AllerFlow Gluten

Environmental Gluten Surface Residue Test Kit

Part No: ALF-GL (25 tests)



Description/Intended Use:

AllerFlow Gluten is an environmental gluten residue test kit used for the detection of gluten residue on food processing surfaces. The kit consists of environmental sample collection swabs and individually packaged lateral flow devices. AllerFlow Gluten is specific to the toxic fraction of gluten from wheat, barley, rye, and oat, with no cross-reactivity with soy, rice, or corn.

Directions:

Instructional Video: www.youtube.com/HygienaTV

Step 1: Sample Collection

Sample collection procedure is described below and shown in Step 1: Sample Collection diagrams (page 2).

- Allow AllerFlow sample collection swab to equilibrate to room temperature (10 minutes at 22 – 26 °C). Holding tube firmly, twist and pull swab out of tube.
- 2. Thoroughly swab a standard 10 x 10 cm (4 x 4 inches) area for a typical flat surface. Swab tip is pre-moistened for maximum sample collection. For irregular surfaces, ensure swabbing technique remains consistent for each test and swab a large enough area to collect a representative sample.

Important swabbing technique tips:

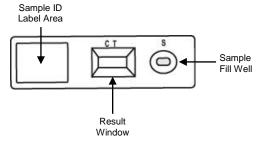
- Do not touch swab or inside of sample device with fingers.
- Rotate swab while collecting sample to maximize sample collection on swab tip.
- Apply sufficient pressure to create flex in swab shaft.
- Swab in a crisscross pattern vertically, horizontally, and in both diagonal directions.
- Refer to instructional video for demonstration: <u>www.youtube.com/HygienaTV</u>
- 3. Re-insert swab into swab tube and firmly seal device.
- Activate device by holding swab tube firmly and using thumb and forefinger to break Snap-Valve by bending bulb forward and backward.
- Squeeze bulb twice to release all liquid to bottom of swab tube.
 Note: Though foaming will occur in the tube, this will not affect test results.
- 6. Gently massage bottom of tube by squeezing tube 3 times.
- Gently shake for 3 seconds. This will help release sample from swab bud and mix sample in liquid.

Step 2: Transfer to Lateral Flow Device

Lateral flow transfer procedure is described below and shown in Step 2: Transfer to Lateral Flow Device diagrams (page 2).

- Remove lateral flow device (cassette) from foil pouch and place on a flat surface. Sample ID may be written on cassette using permanent marker.
 - Note: Lateral flow pouch contains a silica gel pouch; discard pouch.
- 2. Remove swab from AllerFlow sample collection swab tube.
- Carefully tip tube over and pour liquid into sample fill well on cassette until cavity is full. Do not overfill sample well.
- Leave cassette on flat surface for 10 minutes. See "Interpretation of Results".

Diagram 1: Lateral Flow Device



Interpretation of Results:

- Note color change at 10 minutes. Refer to Table 1 below for interpretation.
- Disregard any color change after 10 minutes.
- AllerFlow Gluten is sensitive to 5 μg/swab (5 ppm) gluten.*

*Note: The meaning of ppm is mg gluten/kg sample. It is not possible to accurately report ppm sensitivity from a surface swab because the amount of material captured cannot be precisely measured due to user variation and surface type. The appropriate unit notation for AllerFlow Gluten is μ g/100 cm² (10 cm x 10 cm / 4 in x 4 in) or μ g/swab.

Table 1: Lateral Flow Device Results Interpretation

Result	Appearance	Diagram
Negative	Blue line at "C" (Control)	S O
Positive	Blue line at "C" (Control) and red line at "T" (Test)	© CT S

Note: All test results must show blue line at "C" position. If blue line is not present, repeat test with new lateral flow device.

Storage & Shelf Life:

- Store at 2 25 °C
- 15-month shelf life.
- Refer to expiration date printed on box.

Safety & Precautions:

Components of AllerFlow Gluten do not pose any health risk when used in accordance with Good Laboratory Practices and procedures in this insert.

- Devices are designed for a single use. Do not reuse.
- Do not use devices after expiration date.
- Sampling should be done aseptically to avoid cross contamination.
- For further safety instruction, refer to AllerFlow Gluten Safety Data Sheet (SDS) available from www.hygiena.com

Disposal:

Used devices and cassettes are not a biohazard and may be discarded in the trash.

Hygiena Liability:

Hygiena will not be liable to user or others for any loss or damage whether direct or indirect, incidental or consequential from use of this product. If this product is proven to be defective, Hygiena's sole obligation will be to replace product or at its discretion, refund the purchase price. Promptly notify Hygiena within 5 days of discovery of any suspected defect and return product to Hygiena.

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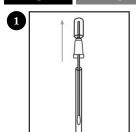
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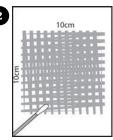
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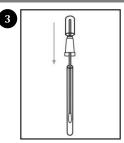
Step 1: Sample Collection



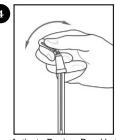
Twist and pull swab out



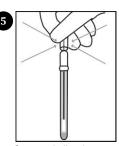
Swab a 10x10cm (4x4 in) area.



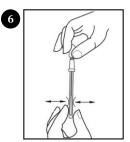
Re-insert swab into swab



Activate Device. Bend bulb to break Snap-Valve.



Squeeze bulb twice to release all liquid to bottom of swab tube.



Gently massage bottom of tube by squeezing tube 3 times.



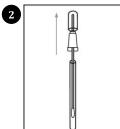
Gently shake for 3 seconds

Step 2:

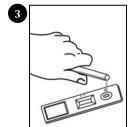
Transfer to Lateral Flow Device



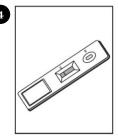
Remove lateral flow device (cassette) from foil pouch and place on a flat surface.



Remove swab from AllerFlow sample collection swab tube.



Tip tube over and pour liquid into sample fill well until cavity is full. Do not overfill sample well.



Leave cassette on flat on surface for 10 minutes. Results will be available in 10 minutes.

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