



AgraStrip® Gluten G12™ test kit

Package insert

Article number 10001995

Intended use

The AgraStrip® Gluten G12™ lateral flow device is an immunoassay designed for the qualitative analysis of gluten content in food samples. Samples can vary from raw to processed foods, from environmental swabs to rinse water. This product is intended for laboratory use.

Minimum performance characteristics

Limit of detection (LOD): Foodstuffs: 5, 10 or 20 ppm (mg/kg) gluten*
Rinse Water: 35 ppb (µg/L) gluten*
Swabs: 4 µg/25 cm² gluten**

* LOD was determined in extraction buffer

** LOD was calculated

Number of tests: 10 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. The onset of the disease has been linked to the presence of one particular 33-mer peptide from gliadin. The G12 antibody detects this immunogenic peptide, ensuring that the most relevant harmful agent from gluten is absent from the samples tested. 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 G12™ test kit

The AgraStrip® Gluten G12™ Test Kit is an immuno-chromatographic test for the detection of gluten in foodstuffs. The test kit uses a new monoclonal antibody called G12 that specifically recognizes the pathogenic fragment of the gliadin protein present in gluten. This 33-mer peptide triggers the auto-immune reaction in coeliac patients. During the test, the sample reacts with a colored conjugate (anti-gliadin 33-mer monoclonal antibody – red-colored microsphere) which forms a complex with the reagent on the strip. This complex spreads along the membrane by capillary action. The AgraStrip® Gluten G12 is easy to use, fast and reliable.

Storage information

The AgraStrip® Gluten G12™ 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 G12™ test kit contains the following items:

- 1 tube containing 10 AgraStrip® Gluten G12™ strips
- 1 bottle of 35 mL of ready-to-use extraction buffer (Bottle A)
- 1 bottle of 35 mL of ready-to-use dilution buffer (Bottle B)
- 2 dropper caps for the buffer bottles
- 10 extraction tubes
- 10 caps for the extraction tube
- 10 dropper tips for the extraction tube
- 10 dilution tubes with caps
- 10 sterile swabs with pre-scored tips
- 1 vial rack

Materials required but not included

- Blender, or mortar and pestle, or homogenizer

Sample specifications

Sampling: The food may contain an uneven distribution of gluten (spot contamination). It is important to sample a representative portion of food as only a small amount of material can be tested with the AgraStrip® Gluten G12™ test.

Effect of pH: Performing the assay in 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 might 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 G12™ 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 might require confirmation or further testing. For further information regarding validation, please contact Romer Labs.

Sample preparation

Before starting

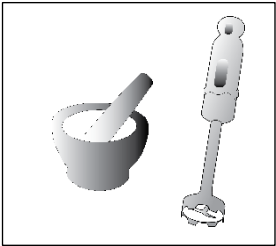
Procedural guidelines:

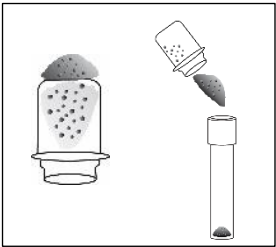
- Make sure you have everything you need ready before starting the assay.
- All reagents and kit components must be equilibrated to room temperature, i.e. 15-25°C (59-77°F), before use.
- Adhere to the incubation times stated in the procedure. Use of incubation times other than those specified may give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

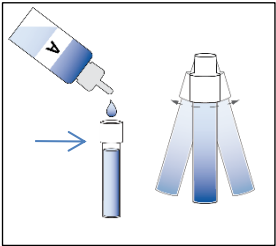
Precautions:

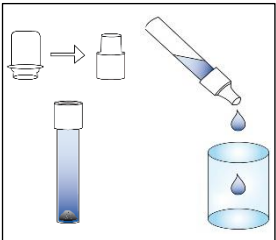
- The components in this test kit have been subjected to quality control tests as a standard batch unit. Do not mix or interchange components from different lots.
- Due to the high risk of cross-contamination, all instruments must be cleaned thoroughly before sample preparation. Follow the instructions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

Foodstuffs and liquid samples

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Obtain a representative sample of the specimen you want to analyze and homogenize it using a blender or a mortar and pestle.
- 

Weigh in **0.2 g** of homogenized sample 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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Fill up the extraction tube with **extraction buffer (Bottle A)** 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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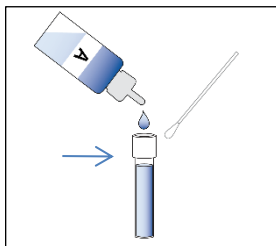
After shaking, remove the cap from the extraction tube and replace it with a fresh dropper tip. Then, transfer **3 drops** or **100 µL** to a dilution tube.

Continue to page 5 (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 dilution tube using a pipette.

Swab samples

1.



Fill one extraction tube with **extraction buffer (Bottle A)** up to the bottom of the neck of the tube, as indicated by the arrow. Take a swab and wet the end by dipping into the buffer.

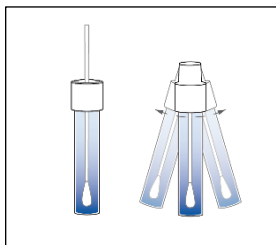
2.



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.

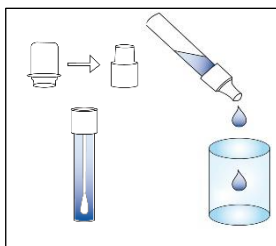


3.



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.

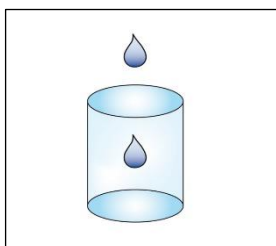


Remove the cap from the extraction tube and replace it with a dropper tip. Transfer **3 drops** or **100 µL** into a dilution tube.

Continue to page 5 (Assay procedure)

Rinse water samples

1.

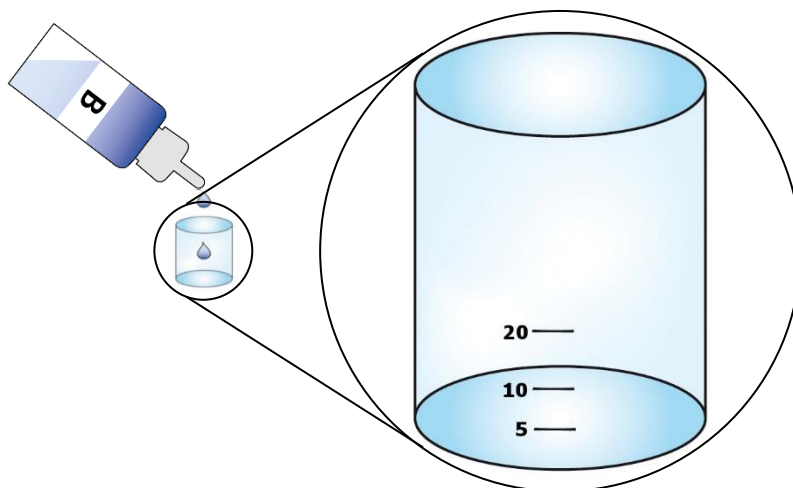


Add **0.5 mL** of rinse water into a dilution tube.

Continue to page 5 (Assay procedure)

Assay procedure

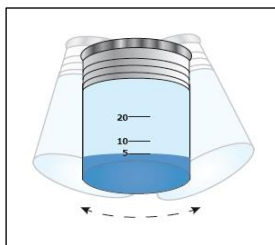
1. Transfer **dilution buffer (Bottle B)** into the dilution tube containing the extract. The dilution tube is graded with 3 marks (see image below) that allows you define which cut-off value you want for your sample in a fast and easy way.



Sample type/cut-off value	Cut-off value	Amount of dilution buffer
Foodstuffs and liquid samples	20 ppm	Fill up to mark "20"
	10 ppm	Fill up to mark "10"
	5 ppm	Fill up to mark "5"
Swab samples	4 µg	Fill up to mark "5"
Rinse water samples	35 ppb	Add 5 drops

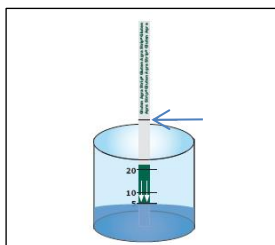
Important note: When filling up the tube up to a mark, make sure that the **bottom** of the meniscus is resting on top of the mark.

2.



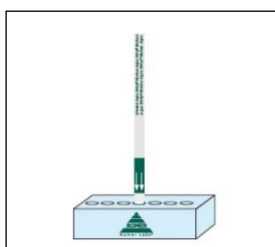
Close the dilution tube with one of the provided caps and shake it vigorously by hand for **15 seconds**.

3.



Take off the cap and place a test strip vertically (white arrows pointing down) into the dilution tube. Allow the liquid to flow up the strip to the wick pad (see arrow in the image to the left). This takes approximately **45 seconds**.

4.



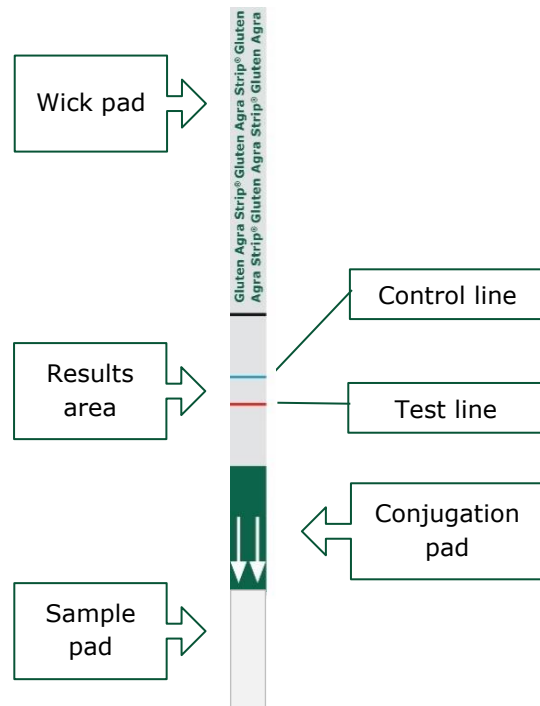
Once the liquid has flowed up to the wick pad, remove the test strip from the dilution tube and place it upright (arrows pointing down) into a slot of the provided vial rack. Allow the strip develop for **10 minutes** and read the result immediately.

Strip components and interpretation of results

Strip components

AgraStrip® Gluten G12™ strips consist of four well-delimited regions: the sample pad, the conjugate pad, the results area and the wick pad.

- Sample pad: located at one of the ends of the test strip, its position is indicated by two arrows. This is the end to submerge in the sample.
 - Conjugate pad: the pad containing the conjugate antibody is covered by a green layer for protection.
 - Results area: a depression in the central region of the test strip. Here is where you can visualize your results. After the incubation time, it will display up to two lines: a control line (blue) and a test line (red).
 - Wick pad: the largest region of the test strip, it serves to ensure a proper flow up the strip and helps to avoid backflow.
- Hold the strip from this end!**



Interpretation of results

It is important to read the results **immediately after the 10-minutes incubation step**. Longer incubation times can lead to false-positive results. The AgraStrip® Gluten G12™ tests have been extensively validated and show reliable results after that exact time.

Negative result: Only the control line appears in the results area of the test strip. The control line is **blue**.

Positive result: The control line and the test line appear in the results area of the test strip. The control line is **blue** and the test line is **red**. The sample contains gluten in a concentration higher than the chosen cut-off value and further investigations should be performed (e.g. quantification of gluten using AgraQuant® Gluten G12™ ELISA test Kit).

Invalid result: No control line appears. Regardless of whether the test line appears or not, 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.



Technical information

AgraStrip® Gluten G12™ test kit approvals

This test kit's performance was reviewed by AOAC Research Institute and was found to perform to the manufacturer's specifications. The following matrices have been validated according to AOAC Performance Tested Methods (PTM) protocols: rice flour, bread, cookies, ice cream and dark chocolate. Stainless steel has been validated per AOAC PTM protocol for environmental surface swab testing.

The rinse water test method has been validated internally by Romer Labs.



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 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**.

Important Information

The extraction buffer may appear cloudy. This is normal. Please shake it well before use. If the extraction buffer exhibits an unpleasant smell, do not be alarmed, as this has no effect on the performance of the kit.

Contact Information

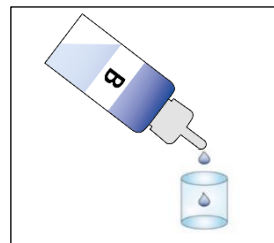
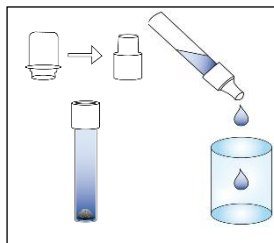
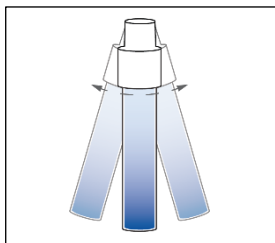
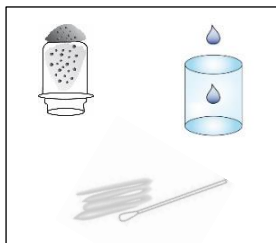
Visit **www.romerlabs.com** to find worldwide contact information.
Or contact us at:

Romer Labs Division Holding GmbH

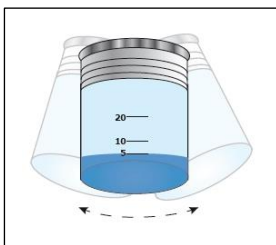
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office-europe@romerlabs.com

Instructions at a glance

1. Prepare and extract your foodstuff, liquid, swab or rinse water sample as indicated in the package insert. Add dilution buffer according to the sample and desired cut-off value

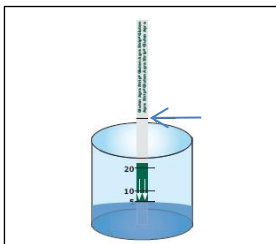


2.



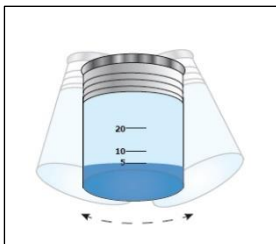
Shake the dilution tube vigorously by hand for **15 seconds**.

3.



Place a test strip vertically into the dilution tube. Allow the liquid to flow up the strip to the wick pad (approximately **45 seconds**).

4.



Place the test strip upright into a slot of the provided vial rack. Allow the strip develop for **10 minutes** and **read the result immediately**.

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®.

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