AlerTox® Sticks

Soy PLUS

Rapid immunochromatographic test for the qualitative detection of soy antigen in food, kitchens and production facilities.

REF KIT3097, KIT3098

Contents

1. Intended Use

AlerTox® Sticks Soy PLUS is a rapid, immunochromatographic, lateral flow test for the qualitative detection of soybean antigen in food, kitchens and production facilities. Samples that are prepared following the instructions below can only be tested using test strips (sticks) from the AlerTox Sticks Soy PLUS Kit, but not from other AlerTox Sticks kits. Please read all the instructions before beginning the assay.

2. Introduction

Soy (*Glycine max*) is a legume of the Fabaceae (also known as Leguminosae) family, which includes beans, peas, chickpeas, alfalfa and lupines. It is one of the most frequent targets for genetic modifications and one of the cheapest protein sources in the food industry.

Soy allergies can display a variety of symptoms, from mild oral allergies or hives to severe, life-threatening systemic reactions, i.e., anaphylactic shock or bronchial asthma. Allergies to soy have an estimated prevalence of 0.1 – 0.2% in different populations; most of the cases are reported in children.

In the US, 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. The European Food Safety Authority (EFSA) established a list of allergens, including soy and its derivatives, whose presence in foods must be indicated according to Regulation (EU) No. 1169/2011 Annex II.

3. Test Applications, Specificity and Sensitivity

AlerTox Sticks Soy PLUS uses specific antibodies against beta-conglycinin and is suitable for the following applications:

- Food samples
- Rinse water testing
- Surface testing

The limit of detection (LOD) of AlerTox Sticks Soy PLUS is 1.5 ppm of soy protein (1.5 mg of soy protein per kg or L of sample). The range of detection (ROD) is 1.5 – 100,000 ppm of soy protein (mg/kg or mg/L). Overloading (signal decrease) may be seen at 500 – 100,000 ppm; however, no total hook effect (false negative) is observed within this range.

On dry surfaces collected by a wet swab, the LOD is approximately 0.15 µg of soy protein/16 cm^2. View the LOD for surface testing on the Certificate of Analysis (search by lot number at www.hygiena.com/documents).

Section 12 contains the list of matrices currently validated for the kit using an LOD of 1.5 ppm of soy protein.

AlerTox Sticks Soy PLUS does NOT detect the antigens of related legumes, including peas, white beans, chickpeas, peanuts, lentils and lupine. To detect peanuts, use the AlerTox Sticks Peanut Kit (KIT3094).

AlerTox Sticks Soy PLUS is a qualitative assay. To quantify the amount of antigen, use the AlerTox ELISA Soy Kit (KIT3047).

NOTES:

- AlerTox Sticks Soy PLUS *cannot* detect phospholipids (e.g., soy lecithin). It is designed to detect proteins and peptides.
- AlerTox Sticks Soy PLUS *cannot* detect soybean protein residues in soy sauces prepared either by natural enzymatic degradation or by chemical treatment (acid hydrolysis). However, AlerTox Sticks Soy PLUS shows a positive reaction in less hydrolyzed soy drinks.
- The test is not suitable for raw crustaceans.
- The sensitivity can decrease drastically in processed samples (e.g., textured soy). The test sensitivity decreases with heating (cooking) and in fat-rich environments (e.g., in the presence of oil or cream). The kit is not suitable for food that has been sterilized (120 °C for > 1 h).
- Invalid results can be obtained with low-pH foods, such as vinegar. Before testing vinegar, adjust the sample to have a pH between 4 and 10.

- Samples that are very viscous, dense or have a high fat content can migrate incorrectly along the chromatography membrane, affecting the assay results (e.g., weakening or suppressing test and control lines). Contact us for more information, as these sample extractions may require larger dilutions that affect the LOD (www.hygiena.com/support).

4. Kit Contents

Component	KIT3098	KIT3097
Soy immunochromatographic test strips in a sealed container	25 (1 container)	10 (1 container)
Sample collection tubes with yellow caps	25	10
Sample extraction buffer in tubes with blue caps, 10 mL	25	10
Spoons	25	10
Small pipettes	25	10
Pipettes, 3 mL (only for testing liquid samples)	25	10
Swabs (only for testing surfaces)	25	10

5. Other Materials Not Supplied

- Grinder, mortar or any other manual or automatic homogenization system to crush the sample
- Vortex mixer/shaker (recommended, not required)
- Scissors (only for surface sampling)
- Optional: Digital scale (sensitive to 0.1 g)

6. Precautions

- All kit components should be stored at 10 to 30 °C (50 to 86°F).
- When opening the container to remove test strips, only remove the necessary number of test strips and close the container immediately.
- Do **NOT** touch the white end of the test strip.
- Use the test strip within 10 minutes after removal from the container.
- Do not use the test strip if it is broken or damaged.
- Do not use the test strips beyond the expiration date.
- Do not combine components from different kits.
- All test kit components are disposable; do not reuse them.

7. Sample Handling

All samples must be at 18 to 35 °C (64.4 to 95 °F) before use.

The test is designed to detect the target antigen in:

- Solid food
- Liquid samples:
  - Beverages
  - Wash water from cutting equipment
- Surfaces

8. Test Procedure for Solid Food Samples

8.1 Before adding the sample to a yellow-capped tube, mash or crush it to obtain the finest crumbs possible. Use a mortar or a grinder, if possible.

8.2 Add 1 g of the sample to the yellow-capped tube.
Alternatively, follow the chart below to add an equivalent amount of sample, using one of the single-use spoons provided.

Food Type	Examples	Spoonfuls
Flours, fine powders	Corn flour, rice flour, milk powder, spices	2
Fine crumbs	Bread, cookies, cakes, snacks	2
Meat, fish and cured meat	Meat, fish, sausage, black pudding, pâté, canned meat and fish	1

8.3 Pour the entire contents of a blue-capped tube (10 mL) into the yellow-capped tube.
Important: Keep the blue cap, as it will be used later.

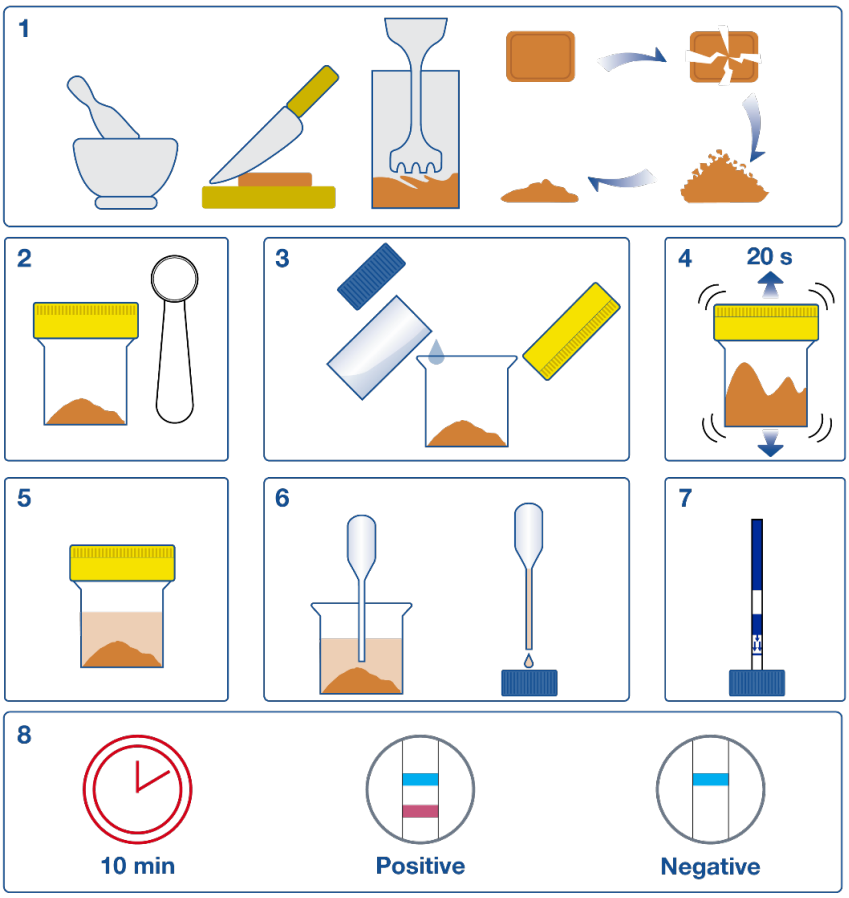
8.4 Close the yellow-capped tube and shake the sample for at least 20 seconds using a vortex mixer to ensure homogenization. Alternatively, shake the tube vigorously by hand.

8.5 Let it rest for 2 minutes so the solids settle.

8.6 Use a small pipette to fill the blue cap with supernatant.
Note: For samples with high fat content, avoid the fat layer of the supernatant.

8.7 Open the container of test strips, carefully remove the needed number of strips by holding the BLUE end and close the container immediately. Then, place the white end of the strip in the blue cap.
Note: Do NOT touch the white end of the test strip.

Workflow for Solid Food Samples



8.8 Wait 10 minutes to read the result.
Note: Do not read results after more than 10 minutes, as results may vary. Do not touch the test strip while waiting.

9. Test Procedure for Liquid Samples

Liquid samples – beverages, wash water 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 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), follow the chart below to add an equivalent amount of sample to the yellow-capped tube, using one of the single-use spoons provided.

Food Type	Examples	Spoonfuls
Liquid and sauces	Milk, juice, condensed milk, yogurt, soup, gravy, sauce, cream	3

Note: Shake the sample to ensure it is homogeneous and that you are taking a representative test portion.

9.2 Add 3 mL of sample extraction buffer from the blue-capped tube to the sample using the 3 mL pipette.
Important: Keep the blue cap, as it will be used later.

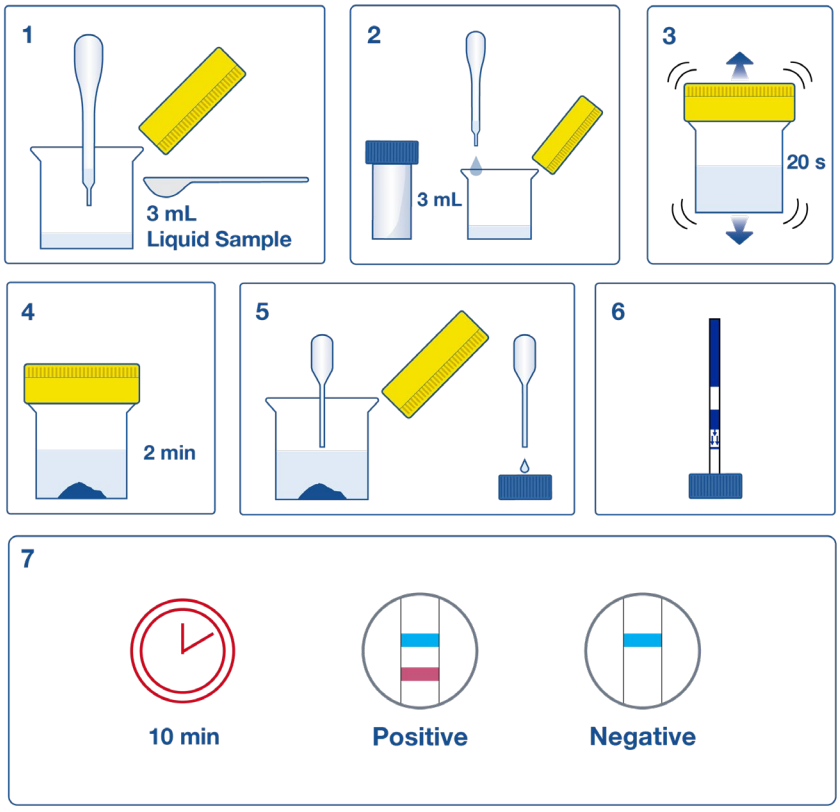
9.3 Close the yellow-capped tube and shake the sample for at least 20 seconds using a vortex mixer to ensure homogenization. Alternatively, shake the tube vigorously by hand.

9.4 If the liquid is cloudy, let it settle for 2 minutes.

9.5 Use a small pipette to fill the blue cap with supernatant.
Note: For samples with high fat content, avoid the fat layer of the supernatant.

9.6 Open the container of test strips, carefully remove the needed number of strips by holding its BLUE end and close the container immediately. Then, place the white end of the strip in the blue cap.
Note: Do NOT touch the white end of the test strip.

Workflow for Liquid Samples



9.7 Wait 10 minutes to read the result.
Note: Do not read results after more than 10 minutes, as results may vary. Do not touch the test strip while waiting.

10. Test Procedure for Surface Analysis

Collect each sample using a clean, unused swab. The swab can be used on working surfaces or equipment.

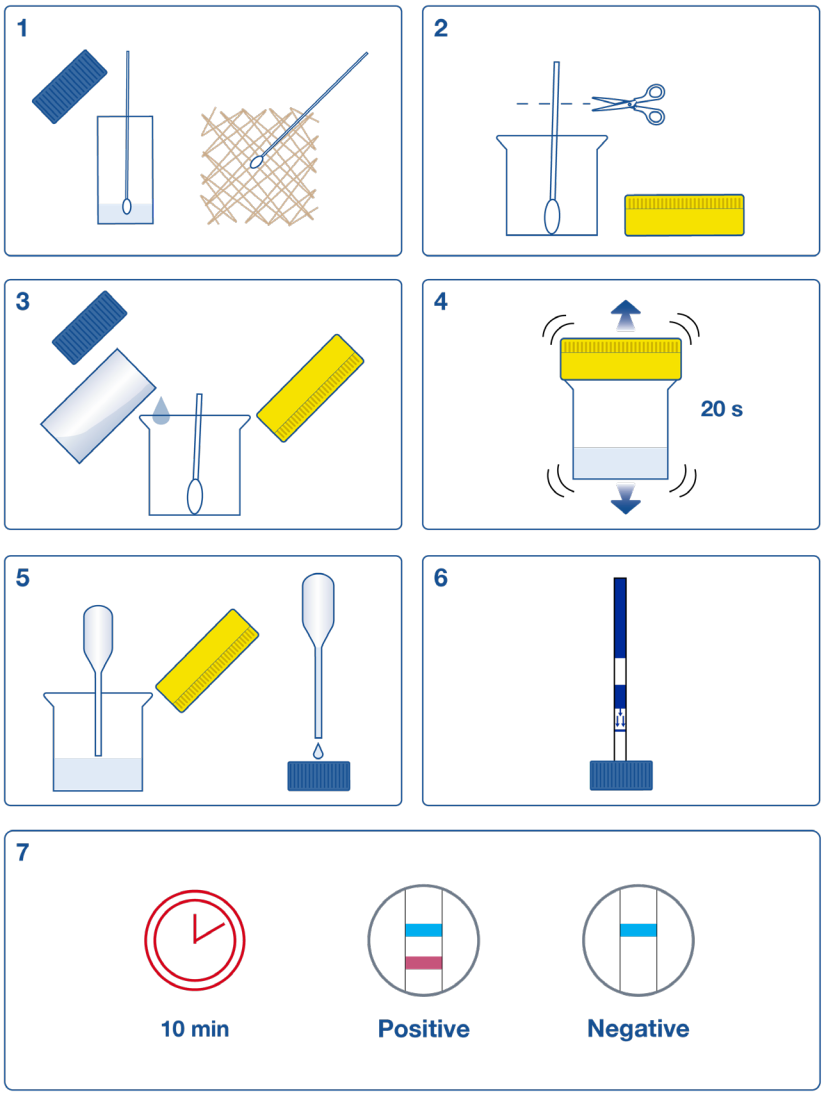
10.1 Wet the swab by dipping it in the blue-capped tube. Then, firmly rub and rotate the swab on the testing surface using a zigzag pattern (at least 16 cm^2/2.5 in^2 or a line of 40 cm/15.6 in).
Note: When possible, swab an approximately 4 cm x 4 cm (1.6 in x 1.6 in) square area. For irregular surfaces, ensure the swabbing technique remains consistent for each test. The area selected for analysis must be representative of the total area of interest.

10.2 Place the swab into the sample collection tube and trim it using scissors.
Note: The swab should fit in the yellow-capped tube when the cap is closed.

10.3 Pour the entire contents of a blue-capped tube (10 mL) into the yellow-capped tube. Then, press the swab tip against the inside wall of the yellow-capped tube to facilitate sample extraction into the buffer.
Important: Keep the blue cap, as it will be used later.

10.4 Close the yellow-capped tube and shake the sample for at least 20 seconds using a vortex mixer to ensure homogenization. Alternatively, shake the tube vigorously by hand.

Workflow for Surface Analysis



10.5 Use a small pipette to fill the blue cap with supernatant.

10.6 Open the container of test strips, carefully remove the needed number of strips by holding the BLUE end and close the container immediately. Then, place the white end of the strip in the blue cap.
Note: Do NOT touch the white end of the test strip.

10.7 Wait 10 minutes to read the result.
Note: Do not read results after more than 10 minutes, as results may vary. Do not touch the test strip while waiting.

11. Interpretation of Results

The test result is POSITIVE if TWO colored lines appear: one in the control zone (C) and one in the test zone (T). The color intensity of the test line may vary, but it is not necessarily proportional to the concentration of soy antigen in the sample.

The test result 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.

If the test is invalid, check for the following and repeat the test with another strip:

- Correct specimen handling
- Correct test procedure
- Expiration date
- Correct storage conditions

For further assistance, contact Hygiena at www.hygiena.com/support.

IMPORTANT NOTE!

AlerTox Sticks is a qualitative test intended to screen samples for internal quality control. Under no circumstances can it replace laboratory analysis testing for quantification.

12. Validation

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

Validated Matrices		
Baby/infant formulas	Dairy-free drinks	Salad dressings
Bakery products (biscuits and breads)	Energy bars	Sauces
Beverages (juice, red wine)	Flours	Shakes
Cereals	Infant foods	Snacks
Chocolate	Meat products	Soups
Dairy (milk, ice cream and yogurt)	Pasta	Soy (beans, flour and fermented soy)

Matrices should be validated before use with AlerTox Sticks Soy PLUS. For additional information about matrix validation, contact Hygiena at www.hygiena.com/support.

13. Disclaimer

Field of use: Use the Hygiena product for research and development, quality assurance and quality control under the supervision of technically qualified persons. The information generated from the Hygiena product is only to be used in conjunction with the user's regular quality assurance program. The Hygiena product should not be used as the sole basis for assessing the safety of products for release to consumers. Data obtained from the Hygiena product must not be used for human diagnostic or human treatment purposes. Before using the product, read the *Limitation of Warranty and Liability* (available in the *Hygiena General Terms and Conditions* at www.hygiena.com/terms-and-conditions).

These products are made from high-quality raw materials. No warranty of any kind is made, either expressed or implied, as to their suitability other than to measure the target antigen content when used exactly in accordance with these instructions, except regarding the quality of these materials.

Use of the kit for any other purpose is outside its intended use. For matrices that have not been previously validated, Hygiena cannot guarantee that the kit is fit for purpose and that the results obtained for these matrices are accurate. Customers may choose to use the product on unvalidated food or surface matrices; however, Hygiena strongly recommends that users perform their own fit-for-use testing to confirm suitability and performance in their specific application. Any damages, including consequential or special damage or expense arising directly or indirectly from using this product, are limited to the replacement value of the kit.

For additional information or assistance with matrix validation, contact Hygiena at www.hygiena.com/support. All Hygiena Terms and Conditions apply and can be found at: www.hygiena.com/terms-and-conditions.

14. Contact Information

For more information, visit www.hygiena.com/contact. For technical support, visit www.hygiena.com/support.

15. Change Index

INS3097 REVA, April 2022
The initial protocol.

INS-KIT3097-3098-001-REVA, July 2025
Updated the ROD. Standardized branding, wording, some graphic workflows and document ID number.

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