit to room temperature 18–30°C (64–86°F) prior to use.
6. The test devices use a pale green loading dye at T (test), O (overload), and C (control) positions for quality purposes. The pale green lines should be visible on the devices prior to use. If the lines are not visible, do not use the device and contact a Neogen representative for assistance.

Test Storage/Sample Stability

Store the Reveal 3-D for Gluten 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

Reveal 3-D for Gluten is qualitative and should only be used as a preliminary screen for gluten content.

A negative test cannot exclude the possibility the food or swabbed surface has gluten present since it may be distributed unevenly on the surface or in the rinse/food and may be below the LOD of the test.

In-house validation should be performed to ensure that the method can detect residual gluten at the desired levels. Validate detection by testing a positive control from the source of the allergen or ingredient that is available in your manufacturing environment and that may pose an allergen contamination risk, to ensure the test can detect the allergen of concern.

Hydrolyzed and fermented protein may not be detectable with antibody-based test methods for allergen testing. Although the protein may be undetectable in the test because of their properties, there still could be allergenic protein residue present.

Chestnut flour, guar gum, and xanthan gum do not cross-react with this test. However, these commodities are known to inhibit the detection of gluten in this test when analyzed at 100% concentration. A decrease in inhibition was observed for all commodities at lower inclusion rates. Contact a Neogen representative for further details.

Sample Extraction

AOAC PTM for CIP rinses and environmental sample from stainless steel surfaces.

Rinses

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

- Extraction buffer bottle
- Reveal 3-D for Gluten device (in foil pouch)
 1. Add the 0.25 mL (250 µL) sample to a new extraction buffer bottle.
 2. Secure the white cap and shake for 1 minute.

Swabs

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

- Bottle of swab wetting solution
- Extraction buffer bottle
- Reveal 3-D for Gluten device (in foil pouch)
- Sterile swab
 1. Estimate a swabbing area of approximately 10 cm x 10 cm. Alternatively, use the swab to collect samples of contamination from problem areas (e.g., of processing equipment).
 2. Gather the sample with the swab, using one of the following methods:
 - For dry surfaces:** Remove a sterile swab from the packaging. Do not moisten swab prior to use. 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.
 3. Insert the swab into an extraction buffer bottle and carefully break off the moistened end at the prescored mark so that it remains in the bottle.
 4. Secure the cap and shake for 1 minute.

Foods

The extraction of food samples requires the use of Neogen's 3-D Gluten food buffer (item number 8503). Additional materials may be required depending on your facility. See additional materials section on page 3.

From the test kit, remove the appropriate number of the following and allow to equilibrate at room temperature before use (20–30 minutes out of refrigerator):

- Reveal 3-D for Gluten extraction buffer bottle
- Reveal 3-D for Gluten device (in foil pouch)

Extract food sample using the buffer and tube provided in the 3-D food extraction kit.

1. Add 20 mL of 3-D Gluten food buffer into a new 50 mL tube. (For liquid samples, add 18 mL).
2. Weigh out 2 g (mL) of sample and add to tube with buffer.
3. Secure the caps and invert to suspend sample. Shake vigorously or vortex for 1 minute.
4. Using a new 400 µL transfer pipette*, dispense 2 times to transfer a total of 800 µL of sample extract into a new Reveal 3-D for Gluten extraction buffer bottle. Cap and invert to mix.

Note: *To use the 400 µL transfer pipettes, hold at a slight angle, squeeze the upper bulb, and draw enough sample into the pipette to fill the stem completely, with any overdrawn amount going into the reservoir (lower bulb). Then discharge the sample in the pipette stem by squeezing the upper bulb with a single squeeze. The excess fluid from the draw will remain in the reservoir. Discard after use.

Sample Testing

1. Following extraction remove the lid and fill it with liquid from the bottle. Any froth should remain in the bottle.
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 liquid is observed 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. Additionally, the devices are pre-stripped with pale green loading dye in positions T (test), O (overload), and C (control). The loading dye assists with quality and manufacturing checks and does not impact test performance. The loading dye is removed from the test window as the sample flows through the device.

Reading Results

Read the results after 5 minutes. Observations after 6 minutes may be inaccurate due to overdevelopment of the device.

1. Negative result
No line at position T (test); lines present at O (overload); and C (control): Level of gluten is below the LOD. (See limitations section).
2. Positive result
Any intensity of line at positions T (test), O (overload), and C (control): Level of gluten above detection limit.
3. High positive results
No line is visible at position O (overload); a line is faintly visible or absent at position T (test); a line is visible at position C (control): Sample is overloaded with gluten.
4. Invalid results
If no line appears at position C (control), then the test may be invalid.

Customer Service

Neogen customer and technical services can be contacted through [Neogen.com](https://www.neogen.com) and product training is available by request.

Safety Data Sheets (SDS) Information Available

SDS are available for all test kits at [Neogen.com](https://www.neogen.com) or by calling 800.234.5333 or 517.372.9200.

Terms and Conditions

Neogen's full terms and conditions are available online.

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