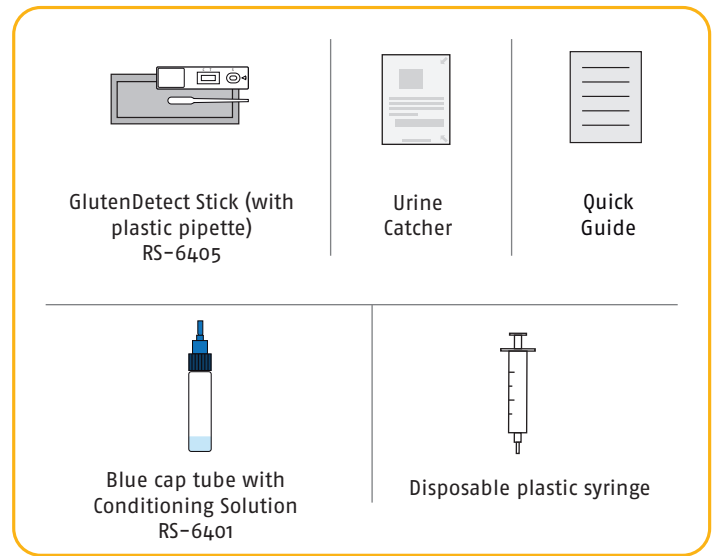


QUICKGUIDE

Rapid test for gluten detection in urine samples

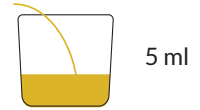
GlutenDetect Urine is an immunochromatographic test that allows the detection of peptides from the gastrointestinal degradation of gluten, in urine samples.

This kit is not a diagnostic test.



Sample collection

- Open the urine collector carefully following the direction of the arrows and stick it to the back of the toilet lid. Alternatively, you can use a clean container (not supplied) to collect urine. 5 ml of urine will be enough to perform a test.
- It is important to avoid fluid consumption from the time the transgression is suspected until the test is performed, in order to obtain maximum sensitivity. Sample collection recommendations: It is recommended that the sample is taken 6-9 hours after the suspected transgression. *(If the time of sampling is in the early morning, collect the first urine of the morning).*
- If the time of the possible transgression is unknown, it is recommended to collect the first urine of the morning or the last urine of the evening.
- If gluten ingestion/transgression is suspected, please consider the following information:



Maximum detection time from ingestion	3 – 15 hours
Optimal detection time from ingestion	6 – 9 hours
Minimum amount of detectable gluten	50 mg

*To maximize the probability of detection of the kit, sampling is recommended 6-9 hours after gluten intake.

Test procedure – <https://youtu.be/ECmJeHnxVal>

1

Use a disposable syringe (included in the kit) and collect 2 ml of urine.

2

Open the blue tube with Conditioning Solution and transfer 2 ml of urine into the tube.

Throw away the syringe once used (do not reuse it with further urine samples).

3

Close the blue cap tube tightly and shake gently for 10 seconds to mix the urine with the Conditioning Solution.

4

Open the protective pouch and remove the Lateral Flow Device (LFD) and place the device horizontally on a clean surface.

Note: Discard the included pipette, you will not need it.

5

Unscrew the clear end of the cap from the blue tube containing the urine/Conditioning Solution mixture.

6

Carefully invert the tube and add 4 drops of the mixture to zone S of the device.

7

Wait a minimum of 15 and up to a maximum of 30 minutes before read the test result. Do not read the result after 30 minutes from when added the drops to the lateral flow device.

Do not shake or move the device during waiting.

Read the results

• (-) NEGATIVE

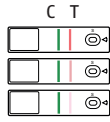


I. A single **GREEN** line appears in the Control Zone (C). The intensity of the line Control (C) is not relevant.
II. If a line appears in the Test Zone (T) of a color other than red (eg grey, yellow, green) and a **GREEN** line appears in the Control Zone (C).

III. If the **RED** line is not complete (eg red dots appear in the T zone) and a **GREEN** line appears in the Control Zone (C).

No gluten has been detected in the urine sample.

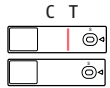
• (+) POSITIVE



If a **GREEN** line in the Control Zone (C) is visible next to a **RED** line in the Test Zone (T), independently of the intensity obtained, the test result is positive.

If you have obtained a positive result, there is a high probability that there has been a gluten ingestion 3-15 hours before performing the test. Check the food eaten to identify the origin of the gluten.

• INVALID



If the **GREEN** line does not appear in the Control Zone (C), the test has not worked correctly and the results are invalid. Review the instructions and perform the test again following the instructions.

Storage conditions

- The product should be stored in a dry place and at a temperature of 15°C-30°C / 59°F-86°F (room temperature).
- For optimal test performance, store the product in its original packaging and use before the expiration date printed on the label.

Recommendations and precautions

- Read this manual carefully before performing the test, it is recommended to strictly follow the instructions described.
- Use this test only for the analysis of human urine samples. This test has not been validated with urine samples from neonates, therefore, its use is not recommended in this segment of the population.
- The test should be performed immediately after opening the bag containing the lateral flow device.
- "Sample collection" section recommendations should be followed.
- Do not ingest any of the solutions included in the kit.
- Poor vision, color blindness or poor lighting can affect the ability to correctly interpret the test.
- Keep this product out of the reach of children.
- Do not use any of the kit materials past the expiration date.
- Do not mix components from multiple kits, or use solutions other than those supplied.
- To avoid possible contamination of the assay by trace amounts of gluten, wash hands thoroughly or wear powder-free gloves when handling the supplied Lateral Flow Device. Once removed from its packaging, the Lateral Flow Device should be used immediately under strict hygienic conditions.
- All test components can be disposed of in regular household waste.