

AlerTox[®]•Sticks

Soy PLUS

Immunochromatographic rapid test for qualitative detection of soy antigen in food, kitchens and production facilities.

AlerTox[®] Sticks

Soy PLUS

Contents

1. Intended use	3
2. Introduction.....	3
3. Test sensitivity and specificity	3
4. Kit contents.....	3
5. Other materials not supplied	4
6. Precautions	4
7. Sample handling	4
8. Test procedure for solid foods	4
9. Test procedure for liquid samples.....	5
10. Test procedure for surface analysis	6
11. Interpretation of results.....	7
12. Validation	7

1. Intended use

AlerTox Sticks Soy PLUS is an immunochromatographic rapid test for qualitative detection of soybean antigen in food, kitchens and production facilities.

2. Introduction

Soy (*Glycine max*) is a legume of the *Fabaceae* (also known as *Leguminosae*) family, which includes bean, pea, chickpea, alfalfa and lupin.

Soy allergy can display a variety of symptoms, from a mild oral allergy or hives to severe, life-threatening systemic reactions, i.e. anaphylactic shock or bronchial asthma. Soy is also one of the most frequent targets for genetic modifications and one of the cheapest protein sources in the food industry used for food adulteration. Allergy to soy has an estimated prevalence 0.1%-0.2% in different populations; most of the cases are reported in children.

The Food Allergen Labeling and Consumer Protection Act (FALCPA) identified soy allergy as one of the major food allergies and the presence of soy must be labeled on the package. In the EU, soy and its derivatives are included in the list of allergens established by the European Food Safety Authority, whose presence must be indicated on the label according to Regulation (EU) No. 1169/2011 Annex II.

3. Test sensitivity and specificity

AlerTox Sticks Soy PLUS uses specific antibodies against beta-conglycinin.

AlerTox Sticks Soy PLUS does NOT detect the antigens of related legumes including pea, white bean, chickpea, peanut, lentil and lupine.

The LOD (limit of detection) of AlerTox Sticks Soy PLUS is 1.5 ppm of soy protein. The range of detection (ROD) is 1.5-10,000 ppm. Above this range, the test can present a hook effect. The hook effect can appear as a negative result or a test line with reduced intensity. If a false negative due to hook effect is suspected, repeat the test on a diluted sample. The sensitivity can decrease drastically in processed samples (textured soy etc.). On dry surfaces collected by a wet swab, the LOD is approximately 0.15 µg of soy protein/16 cm². If you need to quantify the amount of antigen, please use AlerTox ELISA Soy (KIT3047).

NOTE!: AlerTox Sticks Soy PLUS is NOT capable of detecting the residues of soybean proteins in soy sauces prepared either by natural enzymatic degradation or by chemical treatment (acid hydrolysis). However, AlerTox Sticks Soy PLUS shows positive reaction in less hydrolyzed soy drinks. The sensitivity of the test decreases with heating of the food (cooking) and in fat-rich environments (e.g., in presence of oil or cream). The kit is not suitable for food that has been sterilized (120°C for >1h). Invalid results can be obtained with food with low pH such as vinegar. If you wish to test vinegar, we recommend to adjust the pH above 2. AlerTox Sticks Soy PLUS cannot detect phospholipids such as soy lecithin, as it designed to detect proteins and peptides. The test is not suitable for raw crustaceans.

4. Kit contents

Component	KIT3097	KIT3098
Sealed container containing soy immunochromatographic sticks	1 (10 sticks)	1 (25 sticks)
Sample collection tubes (tube with yellow cap)	10	25
Sample extraction buffer tubes, 10 mL (tube with blue cap)	10	25
Spoons	10	25
Pipettes (3 mL- only for testing liquid samples)	10	25
Small pipettes	10	25
Swabs (only for testing surfaces)	10	25
Instructions for use	1	1

5. Other materials not supplied

- Grinder, mortar or any other manual or automatic homogenization system to crush the sample
- Scissors
- Optional: digital scale sensitive to 0.1 g

6. Precautions

- The test sticks must be stored at a temperature between 10°C and 30°C (50°F and 86°F).
- Use the test within 10 minutes after opening the container.
- Do not touch the white end of the stick.
- Do not use the test stick if it is broken or damaged.
- All the components of the test kit are disposable; do not reuse them.
- Do not use the test sticks beyond the expiration date.




7. Sample handling

The samples must be brought to a temperature between 18°C and 35°C (64.4°F and 95°F) before use. The test is designed to detect the target antigen in:

- Solid food
- Liquid samples:
Beverages, washwater from cutting equipment and surfaces used in food processing and storage
- Surfaces

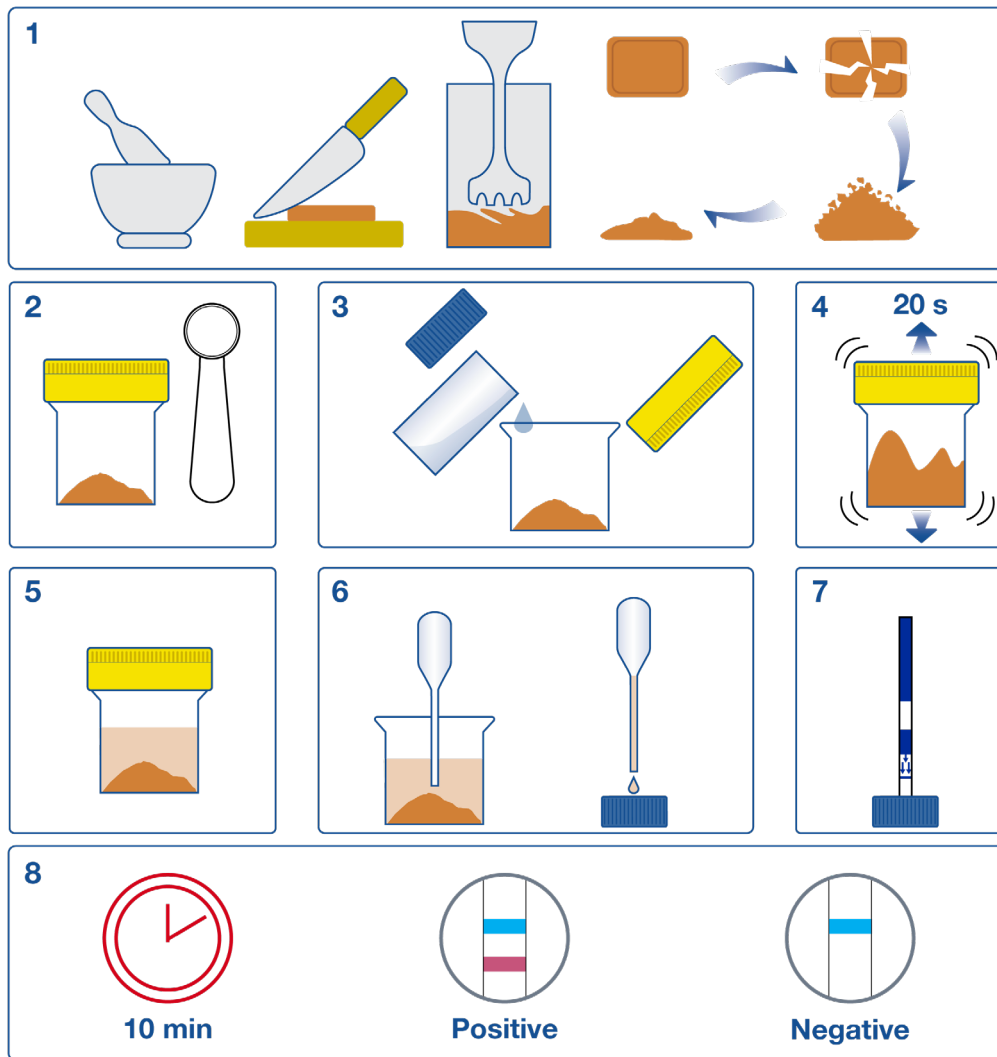
8. Test procedure for solid foods

- 8.1.** Before opening the container containing the test stick, please leave it at room temperature while you process the samples.
- 8.2.** Mash or crush the sample to obtain the finest crumbs possible. Use a mortar or a grinder if possible.
- 8.3.** Use a scale to weigh 1 g of the sample, or follow the chart below to add an equivalent amount of sample to a yellow-capped tube, using one of the single-use spoons provided.

Food type	Examples	Spoonfuls
Flours, fine powders	Corn flour, rice flour, milk powder, spices, etc.	
Fine crumbs	Bread, cookies, cakes, snacks, etc.	
Meat, fish and cured meat	Meat, fish, sausage, black pudding, pâté, canned meat and fish, etc.	

- 8.4.** Pour the entire content of a blue-capped tube (10 mL) into the yellow-capped tube.
Keep the blue cap, as it will be used later on.
- 8.5.** Close the yellow-capped tube and shake it vigorously for at least 20 seconds. Let it rest for 2 minutes so the solids settle.
- 8.6.** With a small pipette, transfer supernatant to the blue cap until it is full.
- 8.7.** Open the container and pull out the stick carefully, by holding its BLUE end. Do **NOT** touch the white end of the stick.
- 8.8.** Place the white end of the stick in the blue cap and wait 10 minutes to read the result. Do not leave the stick longer than indicated, as the results may vary. Do not touch the stick while waiting.

Test procedure for solid foods



9. Test procedure for liquid samples

Liquid samples – beverages, washwaters from kitchen dishes, technological surfaces or cutting machines – may be tested directly. Turbid samples should be filtered (paper or textile filter) or allowed to settle.

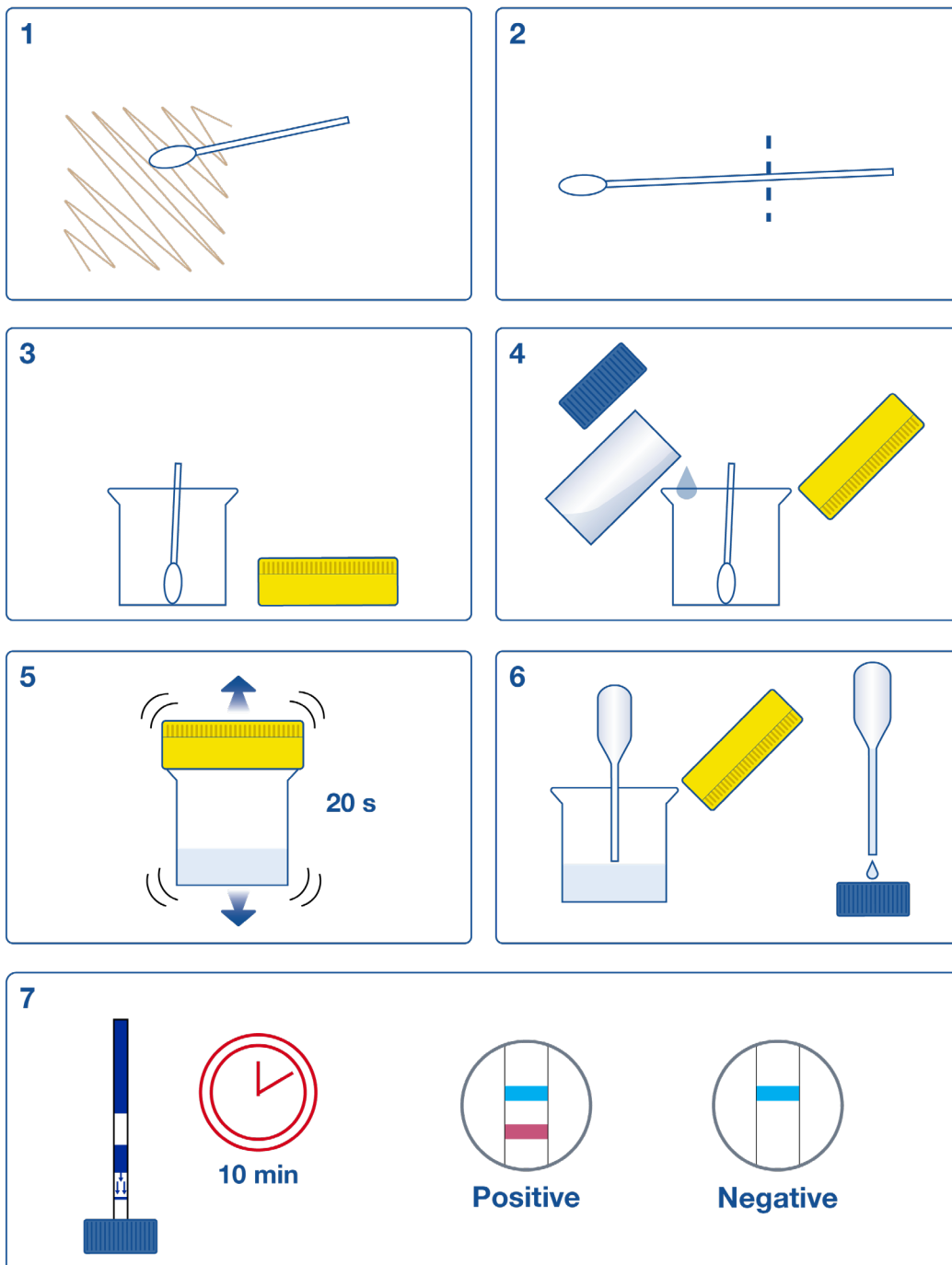
- 9.1. Before opening the container containing the test stick, please leave it at room temperature while you process the samples
- 9.2. Using a provided 3 mL pipette, add 3 mL of your liquid sample to a yellow-capped tube. If the sample is thick (e.g., yogurt, sauce, etc.), follow the chart below to add an equivalent amount of sample to the yellow-capped tube, using one of the single-use spoons provided.
- 9.3. Add an equal volume of sample extraction buffer (3 mL) using the 3 mL pipette, screw the yellow cap and mix by gently shaking the tube for at least 20 seconds. If the liquid is cloudy, let it settle.
Keep the blue cap, as it will be used later on.
- 9.4. With a small pipette, transfer supernatant to the blue cap until it is full.
- 9.5. Open the container and pull out the stick carefully by holding its BLUE end. Do **NOT** touch the white end of the stick.
- 9.6. Place the white end of the stick in the blue cap and wait 10 minutes to read the result. Do not leave the stick longer than indicated, as the results may vary. Do not touch the stick while waiting.

Food type	Examples	Spoonfuls
Liquid and sauces	Milk, juice, condensed milk, yogurt, soup, gravy, sauce, cream, etc.	

10. Test procedure for surface analysis

- 10.1. Firmly rub the swab on the surface that is going to be analyzed (at least 16 cm²/2.46 in², or a line of 40 cm/15.6 in. The area selected for analysis must be representative of the total area of interest.
- 10.2. Introduce the swab into the sample collection tube and, using scissors, trim the swab so that it will fit in the yellow-capped tube with the cap closed.
- 10.3. Pour the entire content of a blue-capped tube (10 mL) into the yellow-capped tube.
Keep the blue cap, as it will be used later on.
- 10.4. Vigorously shake the tube for at least 20 seconds.
- 10.5. With a small pipette, transfer supernatant to the blue cap until it is full.
- 10.6. Open the container and pull out the stick carefully by holding its BLUE end. Do **NOT** touch the white end of the stick.
- 10.7. Place the white end of the stick in the blue cap and wait 10 minutes to read the result. Do not leave the stick longer than indicated, as the results may vary. Do not touch the stick while waiting.

Test procedure for surface analysis



11. Interpretation of results

The result of the test is POSITIVE if TWO colored lines appear: One in the control zone (C) and one in the test zone (T).



The result of the test is NEGATIVE if only ONE colored line is clearly visible, in the control zone (C).



If NO colored line appears in the control zone (C), the test is INVALID.



In the case of an invalid test, repeat the test with another stick, check the correct specimen handling and test procedure, expiry date and storage conditions. Contact your distributor for further details.

IMPORTANT NOTE!

AlerTox Sticks is a qualitative test intended for the screening of samples for internal quality control. Under no circumstances can it replace the quantification test of the laboratory analysis.

12. Validation

AlerTox Sticks Soy PLUS has been validated for the following matrices:

- Meat products
- Flours
- Cereals and infant formula
- Beverages (juice, red wine)
- Baby formula and infant foods
- Soups and sauces
- Snacks
- Shakes, dairy-free drinks and dairy (milk, ice cream and yogurt)
- Energy bars
- Bakery products (biscuits and bread)
- Chocolate
- Pasta
- Salad dressing
- Soy (beans, flour and fermented soy)



Americas:

Hygiena Headquarters

941 Avenida Acaso
Camarillo, CA 93012
1-805-388-8007

Hygiena Canada

2650 Meadowvale Blvd Unit 14
Mississauga, Ontario L5N 6M5
1-833-494-4362 (Toll-free)
or 1-416-686-7962

Hygiena Mexico, S.A. de C.V.

Calle 3 Anegas 409 Bodega 5, Col. Nueva Industrial
Vallejo, Delegación Gustavo A. Madero, C.P. 07700,
CDMX, México.
+52 (55) 5281-4108 y 5281-4146

International:

Hygiena International

8, Woodshots Meadow
Watford, Hertfordshire
WD18 8YU, UK
+44 (0)1923-818821

Hygiena (Shanghai) Trading Co., Ltd.

Rm.7K, No.518, Shangcheng Rd.
Pudong New District
Shanghai, China 200120
+86 21-5132-1081, +86 21-5132-1077,
+86 21-5132-1078

Hygiena Diagnóstica España S.L.

P. I. Parque Plata, Calle Cañada Real 31-35,
41900, Camas, Sevilla, Spain
+34 954-08-1276

www.hygiena.com
enquiries@hygiena.com