



## **AgraStrip® Gluten**

Package insert  
Article number 10002000

### **Intended use**

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The AgraStrip® Gluten lateral flow device is an immunoassay designed for the qualitative analysis of gluten residues in food samples. Samples can vary from raw to processed foods, from environmental swabs to rinse water.

### **Minimum performance characteristics**

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#### **Limit of detection (LOD):**

Foodstuffs and rinse water: 4 ppm (4 mg/kg) gluten\*  
Swabs: 4 µg/25 cm<sup>2</sup> gluten\*\*

\*LOD was determined in extraction buffer

\*\*LOD was calculated

**Range of detection:** 4 – 10,000 ppm (4 – 10,000 mg/kg) gluten

**Number of tests:** 10 strips

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

### **About Gluten**

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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® Gluten test kit

The AgraStrip® Gluten lateral flow devices are very sensitive immunochromatographic assays designed for the detection of gluten residues in foodstuffs. The test kit uses highly purified polyclonal antibodies raised against gluten. 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 gluten residues can be detected and visualized as a purple line. AgraStrip® Gluten can also be used to validate and monitor cleaning procedures using rinse waters and environmental swabs samples. It is easy to use, fast and reliable.

## Storage information

The AgraStrip® Gluten test kit 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

The AgraStrip® Gluten test kit contains the following items:

- 1 tube containing 10 AgraStrip® Gluten strips
- 1 big bottle of 35 mL of ready-to-use extraction buffer
- 1 small bottle of 10 mL of ready-to-use dilution buffer
- 20 extraction tubes
- 20 caps for the extraction tube
- 20 dropper tips for the extraction tube
- 10 sterile swabs with pre-scored tips
- 10 incubation vials in a foil pouch
- 1 vial rack

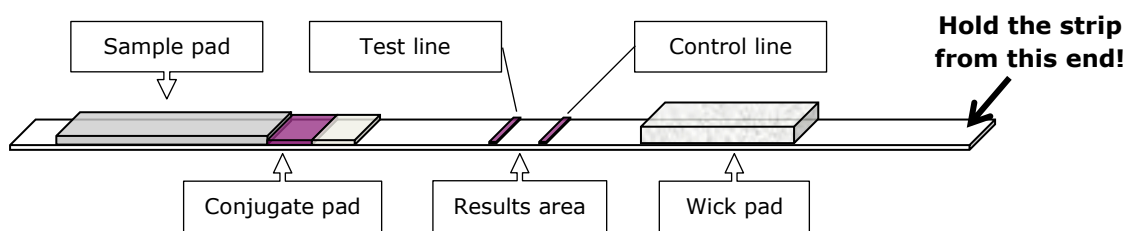
## Materials required but not included

- Blender, mortar and pestle, or homogenizer

## Lateral flow devices – strip components

AgraStrip® Gluten strips consist of four clearly delimited regions: the sample pad, the conjugate pad, the results area and the wick pad.

- Sample pad: located at the bottom of the test strip, this is the end that is submerged in the sample.
- Conjugate pad: presents a purple color given by the gold nano-particles that it contains.
- Results area: where your results are shown. After the incubation time, it will display up to two purple lines: a control line and a test line.
- Wick pad: this pad serves to ensure a proper flow up the strip and helps to avoid backflow.



# Technical information

## Sample specifications

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**Sampling:** The food may contain an uneven distribution of gluten 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® Gluten test.

**Effect of pH:** Performing the assay within a pH range of 6-8 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® Gluten 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® Gluten 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

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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 package insert as well as the certificates of analysis and performance corresponding to your kit from the customer resources section on our website [www.romerlabs.com](http://www.romerlabs.com).

## Important Information

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The results area of the strip can turn pink during testing. In this case, the test line could appear as a white line on a pink background. This indicates a negative test result, and does not affect the performance of the test.

# Sample preparation

## Before starting

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### Procedural guidelines:

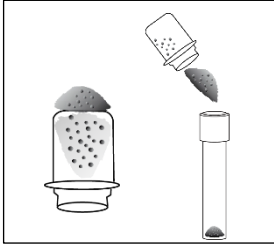
- Make sure you have everything you need ready before starting the assay.
- All reagents and kit components must be equilibrated to room temperature, i.e. 15-25°C (59-77°F), before use.
- Use the incubation times stated in the procedure. Using incubation times other than those specified may return inaccurate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

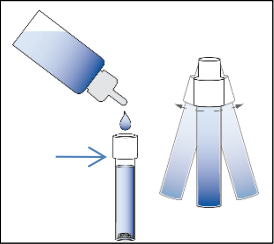
### Precautions:

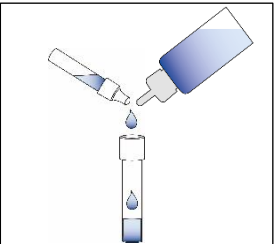
- The components in this test kit have been subjected to quality control tests as a standard batch unit. Do not mix or interchange components from different lots.
- Due to the high risk of cross-contamination, all instruments must be cleaned thoroughly before sample preparation. Follow the instructions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

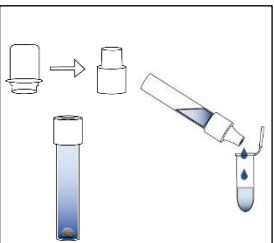
## Foodstuff, liquid and rinse water samples

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1. Homogenize a representative sample of the specimen you want to analyze using a blender or a mortar and pestle. Weigh in **0.2 g** of homogenate (or **0.2 mL** rinse water) into the extraction tube. Alternatively, you can estimate this amount by filling up one extraction tube cap and then transferring the sample into the extraction tube.
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2. Shake the extraction buffer before use, and then fill the extraction tube with **extraction buffer** up to the bottom of the neck of the tube, as indicated by the arrow. Then, close the tube with the cap and vigorously shake by hand for **1 minute**.
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3. Replace the cap with a dropper tip and transfer **6 drops** or **200 µL** to a fresh extraction tube. Add **12 drops (800 µL)** of dilution buffer. Close the tube with a fresh cap and shake vigorously by hand for **15 seconds**.
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4. After shaking, remove the cap from the extraction tube and replace it with a fresh dropper tip. Then, transfer **12 drops** or **400 µL** to an incubation vial and close the lid.

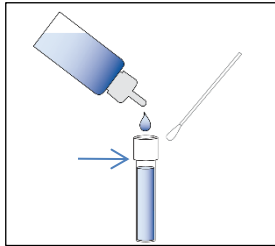
**Continue to page 6 (Assay procedure)**

**Note:** Chocolate and flour samples may block the filter tip of the extraction tube. This can be avoided by allowing the particles to settle after shaking or transferring the extract directly from the extraction tube to the incubation vial using a pipette.

## Swab samples

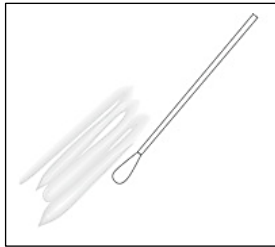
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1.

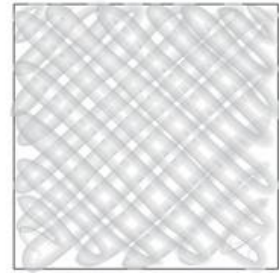
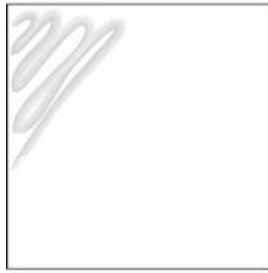


Fill one extraction tube with **extraction buffer** up to the bottom of the neck of the tube, as indicated by the arrow. Take a swab and wet its sampling end by dipping it into the buffer.

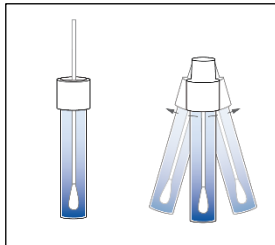
2.



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.

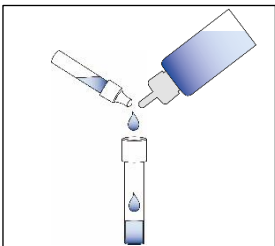


3.



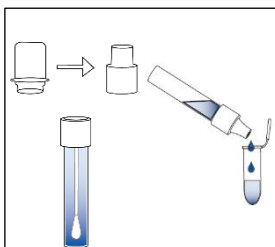
Place the swab into the extraction tube. Carefully break off the end at the pre-scored point. Close the tube with a cap and shake vigorously for **1 minute**.

4.



Replace the cap with a dropper tip and transfer **6 drops** or **200 µL** to a fresh extraction tube. Add **12 drops (800 µL)** of dilution buffer. Close the tube with a fresh cap and shake vigorously by hand for **15 seconds**.

5.

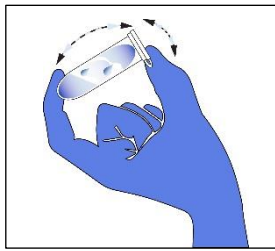


After shaking, remove the cap from the extraction tube and replace it with a dropper tip. Transfer **12 drops** or **400 µL** into an incubation vial and close the lid.

**Continue to page 6 (Assay procedure)**

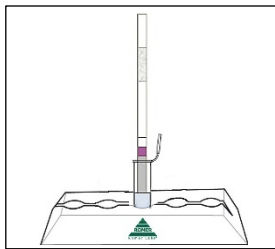
## Assay procedure

1.



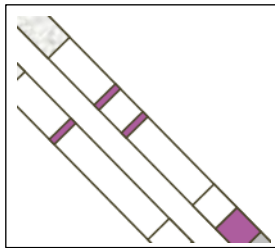
Shake the incubation vial vigorously by hand for **15 seconds**, making sure that the liquid comes in contact with the lid of the vial. Place the vial on the vial rack and let it rest at room temperature for **5 minutes**.

2.



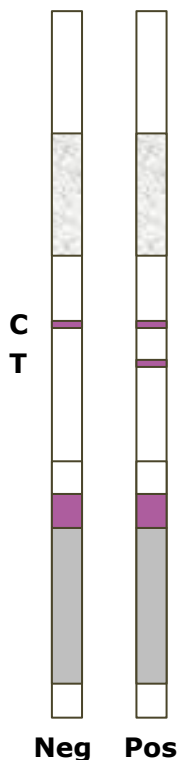
Take one AgraStrip® Gluten test strip from its container and place it vertically (sample pad downwards) into the incubation vial. Incubate for **5 minutes**.

3.



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® allergen test kits have been extensively validated and show reliable results after that exact time.

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

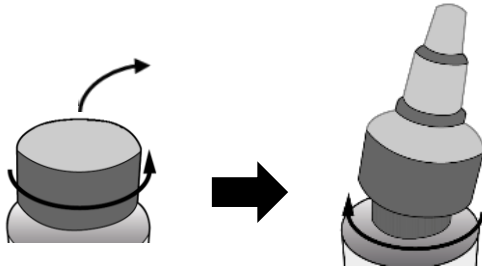
**Positive result:** The control line (C) and the test line (T) appear in the results area of the test strip. This means that the sample contains the target allergen in a concentration higher than the LOD and further investigations should be performed (e.g. quantification of the allergen using AgraQuant®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

**Invalid result:** No control line appears. Regardless of whether the test line (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.

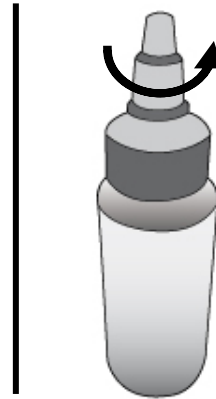
# General information

## Handling of the new improved AgraStrip® extraction buffer bottles

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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

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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](http://www.romerlabs.com)

Or contact us at:

### Romer Labs Division Holding GmbH

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3430 Tulln, Austria  
T: +43 2272 61533  
[office-europe@romerlabs.com](mailto:office-europe@romerlabs.com)

## Warranty statement

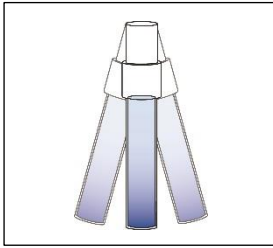
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The user assumes all risk in using Romer Labs products and services. Romer Labs will warrant that its products and services meet all quality control standards set by Romer Labs, and Romer Labs will, at its option, repair or replace any product, components, 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

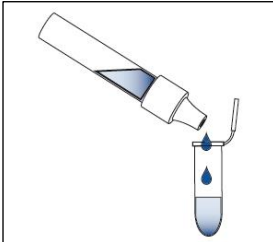
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1.



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

2.



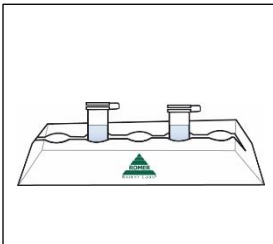
Transfer 12 drops of **diluted extract** to an incubation vial.

3.



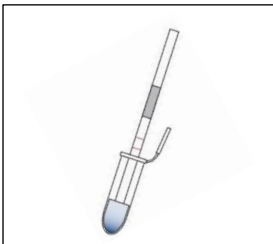
Shake the incubation vial vigorously by hand for **15 seconds**

4.



Incubate 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.**