



EZ Gluten[®]

A Fast, Sensitive, Simple Method for the Detection of Gluten in Foods

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Abstract:

Gluten is the common name for a combination of water-insoluble proteins (gliadin and glutenin) found in the seeds of wheat, rye and barley. Sensitivity to gluten affects nearly 1% of the populations of Europe and North America. Persons with gluten sensitivity have a heightened immunologic response to ingested gliadin and glutenin, resulting in a range of symptoms including anemia, arthralgia, infertility, dermatitis, neurological disorders and celiac disease.

For persons with gluten sensitivity the only treatment for these conditions is the adoption of a gluten-free diet, avoiding foods containing wheat, rye, barley and other related cereal grains. Due to the prevalence of these grains in the food supply, even products that do not contain wheat, rye or barley as ingredients may still contain trace amounts that are significant enough to produce symptoms in gluten-sensitive individuals.

Before the development of the EZ Gluten[®] assay, there was no highly-sensitive, easy to use method for testing foods at home. EZ Gluten[®] can detect the presence of gluten in foods in as little as 15 minutes. It is sensitive enough to detect levels of gluten as low as 10 parts per million (ppm) using an antibody that detects both the gliadin and glutenin fractions of gluten. EZ Gluten[®] is small and portable enough for use at restaurants or when traveling. It can be used to test individual ingredients in foods, or to test finished and cooked products. The 10 ppm sensitivity of EZ Gluten[®] also makes it ideal for use by gluten-free food manufacturers.

Until now, gluten-sensitive consumers have had to rely on the incomplete and often confusing information found in ingredient labels or restaurant menus when making decisions that could impact their health. EZ Gluten[®] is an important advancement in food safety, allowing consumers to easily and affordably test food products in their home.

Method:

1. A food sample is ground to a fine, homogenous mixture
2. 0.5 g of the sample is measured out using the spoon provided
3. The sample is added to the extraction solution
4. The sample and extraction solution are mixed for 2 minutes. The vial is then allowed to settle for 5 minutes.
5. 10 drops from the upper layer of the extract are placed in the provided test tube
6. The test strip is placed in the test tube
7. After 10 minutes, the test strip can be read visually for the presence of gluten



Results/ Conclusions:

In-house validation studies indicate that the EZ Gluten[®] assay has 100% sensitivity and specificity for samples containing >10 ppm of gluten.

The EZ Gluten[®] assay showed 98% correlation with the HAVen High Sensitivity quantitative ELISA assay when comparing sample results for over 100 common grocery store items.

The Hook line the on lateral flow strip allows for accurate interpretation of samples containing high levels (>200 ppm) of gluten.

The EZ Gluten[®] assay can be used to test swabs, using a slightly modified protocol. This is essential for manufacturers who wish to test their cleaning procedures between gluten-containing and gluten-free batches.

The EZ Gluten[®] assay is based on the Skerritt antibody, the same antibody used in the AOAC Official Method for detection of gliadin as a measure of gluten in foods (OMA 991.19, Final Action 2001).

The Skerritt antibody is more sensitive to glutenin than the antibody used in the proposed FDA method for gluten detection (R5). Glutenin is also a trigger for the immune response in gluten-sensitive individuals.