



Intended use

The AgraStrip® Pro Soy are immunoassays designed for the qualitative analysis of soy residues in food samples. It is suitable for a variety of samples, including raw materials, processed foods, environmental swabs and rinse water.

Minimum performance characteristics

Cut-off value:

Foodstuffs and rinse water: 2 ppm (2 mg/kg) soy*

Swabs: $2 \mu g/25 \text{ cm}^2 \text{ soy}^{**}$

*Determined in extraction buffer and confirmed in a selection of matrices

**Cut-off calculated

Range of detection: 2 - 100,000 ppm (2 - 100,000 mg/kg) soy

Number of tests: 15 strips

Assay time: sample preparation – 1 min

total incubation time – 10 min

About Soy

Soybean (Glycine max) is a legume that has been used for thousands of years as food. With 39% of its mass consisting of protein, it is highly nutritious. Soybean contains several allergens such as Gly m3, Gly m4, Glycinin and Trypsin-inhibitor. Soy allergy is an increasing concern, as allergic reactions to soybean tend to be severe. Soy products are widely used in the food industry as texturizers, emulsifiers and protein fillers. Furthermore, potential cross-contamination with soy during food production cannot always be prevented. Soy therefore represents a real threat to allergic individuals, making the detection of soy and its residues in food products and production lines of utmost importance.

Product information

About AgraStrip® Pro Allergen test kit

AgraStrip® Pro Allergen lateral flow devices are very sensitive immunochromatographic assays designed for the detection of allergen residues in foodstuffs. The test kits use highly purified antibodies raised against the allergens of interest. After extraction, the sample is incubated with the antibodies to form allergen-antibody complexes. Thanks to nanoparticle-conjugates present in the strip, very low amounts of allergen residues can be detected and visualized as a purple band. AgraStrip® Pro Allergen LFD kits can also be used to validate and monitor cleaning procedures using rinse waters and environmental swabs samples. They are easy to use, fast and reliable.

Storage information

The AgraStrip® Pro LFD kits must be stored at room temperature (15-25°C (59-77°F)). Do not freeze. Do not open the product until needed. Store the test strips only in their original packaging. Do not use the kit beyond the expiration date indicated on the package.

Content of the kit

AgraStrip® Pro Allergen LFD kits contain the following items:

- 1 tube containing 15 AgraStrip® Pro Allergen strips
- 1 bottle of 45 mL of ready-to-use extraction buffer
- 1 dropper cap for the bottle of extraction buffer
- 15 extraction tubes with dropper caps
- 15 sterile swabs with pre-scored tips
- 15 incubation vials in a foil pouch
- 1 vial rack

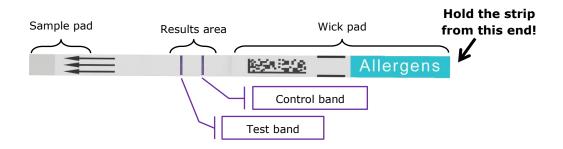
Materials required but not included

Scale, blender, mortar and pestle, or homogenizer

Lateral flow devices – strip components

AgraStrip® Pro Allergen strips consist of three clearly delimited regions: the sample pad, the results area and the wick pad.

- Sample pad: located at the bottom of the test strip and marked by arrows, this is the end that is submerged in the sample.
- Results area: where your results are shown. After the incubation time, it will display up to two purple bands: a control band and a test band.
- Wick pad: this pad serves to ensure a proper flow up the strip and helps to avoid backflow. It also displays a matrix code unique to each strip to facilitate traceability of each test.



Technical information

Sample specifications

Sampling: The food may contain an uneven distribution of allergen residues (spot contamination). It is important to obtain a representative sample of the food as only a small amount of material can be tested with the AgraStrip® Pro Allergen LFD tests.

Effect of pH: Performing the assay within a pH around 7 will lead to reliable results. Highly acidic or alkaline samples can lead to false-positive or false-negative results. If you suspect that your samples could have extreme pH values, please check the pH after sample extraction. Where needed, the pH can be adjusted by adding NaOH or HCl.

Detection: The cut off levels of the AgraStrip[®] Pro Allergen tests is at the low ppm level but will vary depending on the food matrix being tested. To give reliable results, each individual matrix should be validated before the kit is used routinely. Since the assay is for screening purposes, a positive result may require confirmation or further testing. For further information regarding validation, please contact Romer Labs.

Note: The AgraStrip® Pro tests are designed for the detection of trace amounts of allergens. If the sample contains a large percentage of the respective allergen, i.e. more than approx. 1% (10,000 ppm) of the allergen, the test may return a false-negative result.

Technical support

Not sure if the test works with your specific samples or matrices? Let our longstanding experience in food allergen testing work for you. Contact our technical sales representative in your region to learn more.

You can download this product manual as well as the certificates of analysis and performance corresponding to your kit from our website **www.romerlabs.com**.

Sample preparation

Before starting

Procedural guidelines:

- Make sure you have everything you need ready before starting the assay.
- All reagents and samples should be at room temperature, i.e. 15-25°C (59-77°F), before
- Use the incubation times stated in the procedure. Using incubation times other than those specified may return inaccurate results.

Precautions:

- The components in this test kit have been subjected to quality control tests as a standard batch unit. Do not mix or interchange components from different lots.
- Due to the high risk of cross-contamination, all instruments must be cleaned thoroughly before sample preparation. Follow the instructions for test procedures.
- Cover or cap all reagents when not in use and dispose of all materials and containers properly after use.

Foodstuff, liquid and rinse water samples

1.



Obtain a representative sample of the specimen you want to analyze and homogenize it using a blender or a mortar and pestle. For rinse water samples, proceed to step 2.



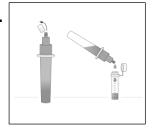
Add **0.2 mL** rinse water (or liquid sample) or weigh in **0.2 g** of homogenized sample into the extraction tube.

3.



Fill the extraction tube with **extraction buffer** up to the neck of the tube, as indicated by the arrow. Close the tube with the dropper cap and vigorously shake by hand for 1 minute. You can press the tube to help the suspension of the sample.

4.



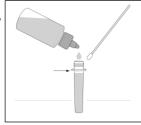
Remove the smaller cap to open the dropper tip, and transfer **6 drops** or **200 \muL** into an incubation vial and close the lid.

Continue to page 6 (Assay procedure)

Note: Chocolate and fine powder samples may impair the flow of the sample This can be avoided by allowing the particles to settle after shaking.

Swab samples

1.



Fill one extraction tube with **extraction buffer** up to the bottom of the neck of the tube, as indicated by the arrow. Take a swab and wet its sampling end by dipping it into the buffer.

2.

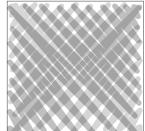


Wipe an area of **5 cm x 5 cm** using side-to-side movements, rotating the swab tip as you go. We recommend the "cross-hatch" swabbing technique indicated below.









3.



Place the swab into the extraction tube. Carefully break off the end at the pre-scored point. Close the tube with a cap and shake vigorously for **1 minute**.

4.



After shaking, remove the cap from the extraction tube and replace it with a dropper tip. Transfer **6 drops** or **200 \muL** into an incubation vial and close the lid.

Continue to page 6 (Assay procedure)

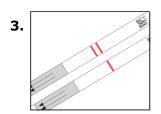
Assay procedure

1.

Shake the incubation vial vigorously by hand for **15 seconds**, making sure that the liquid comes in contact with the lid of the vial. Tap the base onto a surface to ensure that no liquid is remaining in the lid. Let the vial incubate on the rack at room temperature for **5 minutes**.

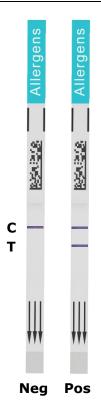
2.

Take one AgraStrip® Pro Allergen strip from its container and place it vertically (arrows point downwards) into the incubation vial. Incubate for **5 minutes.**



Remove the test strip **directly after the 5-minute** incubation period and read the result immediately.

Interpretation of results



It is important to read the results **immediately after the 5-minute incubation step**. Longer incubation times can lead to false-positive results. The AgraStrip® Pro Allergen LFD kits have been extensively validated and show reliable results after that exact time.

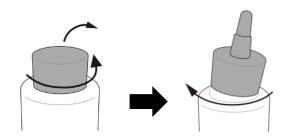
Negative result: Only the control band (C) appears in the results area of the test strip.

Positive result: The control band (C) and the test band (T) appear in the results area of the test strip. This means that the sample contains the target allergen in a concentration higher than the cutoff value and further investigations should be performed (e.g. quantification of the allergen using AgraQuant® Allergen ELISA kits).

Invalid result: No control band appears. Regardless of whether the test band (T) appears, in the case of an invalid result, please repeat the procedure with a new strip. If the problem persists, please contact Romer Labs before continuing.

General information

Handling of the new improved AgraStrip® Pro extraction buffer bottles



When opening a bottle for the first time, please take off the cap and replace it with the dropper cap provided with the kit



To open the bottle just hold the neck of the upper part with your fingers and twist the rigged top screw counterclockwise.

To close the bottle, twist the top screw clockwise.

Contact information

You can find worldwide contact information and learn more about our complete line of products for allergen testing on our website.

Visit us at www.romerlabs.com

Or contact us at:

Romer Labs Division Holding GmbH

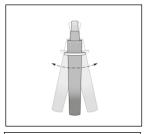
Technopark 5
3430 Tulln, Austria
T: +43 2272 61533
office.romerlabseu@dsm.com

Warranty statement

The user assumes all risk in using Romer Labs products and services. Romer Labs will warrant that its products and services meet all quality control standards set by Romer Labs, and Romer Labs will, at its option, repair or replace any product, components, or repeat services which prove to be defective in workmanship or material within product specific warranty periods or expiration dates and which our examination shall disclose to our satisfaction to be defective as such. This warranty is expressly in lieu of all other warranties, expressed or implied, as to description, quality, merchantability, fitness for any particular purpose, productiveness or any other matter. Romer Labs shall be in no way responsible for the proper use of its products. Romer Labs hereby disclaims all other remedies, warranties, guarantees or liabilities, expressed or implied, arising by law or otherwise, and it shall have no liability for any lost profits or damage, direct, indirect or otherwise, to person or property, in connection with the use of any of its products or services. This warranty shall not be extended, altered or varied except by a written instrument signed by an authorized representative of Romer Labs.

Instructions at a glance

1.



Prepare and extract your foodstuff, liquid, swab or rinse water sample as indicated in the product manual.

2.



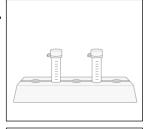
Transfer **6 drops** of extract to an incubation vial.

3.



Shake the incubation vial vigorously by hand for **15 seconds**.

4.



Tap the base of the vial onto a surface to ensure that no liquid is remaining in the lid. Let it incubate on the rack at room temperature for **5 minutes**.

5.



Insert a test strip into the solution and incubate at room temperature for 5 minutes. Read the result immediately.

 $^{\circ}$ 2023 by Romer Labs, All Rights Reserved. This document is the property of Romer Labs Division Holding. 10007070 Product manual, issued version no. 1.

