**AgraStrip® Gluten G12**

**Order #: COKAL0200AS**

### Intended Use

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.

### Materials Supplied With Kit

- 1 Tube containing 10 AgraStrip® Gluten G12 Strips
- 1 White Dropper Bottle containing 35mL Extraction Buffer A
- 1 Opaque Dropper Bottle containing 35mL Dilution Buffer B (Red Label)
- 20 Extraction Tubes and Caps
- 10 Extraction Tube Dropper Tips
- 10 Breakpoint Swabs
- 1 Cardboard Tube Holder

### 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.

### Precautions

1. The product must be stored in its original package, between 15 and 25°C. 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 G12 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. AgraStrip® Gluten G12 may also be used to provide results corresponding to various cut-off values. Please refer to the “Guide for the use of AgraStrip® Gluten G12 at 5, 10 and 20 ppm for Ingredients and Finished Products” also included in the kit box.

To give reliable results each individual matrix should be validated before the kit is used routinely. 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 transferring the extract directly into the 2nd Extraction Tube using a pipette.

### Warranty

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Sample Testing

1. 
   For 5ppm Cut off level Transfer 20 drops (800μl) of the Dilution Buffer B into an empty Extraction Tube (For other cut off levels see Dilution Guide on Page 4). Place this FIRST extraction tube in the holder provided until step 6.

2. Homogenise the sample.(i.e blend, crush, grind)

3. 
   Weigh 0.2g of sample and add to a SECOND empty Extraction Tube. If balance is unavailable 0.2g can be estimated by filling the extraction tube cap provided. Fill SECOND tube with Extraction Buffer A to level shown in diagram.

4. 
   Close SECOND tube with extraction tube cap, and shake vigorously by hand for 1 minute.

5. Remove cap from the SECOND Extraction Tube and replace with dropper tip.

6. 
   Transfer 3 drops (100μl) of the sample liquid (SECOND extraction tube) into the FIRST extraction tube already held in the tube holder.

7. 
   Close FIRST tube with a new extraction tube cap, and shake vigorously by hand for 15 seconds, then return to the tube holder. (the SECOND extraction tube is no longer needed).

8. Remove cap from the FIRST Extraction Tube. Proceed to Results section on page 4

Rinse Water Testing

1. 
   Add 0.5 ml of rinse water into an Extraction Tube

2. 
   Transfer 5 drops of Dilution Buffer B to Extraction Tube. Proceed to Results section on page 4
Swab Testing

1. Transfer 20 drops (800µl) of the Dilution Buffer B into an empty Extraction Tube. Place this FIRST extraction tube in the holder provided until step 8.

2. Mark out or estimate a swabbing area of 5cm x 5cm. The swab can be used directly on problem areas such as equipment or other areas of contamination.

3. Fill SECOND tube with Extraction Buffer A to level shown in diagram.

4. Remove a swab from its packing and wet the end by dipping into Extraction Buffer A. (SECOND tube)

5. Wipe the entire swabbing area with the swab using side to side movements, rotating the swab tip as you go. Repeat using movements at right angles to those used before.

6. Place the swab back into the SECOND extraction tube and carefully break off the end at the pre-scored point.

7. Close SECOND tube with extraction tube cap, and shake vigorously by hand for 1 minute. Remove cap and replace with dropper tip.

8. Transfer 3 drops (100µl) of the sample liquid (SECOND extraction tube) into the FIRST extraction tube already held in the tube holder.

9. Close FIRST tube with a new extraction tube cap, and shake vigorously by hand for 15 seconds, then return to the tube holder. (the SECOND extraction tube is no longer needed).

10. Remove cap from the FIRST Extraction Tube. Proceed to Results section on page 4.
1. Open the container of AgraStrips®, remove the required number of strips and close the tube. Place the test strip vertically, with the arrows pointing down, into the Extraction Tube without exceeding the immersion limit indicated by the arrows. Allow liquid to wick up the strip to the “flow” level line, this takes about 45 seconds, (level shown in diagram).

2. After the liquid has wicked to the “flow” level remove the test strip from the Extraction Tube and place upright (arrows pointing down) into slot of the Tube Holder provided. Allow strip to develop for 10 minutes and then read off the result immediately.

**Results**

**One single blue line in the central part of the test:** negative result

**One red line and one blue line in the result zone:** positive result. The sample contains allergen higher than the cutoff level and further investigations should be performed (e.g. quantification of gluten using AgraQuant® 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.

**Dilution Guide**

By varying the amount of Dilution Buffer B it is possible to adjust the AgraStrip® Gluten G12 cut off level.

**Please Note:** Variation of levels may occur depending on the food matrix being tested. To give reliable results each individual matrix should be validated before the kit is used routinely.

Contact your local Romer Labs representative for assistance with validation of the AgraStrip® Gluten G12.

When desired Fill Level of Dilution Buffer B has been added proceed to step 1 of the sample testing method.

**Fill Level**

- **20 ppm Cut Off** Transfer 80 drops (3.2 mL) of the Dilution Buffer B into an empty Extraction Tube.
- **10 ppm Cut Off** Transfer 40 drops (1.6 mL) of the Dilution Buffer B into an empty Extraction Tube.
- **5 ppm Cut off** Transfer 20 drops (0.8 mL) of the Dilution Buffer B into an empty Extraction Tube.