



AgraStrip® Gluten G12

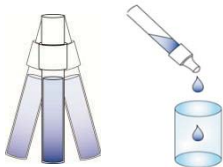


Order #: COKAL0200AS

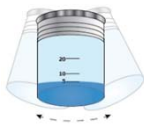
Gluten

Gluten is the main group of proteins in grains and consists of prolamins (in wheat: gliadin) and glutelins (in wheat: glutenins) occurring in the same ratio. Due to its physicochemical characteristics, gluten is used in food products as a binder. Coeliac disease is an autoimmune disorder of the small intestine. It is caused by a reaction to gliadin and the only effective treatment is a lifelong gluten-free diet. Due to Codex Standard 118-1979, "gluten-free" products must comply with gluten levels (including prolamins fractions from wheat, rye, barley and oats) below 20 mg/kg and "foods specially processed to reduce gluten content" must comply with levels between 20 and 100 mg/kg.

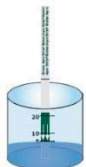
Short instructions



Perform extraction and dilution steps for finished product, rinse water or swab.



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



Place a test strip vertically into the dilution tube and allow liquid to soak up the strip to the „flow“ level line.



Then place the strip upright into a slot of the Tube Holder and allow to develop for **10 minutes** and **read off the result immediately**.

Performance Characteristics:

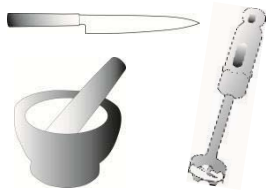
LOD: 5 – 10 – 20 ppm Gluten* (Finished product)
35 ppb Gluten* (Rinse water)
4 µg/25cm² Gluten** (Swab testing)

* LOD was determined in extraction solution

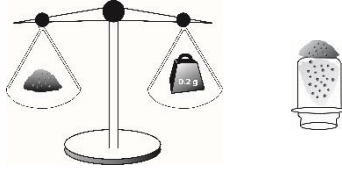
** LOD was calculated

Sample preparation – Finished Products

1. Homogenize the sample (i.e. blend, crush, grind).



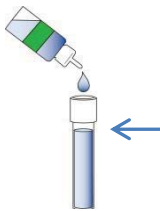
2. Weigh 0.2g of sample (weigh with Balance or estimate by filling up one of the extraction tube caps).



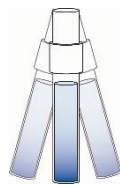
3. Add the sample to extraction tube



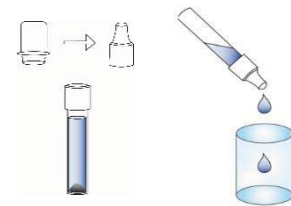
4. Fill Extraction Tube with **Extraction Buffer** to level shown below (blue arrow).



5. Close tube with tube cap and shake vigorously by hand for **1 minute**.



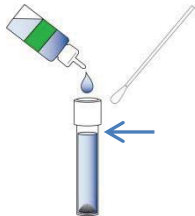
6. Remove cap from the extraction tube and replace with dropper tip. And transfer **3 drops (100µl)** to a dilution tube.



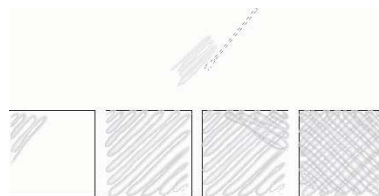
Proceed to the Assay Section (page 3) to complete your test

Sample preparation – Swab Testing

1. Fill extraction tube with **Extraction Buffer** to level shown below (blue arrow), take a swab and wet the end by dipping into the buffer



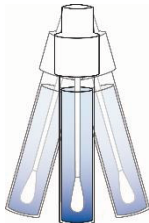
2. Wipe an area of **5cmx5cm** using side to side movements, rotating the swab tip as you go (we recommend the "cross-hatch" swabbing technique indicated below)



3. Place the swab into the extraction tube. Carefully break off the end at the pre-scored point.



4. Close the tube with a cap and shake vigorously for **1 minute**.



5. Remove cap from the extraction tube and replace with dropper tip. And transfer **3 drops (100µl)** to a dilution tube



Proceed to the Assay Section (page 3) to complete your test

Sample preparation – Rinse water Testing

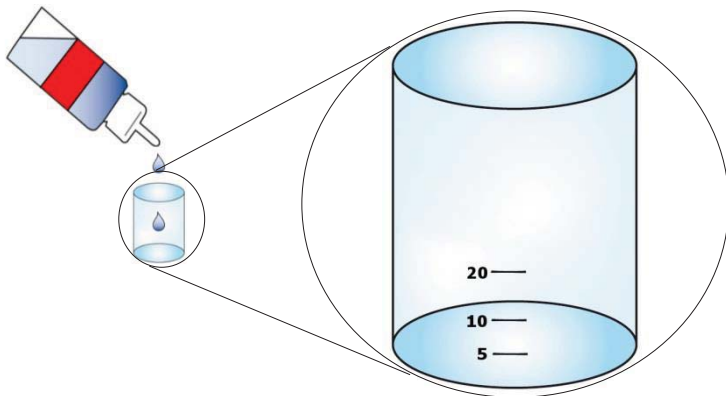


Add **0.5 mL** of rinse water into a dilution tube

Proceed to the Assay Section (page 3) to complete your test

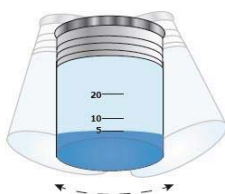
Assay Procedure in detail

1. Transfer various amounts of **Dilution Buffer** (red label) into the dilution tube already filled with extract

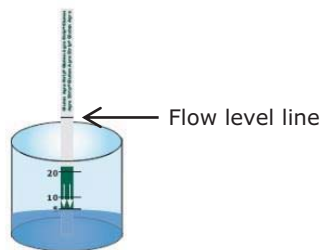


amount of dilution buffer	sample type
Fill up to 20 mark	Finished products with <i>20ppm cut off</i>
Fill up to 10 mark	Finished products with <i>10ppm cut off</i>
Fill up to 5 mark	Finished products with <i>5ppm cut off</i>
Add 5 drops	Swab samples (cut off = 4 µg)
	Rinse water samples

2. Close the dilution tube with the cap and shake vigorously by hand for **15 seconds**
3. Take off cap and place a test strip vertically (arrows pointing down) into the dilution tube and allow liquid to flow up the strip to the „flow“ level line. (this takes about **45 seconds**)
4. After the liquid has soaked up to the “flow” level remove the test strip from the dilution tube and place it upright (arrows pointing down) into a slot of the Tube Holder and allow to develop for **10 minutes** and then read off the result immediately.



15 seconds



~45 seconds



10 minutes

Interpretation of Results



One single blue line (=control line) in the central part of the test = negative result

One red line (=test line) and one blue line in the result zone = positive result. The sample contains Gluten higher than the cutoff level and further investigations should be performed (e.g. quantification of Gluten using AgraQuant® Gluten G12 ELISA Test Kits).

No control line appears = invalid result, regardless of whether the test line 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 further.

Important advice for the proper execution of the test:

It is important to **read the results immediately after the 10 minute incubate step** since the AgraStrip® test system has been validated extensively and shows reliable results after that exact time. Longer incubation times can lead to the development of false positive results.

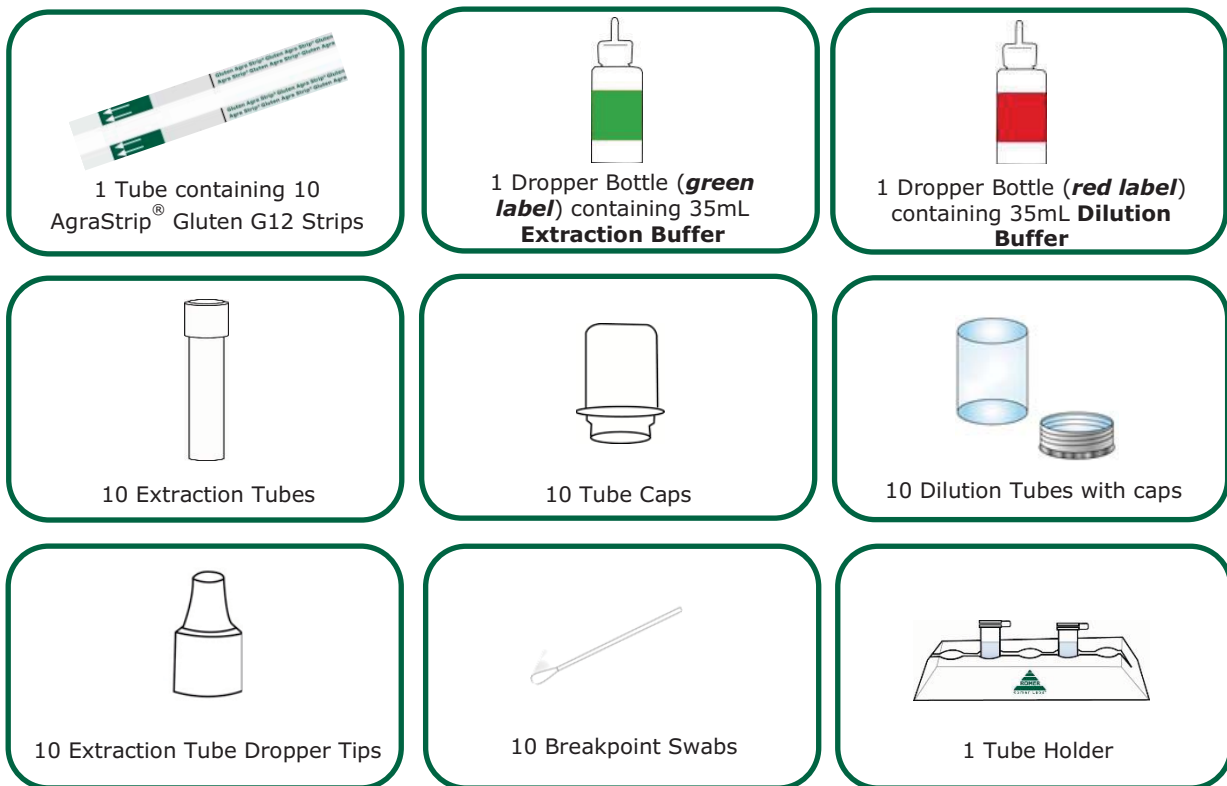
Performance Characteristics in Detail

Limit of detection: 5 – 10 – 20 ppm Gluten (Finished product)
35 ppb Gluten (Rinse water)
4 µg/25cm² Gluten (Swab testing)

Range of detection: 5 – 10000 ppm Gluten

pH range: Performing the assay in a pH range of 6-8 will lead to reliable results. Highly acidic samples can lead to false positive results whereas in an alkaline milieu there is the tendency to false negative results.

Materials Supplied with Kit:



Materials required but not supplied for solid sample preparation

- Blender or Crusher or Blade

Technical and Background Information

The AgraStrip® Gluten G12 Test Kit is a lateral flow assay for the detection of Gluten content in food, rinse waters and environmental swab samples.

Gluten Allergy

Gluten is the main group of proteins in grains and consists of prolamins (in wheat: gliadin) and glutelins (in wheat: glutenins) occurring in the same ratio. Due to its physicochemical characteristics, gluten is used in food products as a binder. Coeliac disease is an autoimmune disorder of the small intestine. It is caused by a reaction to gliadin and the only effective treatment is a lifelong gluten-free diet. Due to Codex Standard 118-1979, "gluten-free" products must comply with gluten levels (including prolamins from rye, barley and oats) below 20 mg/kg and "foods specially processed to reduce gluten content" must comply with levels between 20 and 100 mg/kg.

Assay Principles

The AgraStrip® Gluten G12 Test Kit is an immunochromatographic test for the detection of gluten in foodstuffs. The test kit uses a new monoclonal antibody called G12 that specifically recognises the pathogenic fragment of the gliadin protein present in gluten. This fragment is called 33-mer and triggers the auto-immune reaction in coeliac patients. During the test, the sample reacts with a coloured conjugate (anti-gliadin 33mer monoclonal antibody – red-coloured 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.

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®.



Precautions

1. The product must be stored in its original package, between 15 and 25°C (room temperature). Do not use components beyond the expiration date indicated on the kit labels. Do not open the product until needed.
2. Test strips must be kept inside their original packaging, closed as tightly as possible. Do not freeze.
3. Adhere to the instructions for test procedures.
4. The components in this test kit have been quality control tested as a standard batch unit. Do not mix components from different lot numbers.

Sampling:

Consideration must be taken that the food may contain an uneven distribution of Gluten (spot contamination). It is important to test a representative portion of food as only a small amount of material is tested with the AgraStrip® Gluten test.

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 purpose a positive result might require confirmation or further testing.

For further information regarding validation please contact Romer Labs.

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.



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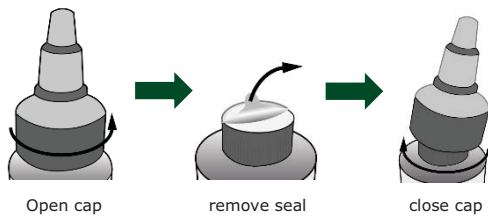
info@keydiagnostics.com.au

www.keydiagnostics.com.au

PO Box 1038, Gymea, NSW, 2227



Handling of the new improved AgraStrip® extraction & dilution buffer bottles



When opening the bottle for the 1st time, please take off the cap, peel off the seal and screw the cap back on the bottle.



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

To **close** the bottle twist the screw top clockwise.

For further information please contact:

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Warranty

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