

Product Manual

AgraStrip® Pro Gluten **Article number 10007062**

Intended use

The AgraStrip® Pro Gluten is an immunoassay designed for the qualitative analysis of gluten 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: 4 ppm (4 mg/kg) gluten*

Swabs: 4 µg/25 cm² gluten**

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

**Cut-off calculated

Range of detection: 4 - 4,000 ppm (4 - 4,000 mg/kg) gluten

Number of tests: 15 strips

Assay time: sample preparation – 1 min
total incubation time – 10 min

About Gluten

Gluten is a group of storage proteins from cereals (in particular wheat, rye, barley and related species) that consists of prolamins (in wheat: gliadin) and glutelins (in wheat: glutenins). Coeliac disease is a complex enteropathy caused by the exposure of predisposed individuals to gluten. It is a life-long disease; persons suffering from it experience severe symptoms when consuming even very small amounts of gluten. Gluten is widely used as a binder in food products due to its physicochemical characteristics. Moreover, cross-contamination of food products and production lines with gluten is often observed. The detection of gluten in products and production lines is therefore of utmost importance. To comply with Codex Standard 118-1979, products labeled “gluten-free” must have gluten levels below 20 mg/kg, while those specially processed to reduce gluten content must keep their levels between 20 and 100 mg/kg.

Product information

About AgraStrip® Pro Allergen test kits

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

AgraStrip® Pro Allergen 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 test 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 bottle of 16 mL of ready-to-use dilution buffer
- 1 dropper cap for the bottle of extraction buffer
- 30 extraction tubes with dropper caps
- 15 sterile swabs with pre-scored tips
- 15 incubation vials in a foil pouch
- 1 vial rack

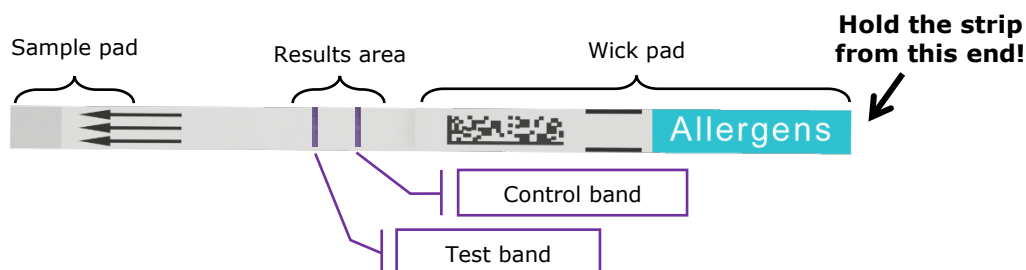
Materials required but not included

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 detection limit of the AgraStrip® Pro Allergen test 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 Allergen 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. Please always shake the extraction buffer before use. It may appear cloudy and exhibit an unpleasant smell. This is normal and have no effect on the performance of the kit.

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:

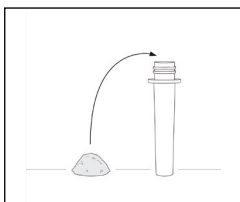
- Make sure you have everything you need ready before starting the assay.
- All reagents and samples should be at room temperature, i.e., 15-25°C (59-77°F), before use.
- Use the incubation times stated in the procedure. Using incubation times other than those specified may return inaccurate results.

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.

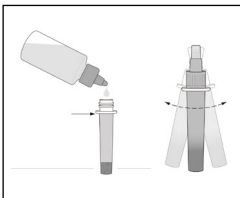
Foodstuff, liquid and rinse water samples

1.



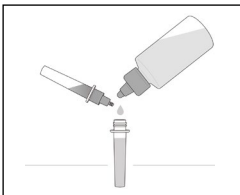
Homogenize a representative sample of the specimen you want to analyze using a blender or a mortar and pestle. Add **0.2 mL** rinse water (or liquid sample) or weigh in **0.2 g** of homogenized sample into the extraction tube.

2.



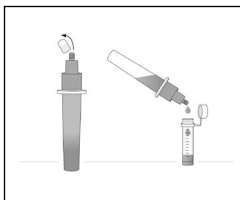
Shake the extraction buffer before use. Fill the extraction tube with **extraction buffer** up to the neck of the tube, as indicated by the arrow. Close the tube with the dropper cap and vigorously shake by hand for 1 minute. You can press the tube to help the suspension of the sample.

3.



Remove the smaller cap to open the dropper tip, and transfer **6 drops** or **200 µL** to a fresh extraction tube. Add **24 drops (800 µL)** of dilution buffer. Close the tube with a fresh cap and shake vigorously by hand for **15 seconds**.

4.



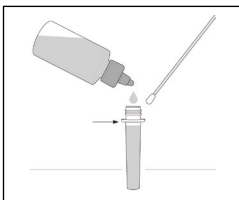
Remove the smaller cap to open the dropper tip, and transfer **6 drops** or **200 µL** into an incubation vial and close the lid.

Continue to step 6 in page 6 for the regular assay procedure.
Continue to step 6 in page 7 for application on the AgraVision™ Pro reader.

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

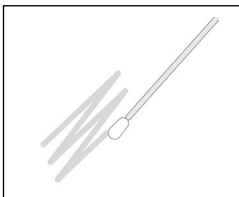
Swab samples

1.

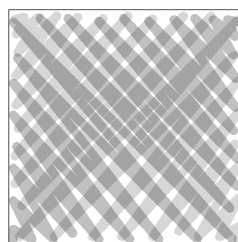
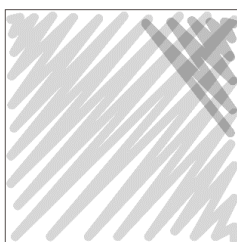
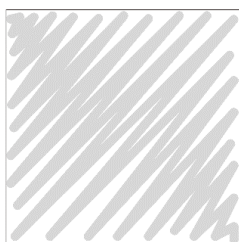
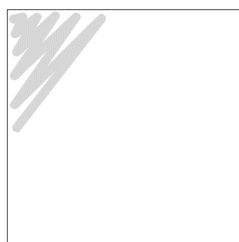


Fill one extraction tube with **extraction buffer** up to the neck of the tube, as indicated by the arrow. Take a swab and wet its sampling end by dipping it into the buffer

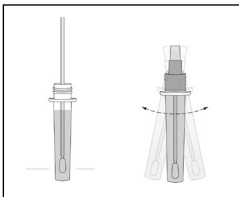
2.



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.

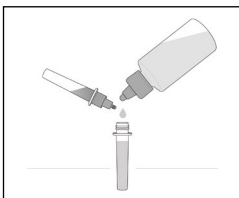


3.



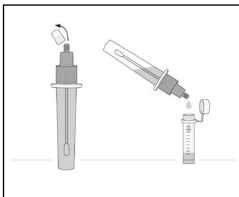
Place the swab into the extraction tube. Carefully break off the end at the pre-scored point. Close the tube with a cap and shake vigorously for **1 minute**.

4.



Remove the smaller cap to open the dropper tip, and transfer **6 drops** or **200 µL** to a fresh extraction tube. Add **24 drops (800 µL)** of dilution buffer. Close the tube with a fresh cap and shake vigorously by hand for **15 seconds**.

5.

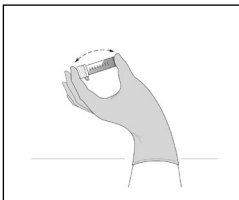


Remove the smaller cap to open the dropper tip, and transfer **6 drops** or **200 µL** into an incubation vial and close the lid.

Continue to page 6 for the regular assay procedure.
Continue to page 7 for application on the AgraVision™ Pro reader.

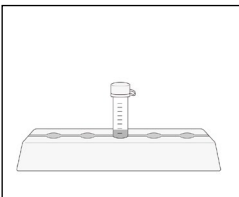
Assay procedure

6.



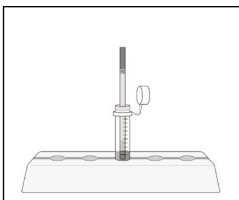
Shake the incubation vial vigorously by hand for **15 seconds**, making sure that the liquid comes in contact with the lid of the vial. Tap the base onto a surface to ensure that no liquid is remaining in the lid.

7.



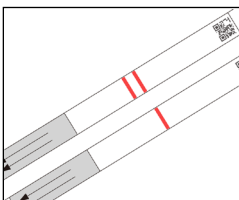
Let the vial incubate on the rack at room temperature for **5 minutes**.

8.



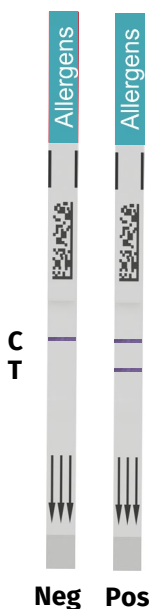
Take one AgraStrip® Pro Allergen strip from its container and place it vertically (arrows point downwards) into the incubation vial. Incubate for **5 minutes**.

9.



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.

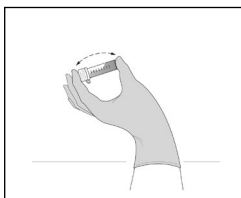
Positive result: The control band (C) and the test band (T) appear in the results area of the test strip. This means that the sample contains the target allergen in a concentration higher than the cut-off value and further investigations should be performed (e.g., quantification of the allergen using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

Application on the AgraVision™ Pro reader*

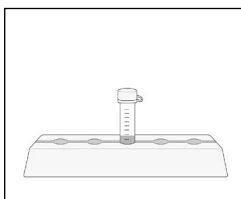
Note: We recommend powering on the AgraVision™ Pro reader, selecting the appropriate testing target, and scanning the relevant QR cards as detailed in the manual before starting the **sample preparation** process.

6.



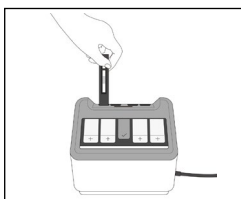
Shake the incubation vial vigorously by hand for **15 seconds**, making sure that the liquid comes in contact with the lid of the vial. Tap the base onto a surface to ensure that no liquid is remaining in the lid.

7.



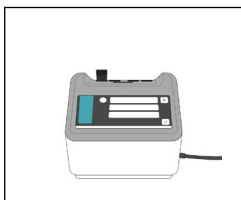
Let the vial incubate on the rack at room temperature for **5 minutes**. Proceed with steps 8., 9. and 10. while the sample is incubating.

8.



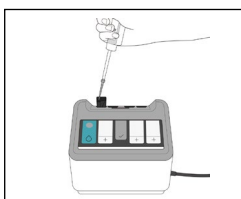
Insert a test strip into the AgraVision™ Pro cartridge. Insert the cartridge containing the test strip into any empty port/slot within the AgraVision™ Pro reader. If the QR card for the respective strip lot has not been scanned previously, you will be prompted to do so at this point.

9.



Enter the sample ID and select your analyte from the drop-down menu, if not already selected. Then, tap the tick mark. A flashing drop symbol indicates that the cartridge is ready to receive the sample.

10.



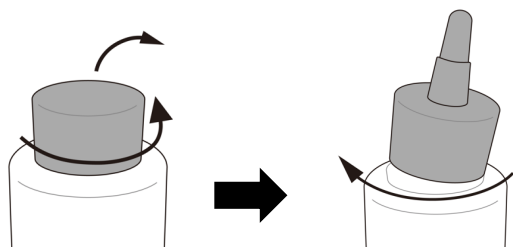
After completing the 5-minute incubation (step 6), use a pipette to extract the entire sample (minimum of 150 µl) from the incubation vial and transfer it into the back of the AgraVision™ Pro cartridge. The reader will then begin the incubation process. The result will be displayed after **5 minutes**.

You can read the results directly from the reader, print them, export them as .csv files into an USB drive. If the reader is connected to a computer directly or through a network, you can also manage your data with the Romer Labs Data Manager. This software allows you to automatically collect all test results from the connected reader, visualize the individual test strips, create PDF reports for individual test results, export results as .csv files and more. For detailed information on how to use the reader and the Romer Labs Data Manager, please read the User Manual of the AgraVision™ Pro reader.

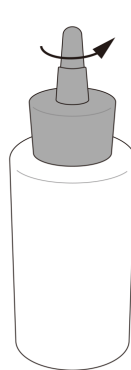
*Currently applicable to environmental samples (swabs, rinse water, CIP, etc.)

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-firmenich.com

Disclaimer/Warranty

The user or buyer assumes all risk in using Romer Labs® products and services.

Romer Labs® makes no warranty of any kind, either expressed or implied, except that the materials from which its products are made are of standard quality.

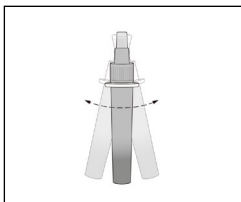
If any materials are defective, Romer Labs® will, at its own discretion and option, repair or replace any product or components, or repeat services, which are proven to be defective in workmanship or material within its warranty periods. There is no warranty of merchantability of the products, or of the fitness of the product for any purpose.

Romer Labs® shall not be liable for any damages, including special or consequential damage, lost profits or expenses arising directly or indirectly from the use of its products or services.

Excepting the aforementioned, Romer Labs® hereby disclaims all other remedies, warranties, guarantees or liabilities, expressed or implied, arising by law or otherwise.

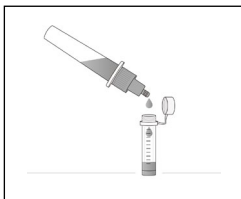
Instructions at a glance

1.



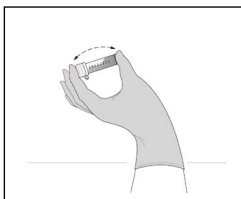
Prepare, extract and **dilute** your foodstuff, liquid, swab or rinse water sample as indicated in the product manual.

2.



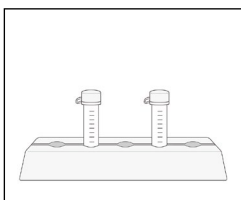
Transfer **6 drops** of extract to an incubation vial.

3.



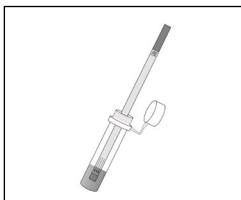
Shake the incubation vial vigorously by hand for **15 seconds**.

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.**