U.S. English

Product Number: 902081S





Reveal® 3-D for Crustacea

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Introduction and Intended Use

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

Reveal 3-D for Crustacea is intended for use only in an industrial food manufacturing and preparation context or 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 a restaurant. The test detects significant low parts per million (ppm) levels of crustacean content in rinses and environmental swabs.

Limit of Detection

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 1–2 ppm crustacean protein (5–10 ppm total crustacea). The presence of cleaners and sanitizers can affect limit of detection 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. In addition, this test was shown to cross-react to garlic. Signal mitigation was demonstrated with appropriate dilutions.

Test Performance

Reveal 3-D for Crustacea has undergone rigorous validation to evaluate the specificity, sensitivity, robustness, intra- and inter-batch variability of the test method on rinses and environmental swabs. A customer validation report is available on request.

Sample Compatibility

Reveal 3-D for Crustacea is designed to detect crustacea on environmental surfaces and in rinses. Although 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 such as Veratox* for Crustacea to help confirm Reveal 3-D for Crustacea results. This process will highlight any problematic matrices encountered.

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, such as Veratox for Crustacea, 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 for Crustacea kit contains the following:

- 1. An instruction leaflet
- 2. 1 foil pouch, containing 10 pink Reveal 3-D for Crustacea devices
- 3. 10 sachets containing Type 8 Extraction Buffer
- 4. 10 sample tubes and caps
- 5. 10 individually packaged, sterile swabs with break-off tips
- 6. 1 bottle of swab wetting solution

Sampling Technique

- 1. Clean-in-place (CIP) rinse water
 - As only a small amount of material (0.25 mL) is required for the Reveal 3-D for Crustacea test, it is important to test a representative portion of liquid.
- 2. Environmental swabbing
 - The swabs supplied are intended to be used to collect environmental samples from which the presence of crustacea can be tested. This method can be used to validate the adequacy of cleaning and to identify problem areas (e.g., unwanted buildup of crustacea in processing equipment).
- 3. Food samples
 - Contact a Neogen representative or distributor for additional details.

Precautions

- 1. For environmental testing in an industrial food manufacturing and 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 bag is tightly sealed after removal of a 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

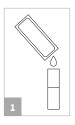
Store the Reveal 3-D for Crustacea kit between 2–8°C (35–46°F), and use within the expiry date stated on the outer label. Extracted samples should be used within 3 hours of extraction.

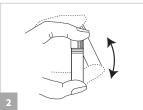
Limitations

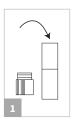
A negative test from a surface or rinse cannot exclude the possibility that the food contains crustacea since it may be distributed unevenly on the surface or rinse and may be below the detection limit of the test. A highly processed crustacea source may also give a negative test.

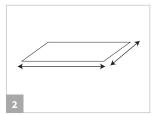
The Reveal 3-D for Crustacea is qualitative and should only be used as a preliminary screen for the presence of shellfish. The validity of results obtained with the test should preferably be viewed in conjunction with data from a quantitative assay.

Validate detection by testing a positive control from the source of the allergen or ingredient available in your manufacturing environment, and that may pose an allergen contamination risk to ensure the test can detect the allergen of concern. Contact Neogen technical services for additional information.



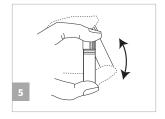












Rinse Sampling

For each sample to be tested, remove the following and allow to equilibrate at room temperature before use (20–30 minutes out of refrigerator):

- 1. 1 sample tube
- 2. 1 Type 8 Extraction Buffer
- 3. 1 Reveal 3-D for Crustacea device (in foil pouch)
- 1. Carefully tear or cut or uncap the Type 8 Extraction Buffer and add the entire contents to the sample tube.
- 2. Add 0.25 mL (250 ul) of sample to the sample tube.
- 3. Secure the white cap and shake for 1 minute.

Swab Sampling

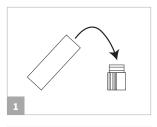
For each sample to be tested, remove the following and allow to equilibrate at room temperature before use (20–30 minutes out of refrigerator):

- 1. 1 sample tube
- 2. 1 Type 8 Extraction Buffer
- 3. 1 Reveal 3-D for Crustacea test device (in foil pouch)
- 4. 1 sterile swab
- 1. Carefully tear or cut the Type 8 Extraction Buffer and add the entire contents to the sample tube.
- 2. Estimate a swabbing area of approximately 10 x 10 cm. Alternatively, use the swab to collect samples of contamination from problem areas (e.g., processing equipment, filler heads).
- 3. Gather the sample with the swab, using one of the following methods:

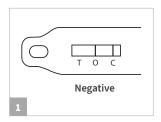
For dry surfaces: Remove a sterile swab from the packaging and wet with swab wetting solution. Swab a $10 \times 10 \text{ cm}$ area by using a crosshatch technique revolving the swab on the surface. Repeat this swabbing procedure using movements at right angles to those used in the first swabbing.

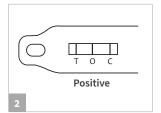
For wet surfaces: Do not moisten swab prior to use. Remove a sterile swab from the packaging and swab a 10×10 cm area by using a crosshatch technique revolving the swab on the surface. Repeat this swabbing procedure using movements at right angles to those used in the first swabbing.

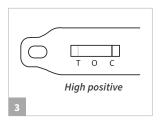
- 4. Place the swab in the extraction buffer in the sample tube and carefully break off the moistened end at the prescored mark so that it remains in the tube.
- 5. Secure the cap of the sample tube, taking care to ensure that the stem does not prevent the tube from being properly sealed. Shake for 1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

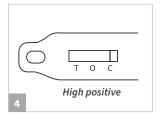












Swab and Rinse Testing

- 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 liquid is seen 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-striped 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 result 5 minutes after dipping. Observations after 6 minutes may be inaccurate due to overdevelopment of the device.

- Negative result
 No line at position T (test): Level of crustacea is below the detection limit. (See limitations section).
- 2. Positive result

 Any intensity of a red line at position T (test): Level of crustacea above detection limit.
- 3. High positive results
 No line is visible at position O (overload), and a red line is faintly visible or absent at position T: Sample is overloaded with crustacea.
- 4. Invalid results
 If no red line appears at position C (control), then the test is invalid.

Customer Service

Neogen customer and technical services can be contacted through <u>neogen.com</u> and product training is available by request.

Safety Data Sheets (SDS) Information Available

SDS are available for all test kits at neogen.com or by calling 800.234.5333 or 517.372.9200.

Terms and Conditions

Neogen's full terms and conditions are available online.

Warranty

Neogen 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.