

# The Need for a Standardized Test Portion When Testing Food for Gluten Using an LFD: A Case Study

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## Objective

- To help inform instructions for lateral flow devices (LFDs) used to test products for gluten by determining the cause of consumer false positive results when testing a powdered drink mix

## Background

- Consumers with celiac disease may use various LFDs to test food for gluten
- False positive results may occur due to various matrix effects and sampling of products tested
- Erroneous findings can cause confusion among consumers and may lead to online criticism of food manufacturers

## Methods

- Gluten Free Watchdog (GFWD) received several complaints about a labeled gluten-free powdered sports drink testing positive for gluten using at least two LFDs
- A consumer's retained sample that tested positive for gluten using an LFD and a new box of the same product were tested by Bia Diagnostics using a sandwich R5 ELISA, a competitive R5 ELISA, and LFD test strips
- 0.5-gram samples and the amount of sample in a level scoop (provided in the test kit) were tested with LFD test strips (LFD kit instructions state either amount can be tested)
- A level scoop of product weighs approximately twice as much as the weight amount recommended for testing by the kit manufacturer
- The consumer reported testing a level scoop of sample
- The pH of a 0.5-gram sample and the amount in a level scoop also were tested along with buffer solutions at known pH levels of 4 and 7

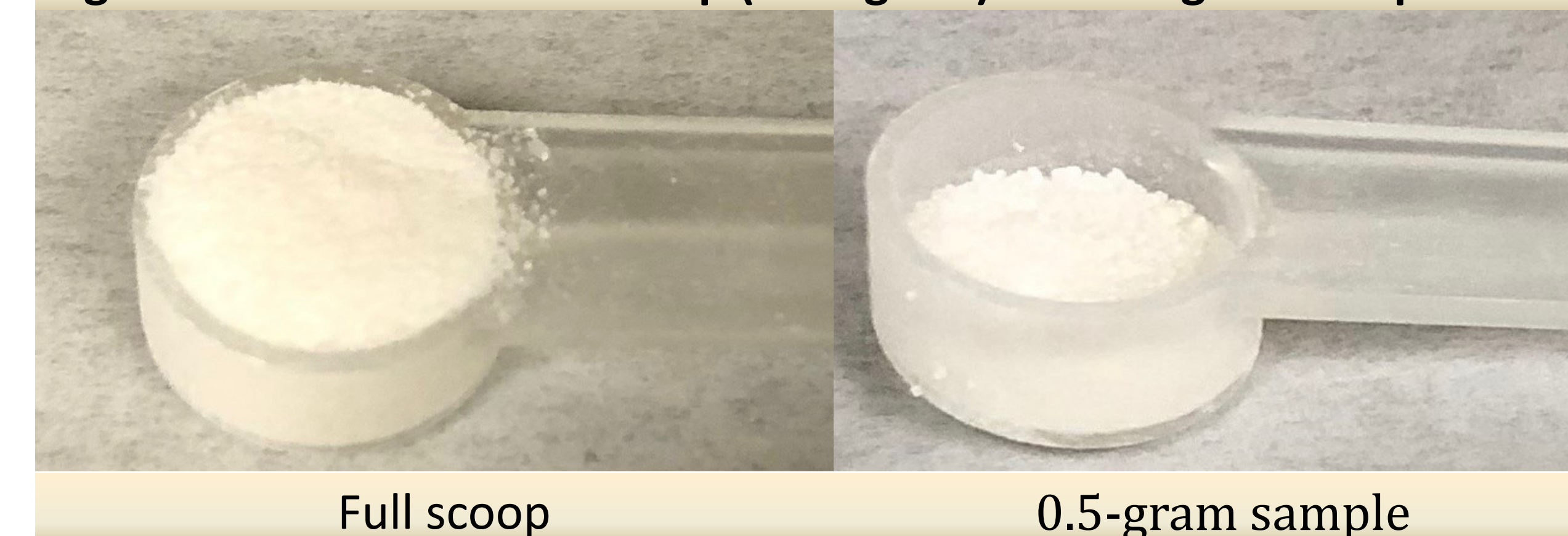
**Table 1: Gluten findings in samples tested**

Sample tested	Sandwich R5 ELISA	Competitive R5 ELISA	LFD (0.5-gram sample)	LFD (1.0-gram level scoop)
Retained consumer sample	< 5 mg/kg (ppm) of gluten (Also tested below the limit of detection of 1 ppm)	< 10 mg/kg (ppm) of gluten (Also tested below the limit of detection of 4.6 ppm)	Negative for gluten	Positive for gluten
Sample purchased by Gluten Free Watchdog	< 5 mg/kg (ppm) of gluten (Also tested below the limit of detection of 1 ppm)	< 10 mg/kg (ppm) of gluten (Also tested below the limit of detection of 4.6 ppm)	Negative for gluten	Positive for gluten

**Table 2: pH and gluten findings in samples tested**

Sample	pH	Gluten findings using LFD
0.5-gram sample amount	6.04	Negative for gluten
1.0-gram level scoop amount	4.83	Positive for gluten
Buffer	4.0	Positive for gluten
Buffer	7.0	Negative for gluten

**Figure 1. Powder in a full scoop (≈1.0-gram) and 0.5-gram sample**



*Ingredients in sample tested: Pure cane sugar, Dextrose, Citric acid, Salt, Potassium citrate, Sodium citrate, Dipotassium phosphate, Silicon dioxide, Stevia leaf extract, Vitamin C, Natural flavor, Vitamin B3, Vitamin B5, Vitamin B6, Vitamin B12*

## Results

### Gluten results

#### Retained consumer sample

- < 5 mg/kg (ppm) gluten using the sandwich R5 ELISA
- < 10 mg/kg (ppm) gluten using the competitive R5 ELISA
- Negative for gluten using the LFD when a 0.5-g sample of product was tested
- Positive for gluten using the LFD when a level scoop of product was tested

#### Sample purchased by GFWD for testing

- < 5 mg/kg (ppm) gluten using the sandwich R5 ELISA
- < 10 mg/kg (ppm) gluten using the competitive R5 ELISA
- Negative for gluten using the LFD when a 0.5-g sample of product was tested
- Positive for gluten using the LFD when a level scoop of product was tested
- ✓ All samples tested using the sandwich or competitive R5 ELISAs also tested below the limit of detection for each assay (1 mg/kg (ppm) of gluten for the sandwich, 4.6 mg/kg (ppm) for the competitive— no detectable gluten was present in the samples tested)

### pH results

- 0.5-gram product sample had a pH of 6.04
- The level scoop of product had a pH of 4.83
- Buffer solutions at a pH of 4 and 7 tested positive for gluten and negative for gluten, respectively

## Conclusion

- False positive results may occur when consumers use LFDs to test food for gluten
- Kit manufacturers should provide very clear user instructions, such as those specified in AOAC's Stakeholders' Guidance Document for Consumer Analytical Devices with a Focus on Gluten and Food Allergens<sup>1</sup>
- Consumers should be advised to test a specified weight amount of product whenever possible
- Consumers should be cautioned that testing a lower or higher weight amount may result in false positive or false negative results
- Consumers should be advised to discuss their proposed sample testing with the kit provider before proceeding in order to understand the potential for matrix effects/interferences which could invalidate their results

## References

- <sup>1</sup>Popping, B, et al. Stakeholders' Guidance Document for Consumer Analytical Devices with a Focus on Gluten and Food Allergens. Journal of AOAC International 2018;101:185-189



### Acknowledgements:

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