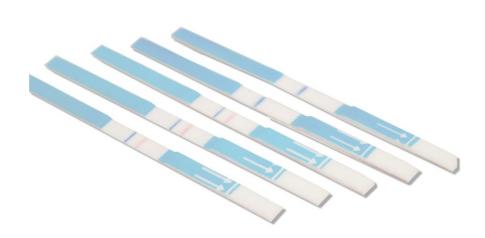


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AlerTox Sticks Hazelnut

Rapid immunochromatographic test for qualitative determination of hazelnut antigen in food, kitchens and production facilities.

Ref: KT-6129





Test for qualitative determination of hazelnut antigen

Contents

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



1. Intended use

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

2. Introduction

Hazelnut is the nut of hazel tree and includes any of the nuts deriving from species of the genus Corylus, especially the nuts of the species Corylus avellana.

Hazelnut 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. Allergy to hazelnut is a common tree nut allergy, most of the cases reported in children.

Hazelnut presence in food is required by the Food Allergen Labeling and Consumer Protection Act (FALCPA) to be labeled on the package. In the EU, tree nuts are included into the list of allergens, established by the European Food Safety Authority, whose presence must be indicated in foods according to Regulation (EU) No. 1169/2011 Annex II.

3. Test sensitivity and specificity

AlerTox Sticks Hazelnut uses a combination of monoclonal antibodies against a major hazelnut antigen, the legumin-like 11S seed storage protein known as allergen Cor a 9).

AlerTox Sticks Hazelnut does NOT detect the antigens of cereals, legumes and other nuts, including walnut, pecan, peanut, almond, cashew nut, macadamia nut, Brazil nut and coconut.

The LOD (limit of detection) of AlerTox Sticks Hazelnut is 20 ppm of hazelnut protein. The range of detection (ROD) is 20-10,000 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.

PLEASE NOTE: AlerTox Sticks Hazelnut does not detect hydrolyzed, low molecular weight fragments of the target protein and therefore it could show a false negative result with fermented hazelnut milk. The sensitivity of the test decreases in an environment rich in fats (for example, in the presence of oil or creams).

If you need to quantify the amount of antigen, please acquire ELISA test Hazelnut (HAZ-E04/HAZ-E01).



4. Kit contents

- 10 immunochromatographic strips individually packed in foil pouches
- 10 sample collection tubes (tube with yellow cap)
- 10 sample extraction buffer tubes, 10 mL (tube with blue cap)
- 10 spoons
- 10 pipettes (3 mL- only for testing liquid samples)
- 10 small pipettes
- 10 swabs (only for testing surfaces)
- Instructions for use

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.
- Use the test within 10 minutes after opening the foil pouch.
- Do not touch the white end of the stick.
- Do not use the test stick when its pouch is torn, or the stick 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 expiry date.

7. Sample handling

The samples must be brought to a temperature between 18 °C and 35 °C 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



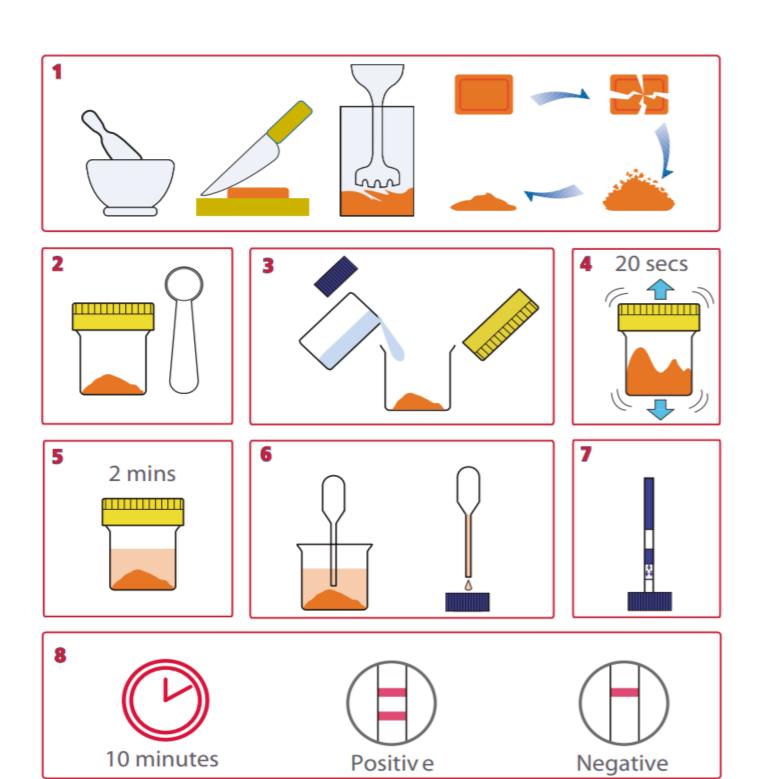
8. Test procedure for solid foods

- 8.1. Before opening the foil pouch containing the test strips, 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 morter 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, pate, canned meat and fish, etc.	

- 8.4. Pour all the content of the 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 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 envelope and pull out the stick carefully, by holding its BLUE end. Do NOT touch the white end of the stick.
- 8.8. Place the strip in the blue cap and wait 10 minutes to read the result. Do not leave the strip longer than indicated, as the results may vary. Do not touch the strip while waiting.

AlerTox® Sticks





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 foil pouch containing the test strips, 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 same pipette, screw the cap and mix by gentle shaking or end-over-end rotation of the tube for 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 envelope 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.	

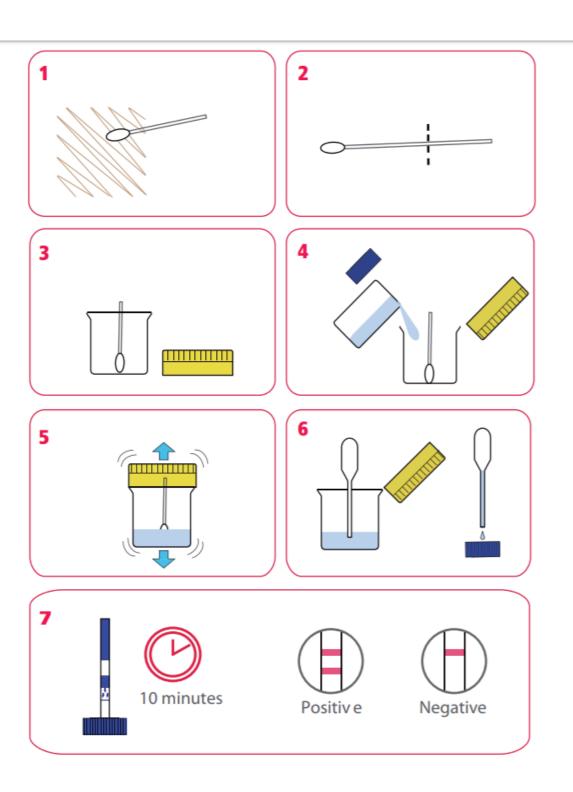


10. Test procedure for surface analysis

- 10.1. Firmly rub the swab on the surface that is going to be analyzed (at least 16 cm², or a line of 40 cm). 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 20 seconds.
- 10.5. With a small pipette, transfer supernatant to the blue cap until it is full.
- 10.6. Open the envelope 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.

See diagram next page

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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 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 Hazelnut has been validated for the following matrices:

- Snacks
- Dairy
- Flours
- Nuts
- Pasta
- Eggs
- Bakery products
- Sauces



Votre interlocuteur en France

LIBIOS SARL

83 Rue Edmond Michelet 69490 Pontcharra-Sur-Turdine France

Tél: +33 (0)4 74 13 03 02

Fax: +33 (0)4 74 05 28 25

Mail: info@libios.fr

Web: www.libios.fr