

Please read the instructions carefully before testing

Introduction & Intended Use

The *BIOKITS* RAPID 3-D Soya 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 Soya. It is not designed to be used quantitatively or for 100% commodities. The tests' 3D technology ensures greater reliability with screening than ever before.

The *BIOKITS* RAPID 3-D Soya Test is intended for use **ONLY** in an industrial food manufacturing/preparation context or for food labelling enforcement testing. Because of the problems of adequately sampling and extracting Soya 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.

Detection Limit

The test is highly sensitive and specific designed to screen for low parts per million (ppm) levels of Soya content in raw and cooked food products and environmental swabs. The limit of detection of the test is highly dependent on the type of sample matrix and the source / processing of the specific Soya (see Customer Validation Report for more information).

The LOD of the RAPID 3-D Soya test has been evaluated by spike recovery experiments and found to be capable of detecting as low as 2.5 ppm in some matrices. Extracted Soya protein from DoSoy and HiSoy can be detected as low as 1 and 2.5 ppm respectively with the RAPID 3-D Soya test. Utilising the environmental swabs supplied, levels of 10 µg/25cm² of Soya protein extract (DoSoy and HiSoy) can be detected.

The LOD of the test should be determined for the sample(s) being tested by performing spike recovery tests utilising the specific source of soya in the production environment which poses the threat of cross-contamination. Contact Gen-Probe Life Sciences or your distributor for details.

Sample Compatibility

The *BIOKITS* RAPID 3-D Soya Test is designed to detect Soya in cooked or uncooked foods. Whilst every effort has been made to validate as many food types and ingredients as possible, there are some that are not suitable for testing.

Note: The *BIOKITS* RAPID 3-D Soya Test is **NOT** suitable for the detection of Soya derived lecithin.

For some matrices (e.g. high tannin content, low pH, high protein raw ingredients, finely ground products and products with high absorbency) a further 1/10 dilution of the extraction may be required before testing to avoid problematic matrix effects. See Customer Validation Report for further information.

Where possible raw ingredients should be tested at the concentration at which they would normally be present in the final product. The *BIOKITS* RAPID 3-D Soya Test is not designed to test 100% ingredients.

Test Performance

The RAPID 3-D Soya Test has undergone rigorous validation to evaluate the specificity, sensitivity, robustness and intra- and inter-batch variability of the test method on a range of ready to consume cooked and uncooked foods and commodities, as well as environmental swabs. A Customer Validation Report is available on request, which includes details of all sample matrices validated in-house. We recommend that this report is read thoroughly prior to testing with the RAPID 3-D Soya Test.

Reagents and materials

Each RAPID 3-D Soya Test kit contains the following:

1. An instruction leaflet
2. A sealed foil pouch, containing 10 Beige RAPID 3-D Soya Test devices and two self-indicating (orange, if dry) desiccant sachets. **DO NOT USE** if sachet is white.
3. Ten sachets containing Extraction Solution
4. Ten sample tubes and caps
5. Ten individually packaged, sterile swabs with break off tips.

Sampling Technique

1. Food Samples

As only a small sample of food is required for the *BIOKITS* RAPID 3-D Soya Test, it is important to test a representative portion of the food. Large food items may be tested by taking several small portions from various parts of the food (or from various parts of a container), and mixing well before testing the mixture. Complex foods may be tested by isolating individual 'high risk' ingredients prior to testing.

2. Environmental Swabbing

The swabs supplied are intended to be used for the collection of environmental samples from which the presence of Soya 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 Soya 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 test 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.

Quality Control

We would recommend that an 'in-house' Soya Positive Control is established from the source of Soya in the production environment which poses the threat of cross contamination. This will serve to ensure functionality of the test against the specific Soya 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.

Test Storage/Stability

Store the RAPID 3-D Soya Test kit between 2°C and 8°C and use 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 SOYA SINCE IT MAY BE **DISTRIBUTED UNEVENLY** IN THE FOOD OR MAY BE **BELOW THE DETECTION LIMIT** OF THE TEST WITH THAT SPECIFIC SAMPLE.

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

Solid Food Sampling

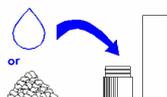
Solid food samples should be crushed or chopped into fine particles. Liquids require no preparation.



Weigh out 0.25g of sample.



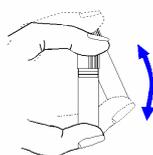
If a balance is unavailable 0.25g may be crudely estimated by half filling a white sample tube cap. Test results will however be less accurate.



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 clear Extraction Buffer sachet
- 1 x *BIOKITS* RAPID 3-D Soya Test device (in foil pouch)

Carefully tear/cut off the top of the clear Extraction 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.



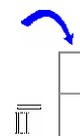
GO TO SAMPLE TESTING

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 clear Extraction Buffer sachet
- 1 x *BIOKITS* RAPID 3-D Soya Test device (in foil pouch)
- 1 x sterile swab

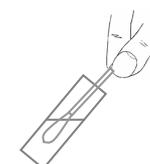
Carefully tear/cut off the top of the clear extraction buffer sachet and add the entire contents to the sample



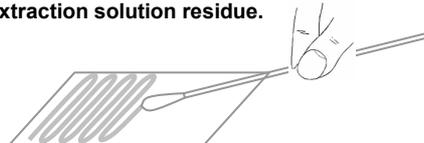
Mark out or estimate a swabbing area of approx 5cm x 5cm. Alternatively use the swab to collect samples of contamination from problem areas e.g. of processing equipment.



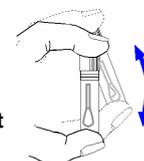
Remove a sterile swab from its packaging and wet the end by dipping into the Extraction Buffer in the sample tube.



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.



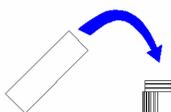
Return the swab to the Extraction Buffer in the sample tube and CAREFULLY break off the viscose end at the pre-scored mark so that it remains in the tube. Carefully secure the cap of the sample tube taking care to ensure that the stem does not prevent the tube from being properly sealed. Shake for one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



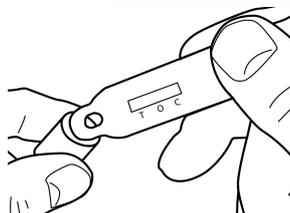
GO TO SAMPLE TESTING

Sample Testing

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



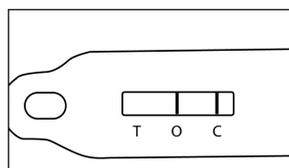
Dip the head of the RAPID 3-D device into the liquid in the lid. Ensuring that the cavity is saturated with the liquid. Leave the cavity saturated until you see the liquid running in the test window. Place device on a flat surface and allow test to develop



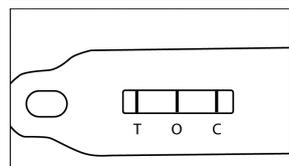
GO TO READING

Reading the *BIOKITS* RAPID 3-D™ Soya Test Result

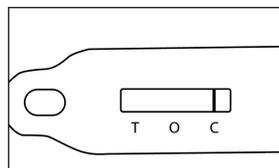
Liquid will flow into the test window; read the result **FIVE MINUTES** after dipping. If distinct lines are NOT visible at positions O and C, refer to 3 or 4 below.



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

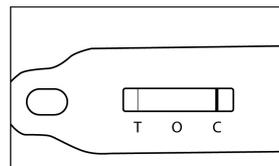


2. POSITIVE Result
Any intensity of line at position T (test): level of Soya **above Detection limit** (see notes on topic above).



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 Soya.

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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