Instructions for use InviRapid® Gluten Allergen Ag Test





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1. Intended use

InviRapid® Gluten Allergen Ag Test is an immuno-chromatographic test for the detection of gluten in food. All reagents required for the test are included in the test kit. Results are interpreted visually. This test is suitable for the detection of unknown ingredient or ambiguous labeling in processed food. InviRapid® Gluten Allergen Ag Test can be used to validate and verify allergen cleaning regimes in manufacturing and analytical environmental. This test is also suitable for quality control in food processing plants specifically with inbound goods, processing stages and final product. Codex Alimentarius (ALINORM 08/31/26) defines gluten-free foods as foods with a gluten content of less than 20 ppm.

- Detection limit: 2 ppm gluten (1 ppm gliadin).
- Specificity: No cross-reaction with seafood, almond, casein, soya, oat, peanut, buckwheat and egg.

2. Kit contents

| COMPONENTS | QUANTITY |
|-----------------------------|-----------------|
| Rapid test strip | 20 pouches |
| Buffer A* | 25 mL, 1 bottle |
| Buffer B | 12 mL, 1 bottle |
| 1.5 mL microcentrifuge tube | 20 pcs |
| 4 mL sample tube | 20 pcs |
| Scoop | 20 pcs |
| Dropper | 20 pcs |
| Swabs | 20 pcs |
| Tubes rack | 2 pcs |
| Instruction manual | 1 manual |
| | |

^{*}Please add 40 mL ethanol (>95%) before use

3. Equipment and materials required (not provided)

- 200 μL and 1000 μL micropipette and tips
- Weighing scale
- Grinder or homogenizer
- Vortex mixer (if available)
- Ethanol >95%
- Clean water

4. Storage instructions

Reagents should be stored between 2 and 30 °C and may be used until the expiration date shown on the package label. It is not recommended the use of the kit after the expiry date stated on the box. Protect reagents from light exposure to prevent degradation. Do not freeze.

5. Preparation of samples

- 5.1 For liquid food/drinks:
 - Measure 300 µL of sample into a 4 mL sample tube with 2.7 mL buffer A.
 - b. Vortex/mix for 30 seconds.
 - c. Leave sample mixture to settle for 1 minute.
 - d. Pipette 50 µL of the sample mixture supernatant into a 1.5mL microcentrifuge tube with 450 µL buffer B.
 - e. Shake/mix for 10 seconds.

5.2 For solid food:

- Weigh 0.3 g of sample (finely grinded) into a 4 mL sample tube or fill the sample up with the provided scoop and then level it off.
- b. Add 3 mL buffer A to the 4 mL sample tube.
- c. Vortex/mix for 30 seconds.
- d. Leave sample mixture to settle for 1 minute.
- e. Pipette 50 $\dot{\mu}$ L of the sample mixture supernatant into a 1.5 mL microcentrifuge tube with 450 μ L buffer B.
- f. Shake/mix for 10 seconds.

5.3 Environmental swab test:

- a. Transfer 500 μ L (or 15 drops by dropper) of buffer A into a 1.5 mL microcentrifuge tube.
- b. Wet the cotton swab with clean water.

- Swab a sampling surface area of 100 cm² (recommended) with the pre-wetted cotton swab.
- d. Place the cotton swab in the 1.5 mL microcentrifuge tube making sure to immerse the cotton swab head in the buffer.
- e. Gently agitate the cotton swab in the buffer for at least 30 seconds.
- f. Remove the cotton swab from the 1.5 mL microcentrifuge tube and leave the tube to rest for 1 minute.
- g. Pipette 50 μL of the sample mixture supernatant into a 1.5 mL microcentrifuge tube with 450 μL buffer B.
- h. Shake/mix for 10 seconds.

6. Test procedure

- Open the aluminum pouch and take out the test strip. (please handle the colored sticker portion only and avoid contact with the reaction zone).
- Insert the test strip into the 1.5 mL microcentrifuge tube.

7. Results and sensitivity

Wait 15 minutes for the results. Please read the results immediately without further manipulation.

7.1 Result analysis:

- Positive result: two colored bands (C and T red test bands) visible within the reaction zone.
- Negative result: one colored band (C red test band) visible within the reaction zone.
- Invalid result: no colored band is visible within the reaction zone or only T red test band; the test is considered invalid.
 Please retest with a new test strip.

8. Warnings and precautions for users

- InviRapid[®] products are for food testing, not for human diagnostics use.
- InviRapid[®] products contain non-toxic buffers. To maintain test accuracy, please keep bottle upright to prevent leakage.
- InviRapid® Tests are designed as a one-use test. Please do not re-use test strip.
- InviRapid[®] Tests are very sensitive to humidity, which could render the test strips useless. Please keep the test strips away from humidity.
- InviRapid[®] Tests are designed for screening purposes only.
 If analysis of ingredients is required, please send the sample to your local laboratory for further analysis.
- To ensure test accuracy, please do not use expired test strips or omit weighing samples or operating by micropipettes.
- All samples require dilution with the buffer A and buffer B in this kit. Do not test the sample directly with the test strip.
- Highly concentrated samples and food samples containing high level of polyphenols (e.g. coffee, tea, wine, chocolate etc.), high fat volume (e.g. peanut butter, oil etc.) or heavy food coloring (e.g. soya sauce) will affect the results of the tests
- Airborne cereal dust and dirty equipment can lead to Gluten contamination of the test strip and affect the results. In order to avoid cross contamination during the operation, please clean equipment and surfaces with 70% ethanol before operating and wear gloves while performing the test to ensure detection accuracy.
- If the sample is too viscous or concentrated, it is recommended to increase the dilution factor of the sample with the buffer A
- The buffer A should only be used for unheated food samples.
- Please complete the test procedure in 30 minutes to ensure optimum accuracy.

Quick Guide

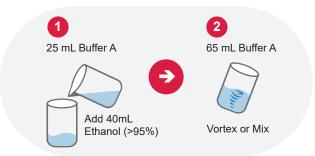
InviRapid® Gluten Allergen Ag Test



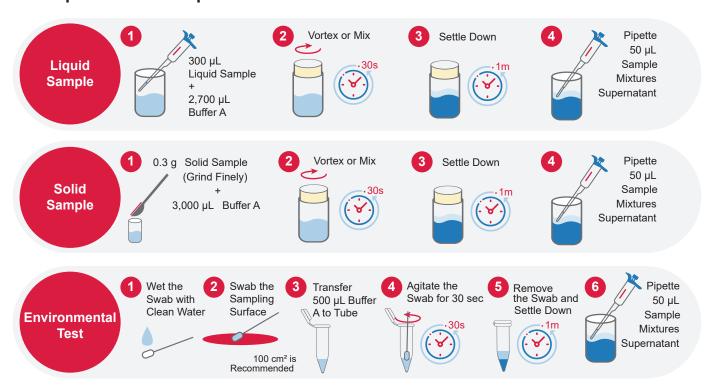
A. Materials Needed

| | Liquid Sample | Solid Sample | Environmental Swab Test |
|-----------------------------|------------------|-----------------|----------------------------|
| 4 mL Sample Tube | • | • | |
| 1.5 mL Microcentrifuge Tube | • | • | • |
| Micropipette or Droppers | • | • | • |
| Scoop | | • | |
| Swab (Optional) | | | • |

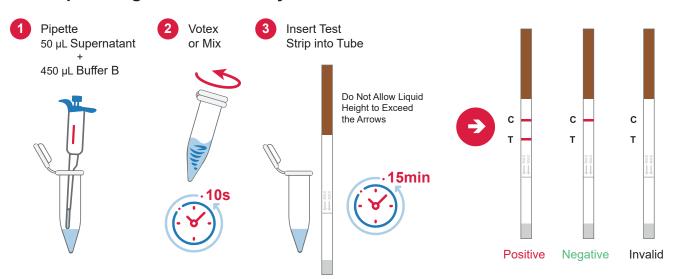
B. Before Use



C. Preparation of Samples



D. Strip Testing and Result Analysis



Positive result: two colored bands (the C and T red test bands) are visible within the reaction zone.

Negative result: one colored band (the C red test band) is visible within the reaction zone.

Invalid result: no colored band or only T red test band is visible within the reaction zone, the test is considered invalid.

