

Validating Reveal[®] 3-D



VALIDATE YOUR TESTING Reveal 3-D Test Kits

The following information is provided as a guide to validating the use of the Reveal 3-D test in routine food allergen testing

The Matrix Effect

The Limit of Detection of the Reveal 3-D will vary depending on the sample matrix to be tested

The Reveal 3-D Tests are designed to detect allergens most effectively in environmental swabs and in some final cooked and uncooked foods. The tests are also validated so they can be used with confidence to test a wide variety of food matrices and production surfaces. However, every food process and factory is different, and therefore in order to control food allergens down to a desired level it is important that validation work is performed on each sample matrix to be tested.

Allergen Spike Recovery

In order to validate the sensitivity of a Reveal 3-D test at a known allergen concentration in a specific sample matrix or swabbing environment, either of the following methods are appropriate. Both involve an allergen spike recovery procedure which means spiking either the food sample or the surface to be swabbed with a known concentration of allergen followed by testing with the Reveal 3-D test.



Meet the Reveal 3-D Family



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METHOD 1

In House Spike Recovery

The spike used ideally should be a source of allergen or ingredient which is available in your manufacturing environment and which may pose an allergen contamination risk.

Example: The addition of 5 mg of a typical **non-fat dry milk** to a 10 g sample would give a Casein spike level of approximately 100 ppm.

It is important that the spiked sample is rendered as homogenous as possible for testing.

Several allergen spike levels should be produced and tested with the Reveal 3-D test down to the desired cut off level.

The protein and allergen content will vary depending on the source of spike material and so it is recommended that tests are performed in parallel with an experienced Allergen Testing Service to accurately quantify the amount of allergen spiked into the matrix.

METHOD 2

Neogen Spike Recovery Validation Service

If you would like Neogen to validate your sample matrix in our laboratory, please contact us to discuss your requirements before sending samples.

PROCEDURE: We will perform spike recovery experiments utilizing our in house reference standards on your behalf.

Prices Available upon request

REMINDERS

A negative test result cannot exclude the possibility that the allergen is present on the food or swabbed surface, because it may be distributed unevenly or may be below the limit of detection of the test. For these and other reasons, the result is best described as “not detected”.

Validation is always advised to ensure detection of residual allergen at the desired levels. The described spiking procedure should be performed for all new sample matrices or for variations of existing formulations.

The Reveal 3-D Tests are QUALITATIVE and are recommended as a preliminary screen for allergen content.



| Allergen | | Product Number |
|------------|-------------|----------------|
| Almond | Yellow | 902086G |
| Casein | White | 902075M |
| Crustacea | Pink | 902081S |
| Egg | Purple | 902082Q |
| Gliadin R5 | Light Green | 8519 |
| Gluten | Green | 901031P |

| Allergen | | Product Number |
|------------|-------------|----------------|
| Hazelnut | Blue | 902087E |
| Mustard | Olive Green | 8405 |
| Peanut | Orange | 901041L |
| Sesame | Light Brown | 8535 |
| Soy | Brown | 902093K |
| Total Milk | Light Blue | 8479 |

Neogen offers Allergen Analytical Services



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