

Disp&FLOW® – Soy Rapid test for the detection of specific protein N° cat. : BIO.037.1 Number of test : 1



Rapid immuno-chromatographic test for the qualitative determination of soybean antigen found in foods, kitchens and food production facilities.

The Disp&FLOW - Soy test has been designed to detect the target antigen in two main types of specimens:

- Solid food samples / solid food products / kitchen utensils / preparation surface.
- Liquid samples of the following types: beverages; rinsing water from food preparation tools, kitchen utensils and surfaces used for cutting, processing and storing food products.

How it works

Soy antigens are among the main food allergens. With the increasing use of soya-derived products in the food industry, consumers suffering from soya allergies are increasingly faced with the risk of serious or even fatal reactions due to mislabeling or failure to describe the use of soya-derived products.

The potential presence of food allergens must be indicated on the packaging.

The Disp&FLOW - Soy test can be used for the qualitative determination of specific soybean/soya bean antigens present in foodstuffs, kitchens and production facilities.

The Disp&FLOW - Soy test can also be used to detect the adulteration of foodstuffs (meat, milk powder, egg powder) by cheaper soya derivatives.

The Disp&FLOW - Soy test is based on the principle of rapid immuno-chromatography on a strip (lateral flow migration). The target antigen present in the sample is absorbed by the strip and then recognized by specific antibodies conjugated to colored microparticles that are free to move. Once formed, this complex migrates along the strip to a highly focused area where it meets another specific antibody attached to the support. The accumulation of microparticles quickly forms a colored line indicating a positive result. The presence of a second control line guarantees that the test is working properly.

Test specificity and sensitivity

The Disp&FLOW - Soy test uses a combination of antibodies to detect a specific antigen present in the variety of different forms of soya derivatives used in the food industry. The target antigen of the Disp&FLOW - Soy test is resistant to pasteurising heat treatment, including UHT.

The Disp&FLOW - Soy test does not detect antigens from vegetables including peas, white beans and lentils. Detailed, up-to-date data on the specificity of the Disp&FLOW - Soy test can be requested from info@biotem.fr.

The sensitivity of the Disp&FLOW - Soy test for soybean antigens is evaluated at at least 30 ppm or 0.003%.

The Disp&FLOW - Soy test does not detect soya protein residues in sausages made from soya, either because of their chemical treatment (acid hydrolysis) or because of natural enzymatic degradation.



These products do not contain high molecular weight components and should not have any allergic potential for patients at risk.

However, if visual assessment could lead to dubious results, we recommend that you test the sample in the laboratory using quantitative methods such as ELISA or PCR.

Kit content

The Disp&FLOW - Soy test contains the following elements:

- A test strip packaged in a hermetically sealed foil pouch containing a desiccant.
- A sample collection swab.
- A polypropylene test tube containing 3 mL extraction buffer for sample preparation and test migration.
- A transfer pipette.
- Instructions for use.

Storage and stability

- The kit should be stored at between +2 and +30°C in a dry atmosphere away from direct sunlight.
- The strips should not be frozen and should be kept in their hermetically sealed sachet.
- The kit must be used before the expiry date indicated on the packaging.

Equipment required but not supplied

- Sampling spatula, preferably single-use.
- Pair of gloves

Precautions

- The kit components are for *in vitro* use only.
- The kit can be used until its expiry date if it has been stored under the recommended conditions.
- Do not use the test after its expiry date.
- Heat-sealed bags containing test strips should be stored between +2 and +30°C.
- All handling associated with the use of this test must be carried out in strict compliance with the conditions for non-contamination of samples; in particular, gloves must be worn during handling.
- The strips should be handled by their colored upper part. Do not directly touch the central part of the strip or its absorbent end.
- The strips must be kept in their sealed foil pouch (the strips are very sensitive to humidity) do not use a strip more than 10 minutes after opening the pouch.
- Do not use the test if the foil pouch has been torn.
- Proceed with caution when opening the foil pouch (see test procedure), so as not to cut or damage the strip.
- Only use the tube containing the extraction buffer supplied in the kit. Never use components from different kits.
- Take care not to immerse the strip deeper than the line under the arrows.
- The Disp&FLOW Soy test contains only single-use components; do not use again.

Waste disposal

- Dispose of all used consumables in accordance with biomedical waste regulations.
- All users are responsible for managing the waste they produce and for ensuring that it is disposed of in accordance with applicable regulations.

Preparation of samples

Prior to testing, samples should be brought to a temperature between $+18^{\circ}$ C and $+35^{\circ}$ C; analysis of colder samples reduces the sensitivity of the test; analysis of warmer samples is not possible due to the risk of degradation of the antibodies present in the strip. Make sure that the material to be tested is a mixture of all the ingredients that make up the final solid food product.

Liquid samples can be tested directly.

The test detection limit for liquid samples depends on their viscosity and turbidity (presence of particles).

If the sample is viscous and cannot reach the test zone, it must be diluted in the dilution/extraction buffer. In this case, the sensitivity of the test must be adjusted by the dilution factor. Cloudy specimens should be filtered through a textile or paper

filter.

Using the transfer pipette supplied, insert the liquid sample (1-2mL) into the test tube containing 3 mL of dilution/extraction buffer.

- 1. Hermetically seal the tube with the stopper.
- 2. Vigorously shake the tube manually or using a vortex at maximum speed for 20-30 seconds.
- 3. Place the tube vertically on a stand and allow the contents to settle or centrifuge at low speed in a centrifuge, the supernatant is then ready for testing.

<u>Powdered products must be tested using the following procedure:</u>

- 1. Weigh out approximately 0.5g of the dry material and introduce it into the tube containing the dilution/extraction buffer.
- 2. Hermetically seal the tube with the stopper.
- 3. Shake the tube vigorously manually or by vortexing at maximum speed for 25-30 seconds.
- 4. Place the tube upright on a stand and allow the contents to settle or centrifuge at low speed in a centrifuge, the supernatant is then ready for testing.

For testing solid materials, utensils or other surfaces, we recommend the following procedure:

- Using clean, sharp tools (preferably disposable), cut off a small piece (0.1 to 0.5 g) of the test material and place it in the tube containing the dilution/extraction buffer.
- For utensils or other surface tests, use the swab provided and pass it over the surface of the object to be analyzed in a criss-cross motion, first in one direction, then in the other, then diagonally.
- 3. Then insert the swab into the test tube and shake for 10 to 15 seconds in the extraction buffer.
- 4. Hermetically seal the tube with the stopper.
- 5. Vigorously shake the tube manually or using a vortex at maximum speed for 25-30 seconds.
- Place the tube vertically on a stand and allow the contents to settle or centrifuge at low speed in a centrifuge, the supernatant is then ready for testing.

Test procedure

- 1. Bring the samples to a temperature between +18 and +35°C.
- 2. Remove the foil pouch (without opening it) and leave it at room temperature for 5 to 10 minutes.
- 3. Open the pouch containing the test strip, taking care not to cut the strip.

4. Grasp the strip by the top colored part and dip the other end vertically into the supernatant in the test tube. Caution: make sure that the strip

is not immersed too deeply - see diagram opposite →

 Soak the strip for 20 to 30 seconds and then place it on a CLEAN, horizontal surface; do not touch or move the strip for 10 minutes while the sample migrates.



6. Read the result and interpret it in accordance with the diagrams and instructions below.

Interpretation of results

The test is positive if 2 red lines appear clearly in the central area of the strip (test line and control line, see below). Ignore the order in which the 2 lines appear and any nuances in color intensity.



The test is negative if a single red line appears (see below): this is the control line which guarantees that the test is working correctly.

If only the test line appears (see below), the test cannot be interpreted, and no result is validated.

If no line appears (see below), the test cannot be interpreted and no result is validated.



In the latter two cases, before starting again with another Disp&FLOW - Soy test, it is important to ensure that all the test preparation, storage and implementation instructions have been followed, as well as the expiry date.



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