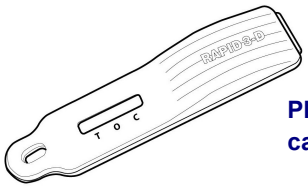
GEN-PROBE

BIOKITS RAPID 3-D™ Peanut Test

Cat. No. 901041L



Please read the instructions carefully before testing

Introduction / Intended Use

The *BIOKITS* RAPID 3-D Peanut Test is uniquely designed with 3 lines of detection and can be used virtually anywhere to screen foods and environmental swabs for the presence of significant levels of Peanut. The tests 3-D technology ensures greater reliability with screening than ever before.

The *BIOKITS* RAPID 3-D Peanut Test is intended to be used ONLY in an industrial food manufacturing/preparation context or for food labelling enforcement testing. Because of the problems of adequately sampling and extracting peanut in foods, it is NOT SUITABLE for the testing of foods to be consumed e.g. in the home or in a restaurant by allergic individuals. The test detects significant (low parts per million; ppm) levels of peanut content in uncooked and cooked foods and in environmental swabs.

Detection Limit

The test utilises highly specific antibodies to detect an allergenic protein from peanuts (Conarachin II [*Ara h 1*] a storage protein). Peanut can be detected in many processed foods, nuts, pulses, grains, seeds and other ingredients. The limit of detection (LOD) of the test is highly dependent on sample type and extraction efficiency. The LOD of the RAPID Peanut Test has been evaluated by comparing it to the *BIOKITS* Peanut Assay Kit for testing a range of peanut-containing and "nut-free" foods. Positive RAPID Test results were observed at levels in the range 5 to 50ppm, and below, depending on sample type (e.g. recovery can be low from plain chocolate)*. The LOD of the test should be determined for the sample(s) being tested by comparison to the *BIOKITS* Peanut Assay, contact Tepnel or your distributor for details.
*LOD will be higher if the amount of food sample tested is reduced below the recommended 0.25g weight.

Utilising the environmental swabs supplied levels below ~50ng/cm^2 of peanut on surfaces can be detected.

Cross Reactivity

The test was used to analyse a panel of 32 potentially cross reacting commodities. All 32 gave negative results in the test.

Sample Compatibility

The RAPID 3-D Peanut Test is designed to detect peanut in a wide range of cooked and uncooked foods. While every effort has been made to validate as many food types as possible, there may be some foods that are not suitable for testing. The test is best used in conjunction with a validated laboratory assay e.g. the *BIOKITS* Peanut Assay kit to help confirm RAPID 3-D Peanut Test results.

Some foods e.g. powders, rice cakes etc absorb a large quantity of extraction solution. Reducing the sample weight to extraction solution ratio may be necessary for these samples: detection limit may be affected by changes in sample weight.*

Reagents and materials

The Rapid Peanut Test pack contains the following:

1. An instruction leaflet.
2. One foil pouch, containing 10 Orange Rapid Peanut Test devices and two self-indicating (orange, if dry) desiccant sachet. DO NOT USE if sachets are white.
3. Ten sachets containing extraction solution Type 3.
4. Ten sample tubes and caps.
5. Ten individually packaged, sterile swabs with break off tips.

Quality Control

We would recommend that an 'in-house' Peanut Positive Control is established from the source of Peanut in the production environment which poses the threat of cross contamination. This will serve to ensure functionality of the test against the specific Peanut ingredient and can also be used to familiarise yourself with the test (contact Gen-Probe Life Sciences or your distributor for details). Once you are familiar with the test, the Control can be used as part of a regular Quality Control programme to help ensure the validity of test results.

Sampling Technique

1. Food Samples

As only a small amount of material (0.25g) is required for the *BIOKITS* Rapid 3-D Peanut Test, it is important to test a representative portion of food. Large food items may be sampled by taking several small portions from various parts of the food (or from various parts of a container) and mixing well before preparing to test. When sampling products comprised of mixtures of commodities/ ingredients e.g. muesli-type cereals it may be appropriate to select out individual 'high risk' ingredients for testing.

2. Environmental Swabbing

The swabs supplied are intended to be used for the collection of environmental samples from which the presence of Peanut 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 Peanut in processing equipment.

Precautions

1. For food testing in an industrial food manufacturing/ preparation, or labelling 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.
   Do not use the device if the desiccant in the foil pouch has turned completely white.
4. Always store the kit between 2°C and 8°C; avoid freezing.
5. Ensure the foil bag is tightly sealed after removal of a device.

Test Storage / Stability

Store the Rapid Peanut Test kit between 2°C and 8°C. The kit should be used within the expiry date stated on the outer label.

Sample Stability

Extracted samples should be used within 3 hours of extraction.

Limitations

A NEGATIVE TEST CANNOT EXCLUDE THE POSSIBILITY THAT THE FOOD CONTAINS PEANUT SINCE IT MAY BE DISTRIBUTED UNEVENLY IN THE FOOD OR MAY BE BELOW THE DETECTION LIMIT OF THE TEST.

The *BIOKITS* RAPID 3-D Peanut Test is QUALITATIVE and should only be used as a preliminary screen for the presence of peanut. The validity of results obtained with the test should preferably be viewed in conjunction with data from a validated laboratory assay.

Test Performance

A panel of foods were tested using the *BIOKITS* Peanut Assay **.

33 samples contained < 2 ppm Peanut (classified as Negative).
17 samples contained > 2 ppm Peanut (classified as Positive).

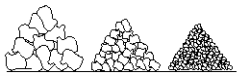
The samples were then tested in the Rapid Peanut Test:

No false negative results were obtained.
Four "false positive" Rapid results were obtained; the four samples were all positive for peanut by ELISA (0.2 - 0.6 ppm).

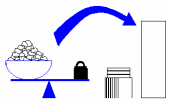
Using the *BIOKITS* RAPID 3-D Peanut Test

Solid Food Sampling

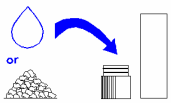
Solid food samples should be crushed or chopped into fine particles. Liquids require no preparation.



Weigh out 0.25g of sample.



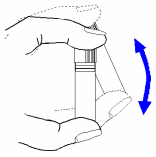
If a balance is unavailable 0.25g may be crudely estimated by half filling a white sample tube cap. Test results will however be less accurate.



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

1 x sample tube
1 x 'Type 3' buffer sachet
1 x *BIOKITS* RAPID 3-D Peanut Test device (in foil pouch)

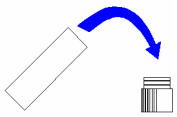
Carefully tear/cut off the top of the clear 'Type 3' buffer sachet and add the entire contents to the sample tube. Add the 0.25g sample to the sample tube. Secure the white cap and shake for one minute.



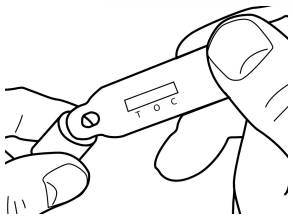
GO TO SAMPLE TESTING

Sample Testing

Remove the lid and fill it with the liquid from the tube. Any froth should remain in the tube.



Dip the head of the RAPID 3-D device into the liquid in the lid. Ensuring that the cavity is saturated with the liquid. Leave the cavity saturated until you see the liquid running in the test window. Place device on a flat surface and allow test to develop



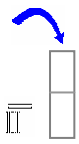
GO TO READING

Swab Sampling

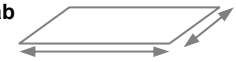
Remove the following and allow to equilibrate at room temperature before use (20-30 mins out of the fridge):

1 x sample tube
1 x 'Type 3' buffer sachet
1 x *BIOKITS* RAPID 3-D Peanut Test device (in foil pouch)
1 x sterile swab

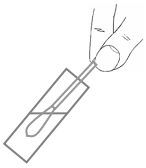
Carefully tear/cut off the top of the 'Type 3' buffer sachet and add the entire contents to the sample tube.



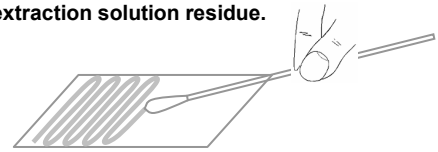
Mark out or estimate a swabbing area of approx 5cm x 5cm. Alternatively use the swab to collect samples of contamination from problem areas e.g. of processing equipment.



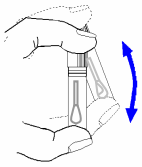
Remove a sterile swab from its packaging and wet the end by dipping into the Extraction Buffer in the sample tube.



Using the wetted swab wipe the entire swabbing area using side to side movements of the swab and revolving the viscose end on the surface; repeat this swabbing procedure using movements at right angles to those used in the first swabbing. Note: After swabbing, wipe the area with a clean, damp cloth to remove any extraction solution residue.



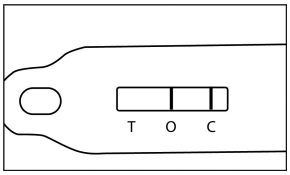
Return the swab to the Extraction Buffer in the sample tube and CAREFULLY break off the viscose end at the pre-scored mark so that it remains in the tube. Carefully secure the cap of the sample tube taking care to ensure that the stem does not prevent the tube from being properly sealed. Shake for one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



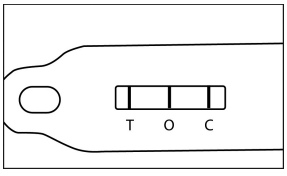
GO TO SAMPLE TESTING

Reading the *BIOKITS* RAPID 3-D™ Peanut Test

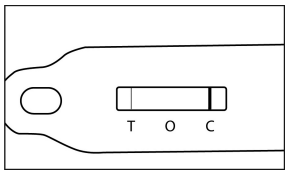
Liquid will flow into the test window; read the result FIVE MINUTES after dipping.
If distinct lines are NOT visible at positions O and C, refer to 3 or 4 below.



1. NEGATIVE Result
No line at position T (test): level of Peanut **undetectable (See Detection Limit notes above).**

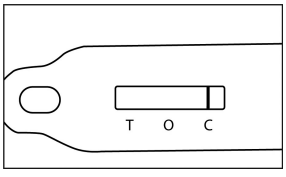


2. POSITIVE Result
Any intensity of line at position T (test): level of Peanut **above Detection limit (see notes on topic above).**



3. HIGH Results
No line is visible at position O (overload).

A line is faintly visible……..



…….or absent at position T.

sample is OVERLOADED with Peanut.

4. INVALID Results: If no line appears at position C (Control) then the test may be invalid.

Contact us for further information

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