

CUSTOMER SERVICE

Neogen Customer Assistance and Technical Service can be reached between 8 a.m. and 7 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, Eggs, Gliadin, Hazelnut, Lupine, Milk, Mustard, Peanuts, Sesame, Crustacea, Soy, Walnut

Genetic Modification

- CP4 (Roundup Ready®)

Ruminant By-products

- Meat and Bone Meal, Feed



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800/234-5333 (USA/Canada) or 517/372-9200 • fax: 517/372-2006

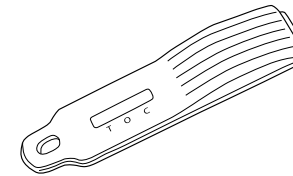
e-mail: foodsafety@neogen.com • www.neogen.com

Read instructions carefully before starting test

Reveal 3-D Crustacea Test

INTRODUCTION AND INTENDED USE

The Reveal® 3-D Crustacea 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 crustaceans and shelled molluscs. The test's 3-D technology ensures greater reliability with screening than ever before.



The Reveal 3-D Crustacea Test is intended for use ONLY in an industrial food manufacturing/preparation context or for food labeling enforcement testing. Because of the problems of adequately sampling and extracting crustacea, it is NOT SUITABLE for the testing of foods in the home or in a restaurant. The test detects significant (low parts per million; ppm) levels of crustacean content in rinses and in environmental swabs.

DETECTION LIMIT

The test uses highly specific antibodies to detect an allergenic protein from crustacea (tropomyosin). Residues of crustacea can be detected from various surfaces using the provided environmental swabs or from rinses.

Utilizing the environmental swabs, levels of 40 µg/100 cm² of cooked prawn extract can be detected.

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

CROSS-REACTIVITY

The test was used to analyze a panel of crustacea from the same genus. The following were found to give a positive result: crab, lobster, brown shrimp, tiger prawn, langoustine and crayfish.

TEST PERFORMANCE

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

Users should perform "in house" matrix-specific spike recovery validation work in conjunction with a validated laboratory assay like the BioKits Shellfish Assay kit to help confirm Reveal 3-D Crustacea Test results.

Note: Some highly processed crustacea extracts 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, like BioKits, 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 Reveal 3-D Crustacea Test pack contains the following:

1. An instruction leaflet
2. One foil pouch, containing 10 pink Reveal 3-D Crustacea Test devices
3. Ten sachets containing extraction solution Type 3
4. Ten sample tubes and caps
5. Ten individually packaged sterile swabs with break-off tips

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

As only a small amount of material (0.25 mL) is required for the Reveal 3-D Crustacea Test, it is important to test a representative portion of liquid.

2. Environmental Swabbing

The swabs supplied are intended to be used for the collection of environmental samples from which the presence of crustacea can be tested. This method can be used to validate the adequacy of cleaning and/or to identify problem areas, e.g. unwanted build-up of crustacea in processing equipment.

3. Food Samples

Contact your Neogen representative or distributor for additional details.

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

TEST STORAGE / SAMPLE STABILITY

Store the Reveal 3-D Crustacea 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 contains crustacea since it may be distributed unevenly on the surface or rinse and may be below the detection limit of the test. A highly processed crustacea source may also give a negative test.

The Reveal 3-D Crustacea Test is **QUALITATIVE** and should only be used as a preliminary screen for the presence of shellfish. The validity of results obtained with the test should preferably be viewed in conjunction with data from a quantitative assay.

RINSE SAMPLING

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

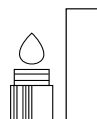
- 1 sample tube
- 1 "Type 3" buffer sachet
- 1 Reveal 3-D Crustacea Test device (in foil pouch)

1. Carefully tear/cut off the top of the "Type 3" buffer sachet and add the entire contents to the sample tube.

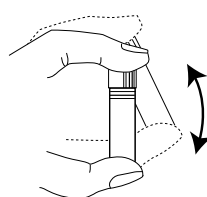


OR

2. Add the 0.25 mL (250 µL) sample to the sample tube. If a pipette is unavailable, 0.25 mL may be 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.

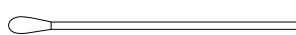


PROCEED TO SAMPLE TESTING

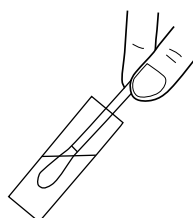
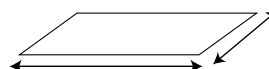
SWAB SAMPLING

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

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

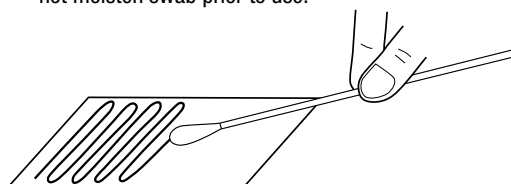


1. Carefully tear/cut off the top of the "Type 3" buffer sachet and add the entire contents to the sample tube.
2. Estimate a swabbing area of approx. 10 cm x 10 cm. Alternatively use the swab to collect samples of contamination from problem areas (e.g., processing equipment.)

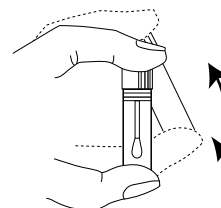


For dry surfaces: Remove a sterile swab from the packaging and wet with extraction buffer in the sample tube. Swab a 10 x 10 cm area by using a crosshatch technique revolving the swab on the surface. Repeat this swabbing procedure using movements at right angles to those used in the first swabbing.

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.



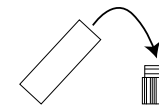
4. Return the swab to the Extraction Buffer in the sample tube and carefully break off the swab end at the pre-scored mark so that it remains in the tube.
5. Secure the cap of the sample tube, taking care to ensure that the stem does not prevent the tube from being properly sealed. Shake for 1 minute.



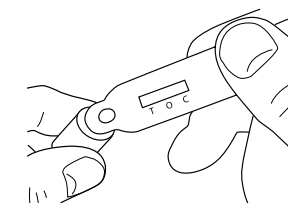
PROCEED TO SAMPLE TESTING

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.



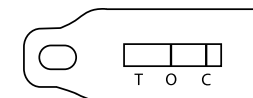
GO TO READING RESULTS

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

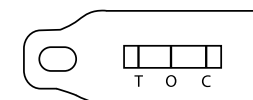
No line at position T (test): Level of crustacea undetectable. (See LIMITATIONS section).



Negative

2. POSITIVE Result

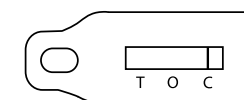
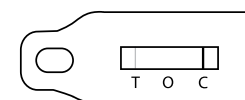
Any intensity of line at position T (test): level of crustacea above detection limit.



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 crustacea.**



4. INVALID Results

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