hygiena™

AlerTox® Sticks

Peanut

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

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REF KIT3094

AlerTox® Sticks
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Contents

1. Intended use

AlerTox Sticks Peanut is an immunochromatographic rapid test for the qualitative detection of peanut antigen in food, kitchens and production facilities.

2. Introduction

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

Peanut allergy can display a variety of symptoms, from mild oral allergy or hives to severe life-threatening systemic reactions, i.e. anaphylactic shock or bronchial asthma. Peanut-induced anaphylaxis is considered the most fatal among all food allergies. Allergy to peanuts affects more than 0.5% children in the general population.

The Food Allergen Labeling and Consumer Protection Act (FALCPA) identified peanut allergy as one of the major food allergies, and the presence of peanut must be labeled on the package. In the EU, peanuts 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 applications, sensitivity and specificity

AlerTox Sticks Peanut uses a monoclonal antibody against a major peanut antigen.
AlerTox Sticks Peanut is suitable for the following applications:

- Surface testing
- Rinse water testing
- Food samples

Before using AlerTox Sticks Peanut, **please consult Section 12 of this manual** to check for sample compatibility. AlerTox Sticks Peanut **can produce false positive or false negative results** with certain commodities and food ingredients, when present at high levels (> 20g/Kg) in the sample. The list of matrices currently validated for the kit LOD (1 ppm peanut protein) can be found at the end of Section 12.
Please contact Hygiena for matrix validation information.

The LOD (limit of detection) of AlerTox Sticks Peanut is 1 ppm of raw or roasted peanut protein. The range of detection (ROD) is 1-10000 ppm of peanut protein. Above this range, reduction of test line intensity due to hook effect can result in a false negative result. If a false negative due to hook effect is suspected, repeat the test on a diluted sample.

The LOD of AlerTox Sticks Peanut for surface analysis is approximately 4 ug of peanut protein/16 cm^2 on a model, dry surface (stainless steel), sampled with a wet swab.

If you need to quantify the amount of antigen, please acquire AlerTox ELISA Peanut (KIT3048).

4. Kit contents

- 10 immunochromatographic sticks, in a tube
- 10 sample collection tubes (tube with yellow cap)
- 10 swabs (only for testing surfaces)
- 10 sample extraction buffer tubes, 9 mL (tube with blue cap)
- 10 spoons
- 10 pipettes (3mL - only for testing liquid samples)
- 10 small pipettes
- Instructions for use (download from webpage)

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
- Skimmed milk powder (see Section 12)

6. Precautions

- The tube with the test sticks must be stored at a temperature between 10 ºC and 30 ºC (50 ºF and 86 ºF).
- Open the tube with test sticks, take out the number of sticks necessary and close the tube immediately.
- Always manipulate the sticks by holding them by their BLUE end. Do **NOT** touch the white end of the sticks.
- All the components of the test kit are disposable; do not reuse them or combine components from different kits.
- Do not use the test sticks beyond the expiry date.

7. Sample handling

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

- Solid food
- Liquid samples: beverages, rinse water from cutting equipment, and surfaces used in food processing and storage
- Surfaces

8. Test procedure for solid foods

8.1. Before opening the tube containing the test sticks, 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.

The matrices listed in Section 12 requiring skimmed milk powder should be used as follow:

- **Almond: add 2g of skimmed milk powder** to the sample in the yellow-capped tube. Follow the rest of the procedure and **read the result after 60 minutes**. The reading can be performed at 20 min if the extracted sample is paper filtered.
- **Other matrices listed: add 1g of skimmed milk powder** to the sample in the yellow-capped tube. Follow the rest of the procedure and **read the result after 20 minutes**.

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, pâtè, canned meat and fish, etc.	

8.4. Pour the entire content of a blue-capped tube (9 mL) into the yellow-capped tube. Keep the blue cap, as it will be used later on.

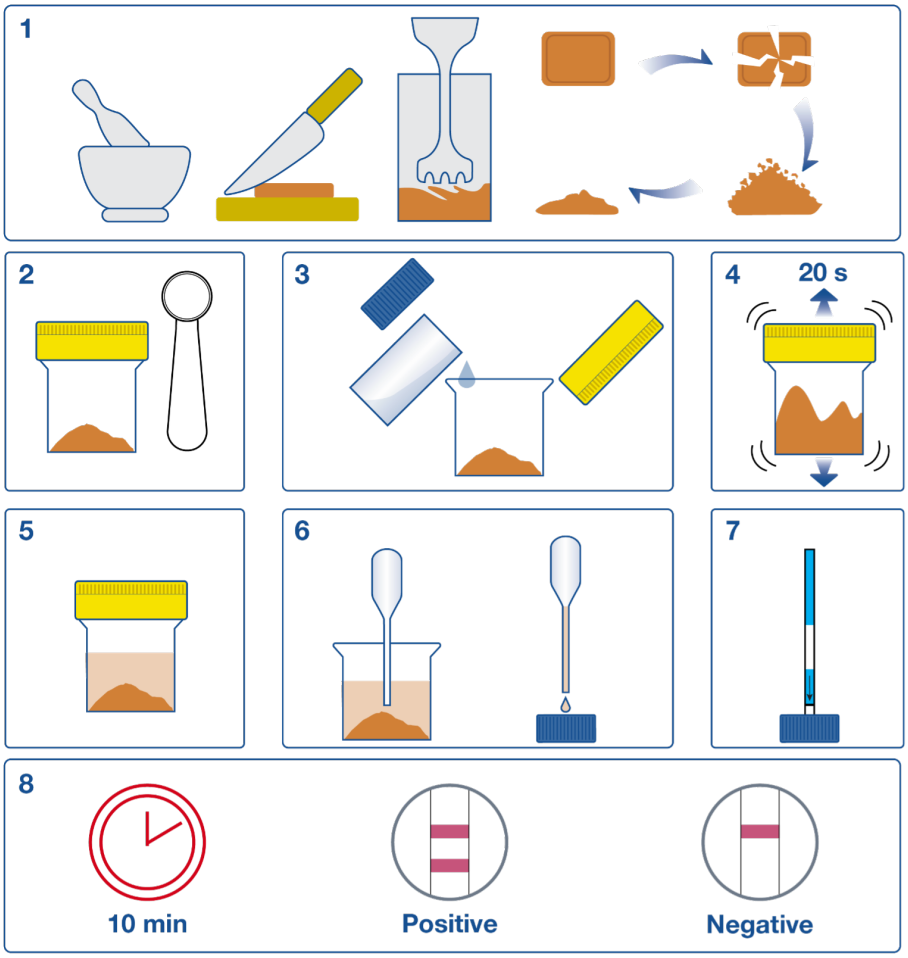
8.5. Close the yellow-capped tube and shake it vigorously for at least 20 seconds. Let it rest for 2 minutes so the solids settle.

8.6. With a small pipette, transfer supernatant to the blue cap until it is full.

8.7. Open the tube containing the test sticks and pull out a 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, rinse 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. Before opening the tube containing the test sticks, please leave it at room temperature while you process the samples.

9.2. Using a provided 3 mL pipette, carefully transfer **1 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. Pour the entire content of a blue-capped tube (9 mL) into the yellow-capped tube 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.

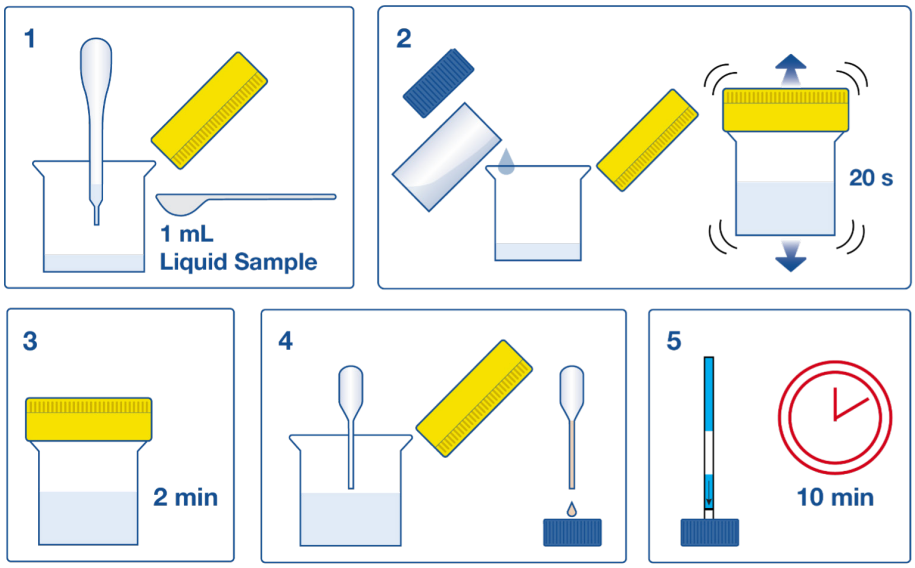
9.4. With a small pipette, transfer supernatant to the blue cap until it is full.

9.5. Open the tube containing the test sticks and pull out a 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.	

Test procedure for liquid samples



10. Test procedure for surface analysis

10.1. Wet the swab by dipping it in the blue-capped tube. Firmly rub the swab on the surface that is going to be analyzed (at least 16 cm^2/2.46 in^2, 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 (9 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 tube containing the test sticks and pull out a 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

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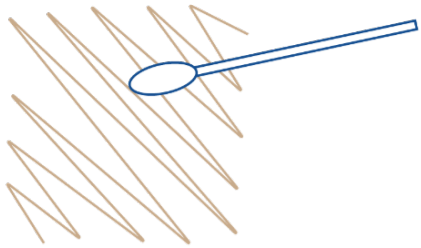

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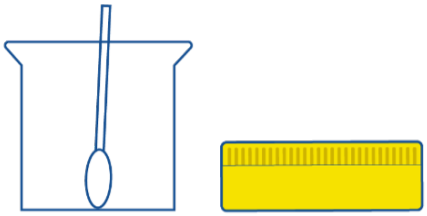

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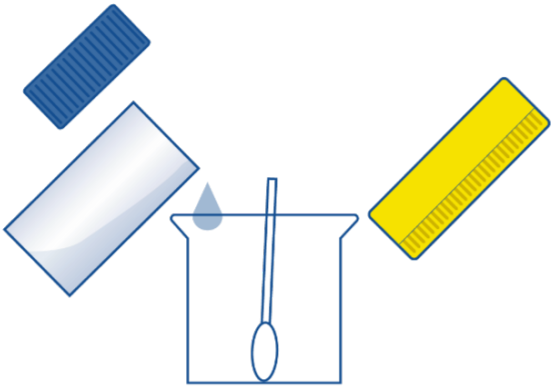

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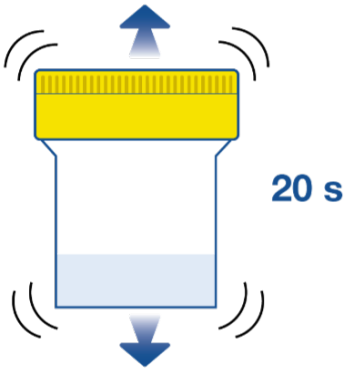

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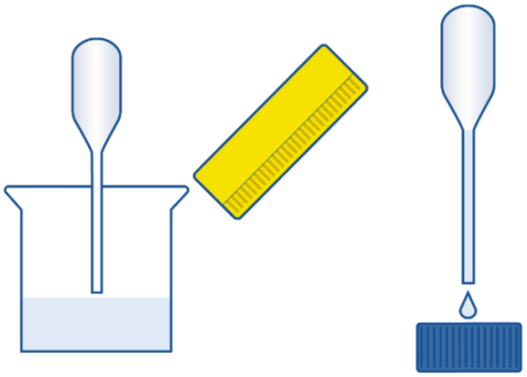

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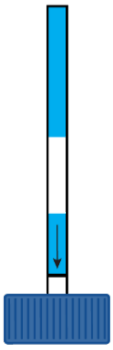

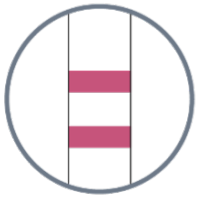

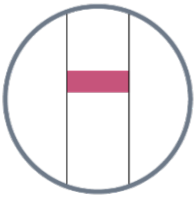

11. Interpretation of results

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 red 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 distibutor 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 Peanut showed no detectable cross-reactivity or interference with the following commodities, when present at 4000 ppm in the extracted sample:

- **Cereals:** barley, buckwheat, wheat, rice, rye, oat, corn.
- **Legumes and vegetables:** soybean, green pea, lima (butter) bean, chickpea.
- **Seeds:** sunflower, pumpkin, sesame, poppy.
- **Tree nuts:** almond, brazil nut, cashew, chestnut, coconut, hazelnut, macadamia, pistachio, pecan, pine nut, walnut.
- **Other:** skimmed milk powder, lecithin, porcine gelatin.

Caution Note: when tested at high concentration (>20 g/kg in food sample before extraction), certain commodities (i.e., barley, rye, oat, lima (butter) bean, pumpkin seed, sesame, almond, coconut, hazelnut, macadamia, pistachio, pecan, pine nut, cocoa, paprika, lemon juice) can cause false positive results that can be prevented by **adding 1g of skimmed milk powder**, together with the sample to be analyzed, to the yellow-capped tube in step 8.3. Follow the rest of the procedure and **read the result after 20 minutes**.

For almond, false positive results can be prevented by **adding 2g of skimmed milk powder**, together with the sample to be extracted, to the yellow-capped tube in **step 8.3**. Follow the rest of the procedure and **read the result after 60 minutes**, or paper filter the extracted sample before testing it and **read the result after 20 minutes.**

Caution Note: The limit of detection (LOD) in samples containing these commodities at high concentration can be higher than 1 ppm peanut protein.

Brazil nut, **buckwheat** and **walnut** are **not suitable** for AlerTox Sticks Peanut when present in the sample at >20 g/kg. Use AlerTox ELISA Peanut (KIT3048).

AlerTox Sticks Peanut has been validated for the following matrices:

• Butter cookies, cow milk, yogurt, ice cream (vegan), whipped cream (vegan), soy milk, soy flour, soy sauce, pâtè, cornstarch, cocoa spread (vegan), muffins (vegan), cream wafers (vegan), snack mix (vegan), onion breadsticks (vegan), chicken nuggets (gluten-free).

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