

## Research Note

## Evaluation of a Handheld Gluten Detection Device

STEVE L. TAYLOR,\* JULIE A. NORDLEE, SHYAMALI JAYASENA, AND JOSEPH L. BAUMERT

*Food Allergy Research & Resource Program, Food Innovation Center, University of Nebraska–Lincoln, 1901 North 21st Street, Lincoln, Nebraska 68588-6207, USA*

MS 18-184: Received 27 April 2018/Accepted 28 June 2018/Published Online 21 September 2018

## ABSTRACT

A portable, handheld gluten detection device, the Nima sensor, is now available for consumers wishing to determine if gluten is present in food. By U.S. regulation, gluten-free foods should contain <20 ppm of gluten. Thirteen gluten-free foods (muffins, three different types of bread, three different types of pasta, puffed corn snack, ice cream, meatballs, vinegar and oil salad dressing, oatmeal, and dark chocolate) were prepared; each food was spiked on a weight to weight basis with gluten levels of 0, 5, 10, 20, 30, 40, and 100 ppm before processing or preparation. Unprocessed and processed foods were tested with the handheld gluten sensor and by two gluten-specific enzyme-linked immunosorbent assays (ELISAs) on the basis of the R5 and G12 monoclonal antibodies, respectively. The portable gluten detection device detected gluten in all food types at the 30-ppm addition level, failing to detect gluten in only 5 (6.4%) of 78 subsamples. At the 20-ppm addition level, the portable gluten detection device failed to detect gluten in one type of pasta but detected gluten residues in 63 (87.5%) of 72 other subsamples. The device was able to detect gluten at the 10-ppm addition level in 9 of the 13 food matrices (41 of 54 subsamples, 75.9%) but not in the three types of pasta and the puffed corn snack. The gluten-sensing device did not perform reliably at the 5-ppm addition level in 11 of 13 food matrices (exceptions: ice cream and muffins). In contrast, the ELISA methods were highly reliable at gluten addition levels of  $\geq 10$  ppm in all food matrices. The portable gluten detection device yielded a low percentage of false-positive results (4 of 111, 3.6%) in these food matrices. Thus, this handheld portable gluten sensor performed reliably in the detection of gluten in foods having  $\geq 20$  ppm of added gluten with only 18 (5.9%) of 306 failures, if results of the one type of pasta are excluded. The device worked with greater reliability as the gluten levels in the foods increased.

Key words: Celiac disease; Consumer; Detection; Gluten; Nima; Sensor

Gluten is the principal protein fraction of wheat, rye, barley, triticale, and related grains (20). Gluten contains alcohol-soluble (prolamin) and alcohol-insoluble (glutelin) fractions found in the proteins of gluten-containing grains. Although gluten is safely ingested by and nutritious for the majority of consumers, various forms of gluten sensitivity or intolerance are known, including celiac disease, dermatitis herpetiformis, and gluten sensitivity (3, 17). Additionally, a smaller percentage of consumers experience allergic reactions to specific gluten-containing grains, principally wheat (6).

Celiac disease is an autoimmune disorder of the small intestine associated with the consumption of gluten-containing foods or ingredients derived from those foods (12). The inflammatory response associated with celiac disease results in a loss of the absorptive capability within the small intestine. The symptoms of untreated celiac disease include weight loss from inability to absorb nutrients, anemia from inability to absorb iron, bone pain from inability to absorb calcium, diarrhea, and other manifestations. Celiac disease has a prevalence in the United States of approximately 1%, although more individuals have the

genetic predisposition to develop celiac disease than individuals who actually have the manifestations (11). Dermatitis herpetiformis is an infrequent manifestation of celiac disease characterized by the presence of intensely itchy, chronic papulovesicular lesions (blisters) on the skin (4). Dermatitis herpetiformis occurs in about 1% of individuals with celiac disease (4). Gluten sensitivity is a more recently recognized form of gluten intolerance that is neither an autoimmune disorder nor a form of food allergy (3). The symptoms of gluten sensitivity seem confined to the gastrointestinal tract, primarily diarrhea. Although the mechanism of nonceliac gluten sensitivity remains unknown, this condition may be more common than celiac disease (8). Immunoglobulin (Ig) E-mediated allergic reactions occur in a small percentage of individuals to the ingestion of specific gluten-containing grains (14). Wheat is one of the more common causes of IgE-mediated food allergies, especially in infancy (18), but less frequently, allergies to barley and rye also happen (13). Gliadin, the prolamin component of wheat gluten, is recognized as one of the allergens in an IgE-mediated wheat allergy, especially a wheat-dependent, exercise-induced allergy, but other wheat proteins are also identified as allergens (19).

The various clinical forms of gluten intolerance are controlled by a lifelong adherence to diets avoiding the

\* Author for correspondence. Tel: 402-472-2833; Fax: 402-472-5307; E-mail: [staylor2@unl.edu](mailto:staylor2@unl.edu).

intake of gluten from all sources (17). Individuals with wheat, barley, or rye allergy must only avoid those specific sources of gluten in most cases. Consumers with any of these clinical conditions follow gluten-free diets. However, adherence to a gluten-free diet is challenging for several reasons, including (i) agricultural comingling of gluten-containing grains with other crops during harvesting, storage, and transportation, (ii) the possibility of cross contact from the use of shared equipment in mixed-use food manufacturing and restaurant environments, (iii) labeling and packaging oversights, errors, and misuse of gluten-free claims, and (iv) poor application of testing methodologies. Consequently, gluten-intolerant consumers experience lapses in the ability to avoid gluten that result in adverse reactions of variable severity, depending upon the dose of exposure and the individual's degree of sensitivity to gluten.

Numerous gluten-free options are increasingly offered to consumers as packaged foods and in restaurant and other food service settings. The U.S. Food and Drug Administration has defined that gluten-free foods must contain <20 ppm of gluten (24). Methods, especially enzyme-linked immunosorbent assays (ELISA), have been developed with the appropriate specificity and sensitivity to detect gluten residues contaminating other foods (15, 21). However, these testing approaches are not amenable for use by consumers. A need exists for a simple-to-use, economical, fast, accurate, and portable testing device for use by gluten-intolerant consumers. Recently, Nima has developed a portable gluten detection device intended for use by gluten-intolerant consumers. The Nima device is essentially a lateral flow strip mounted within the automated testing device that extracts the test sample, performs the lateral flow analysis, and detects any positive response with an optical sensor. The lateral flow strip is impregnated with proprietary antiglutin antibodies. The device comes with one-use test capsules that are used for product sampling. Our objective was to evaluate this device against the existing ELISA methods with respect to its accuracy, sensitivity, and specificity.

## MATERIALS AND METHODS

**Materials.** Commercial all-purpose wheat flour served as the source of gluten. All other ingredients were obtained from typical commercial sources or local grocery outlets. Nima provided three of the portable testing devices and the testing capsules for this project. The Neogen Veratox for Gliadin R5 and the Romer Laboratories AgraQuant Gluten G12 ELISA kits were obtained from Neogen Corp., Lansing, MI, and Romer Laboratories, Inc., Newark, DE, respectively.

**Gluten detection by quantitative ELISA.** For measurement of gluten levels in various foods, three 10-g portions of all products (except the liquid ones: salad dressing and thawed ice cream) were ground together by using a blender with removable and washable separate blades and containers. The levels of gluten were then independently determined by using the Neogen Veratox for Gliadin R5 and the Romer Laboratories AgraQuant Gluten G12 ELISA kits by using instructions provided by those manufacturers. Triplicate extractions were done according to kit instructions, and duplicate measurements were made of each extraction. The gluten concentrations in each sample, including dilution factors, were

interpolated from the standard curve by using the software supplied by the kit manufacturers.

### Selection and formulation of gluten-free food products.

Thirteen different gluten-free food products were selected to represent a wide range of different compositions and processing and preparation conditions: bread (three types), chocolate, puffed corn snack, ice cream, meatballs, muffins, oatmeal, pasta noodles (three types), and salad dressing. These products also represent typical gluten-free options found in grocery stores and restaurants.

Wheat flour was well mixed, and the gluten level determined after appropriate dilution by using the Veratox for Gliadin R5 ELISA kit (see the following). Dry dilutions of the wheat flour were prepared in a gluten-free baking mix (Bob's Red Mill 1 to 1 Baking Flour), and the gluten content was determined by the Veratox for Gliadin R5 ELISA kit. The various dilutions of the mix were added to each product formulation prior to processing or preparation in quantities needed to provide formulations with 5, 10, 20, 30, 40, and 100 ppm of gluten in the finished food product (on a weight to weight basis, assuming 100% recovery). Each batch of food was thoroughly mixed to assure homogeneity of gluten distribution. A batch was tested for homogeneity before processing by testing five subsamples for gluten content by using the Veratox for Gliadin R5 ELISA kit; agreement within a 20% range was considered as acceptable. For several of the foods, the amount of the diluted gluten mix added to the formulations was adjusted to account for weight loss or gain from processing noted after the production of the gluten-free version of each food product (muffin, bread, puffed corn snack, meatball, and pasta). The gluten-free version of the food product served as the unspiked control. The gluten-free status of each unspiked food product was verified by the Veratox for Gliadin R5 ELISA kit before production of the gluten-containing versions.

Food products were processed or prepared in either the pilot plants or food preparation kitchen facilities of the Food Processing Center at the University of Nebraska–Lincoln. Most products were made in suitable small batches with kitchen equipment by approaches that simulated commercial processing, with one exception. The puffed corn snack was processed in a Wenger TX-52 twin-screw extruder located in the Food Processing Center Pilot Plant. Foods were frozen until thawed for extraction and analysis.

### Gluten detection with the handheld gluten detection device.

The Nima device was used for the detection of the presence of gluten in the finished food products by using the instructions provided by the manufacturer (<https://nimasensor.com/>). Six separate determinations were made on each product. The Nima device was used on both intact and ground samples of the food products. For intact food products, separate, small, pea-sized pieces of the foods at typical serving temperatures for that food (60°C for meatballs, pasta, and oatmeal; frozen for ice cream; and room temperature for all others) were introduced into the Nima capsule and processed as indicated in the device instructions. Additionally, food products, except the liquid ones (salad dressing and thawed ice cream) were ground as described previously. Pea-sized samples of these ground products were introduced into the Nima capsule and tested in triplicate in the Nima device, as indicated in the device instructions.

## RESULTS

Thirteen different food products were intentionally spiked with gluten on a weight to weight basis at levels

ranging from 5 to 100 ppm of gluten. Gluten was added to these foods in the form of wheat flour diluted into a gluten-free baking mix. The level of gluten in this spiking mix was determined by using the Veratox for Gliadin R5 ELISA kit. This concentration of gluten in the spiking mix served as the benchmark for making food products with various “known” levels of gluten.

As shown in Table 1, the Nima device was reliable for the detection of gluten residues in all 13 food matrices at levels of  $\geq 20$  ppm. Only one replicate among six subsamples was missed at either the 100-ppm level (pasta brand A) or 40-ppm level (corn puff). The device failed to detect gluten in only 5 (6.4%) of 78 samples incurred with 30 ppm of gluten (two breads brand C, two pastas brand A, and one pasta brand C). At 20 ppm of gluten, the device failed to detect gluten in one type of pasta but detected gluten in five of six subsamples of each of the other two types of pasta that were evaluated and in all subsamples of the other types of foods, with the exception of bread brand A (three of six), bread brand B (five of six), and corn puffs (three of six). Gluten was detectable with the device at the lower levels of 5 and 10 ppm of incurred gluten in some of the food matrices, although not uniformly in all subsamples with all foods. The device worked best in the detection of gluten residues at 5 ppm in ice cream and muffins. As shown in Table 1, pregrinding of the solid food samples did not improve the performance of the portable gluten sensor.

By comparison, the two ELISA methods, based on the R5 and G12 monoclonal antibodies, were uniformly able to detect gluten residues in all 13 food matrices at incurred levels of  $\geq 10$  ppm. In contrast to the handheld sensor, the gluten ELISAs yielded quantitative results. However at the critical concentration of 20 ppm, the quantitative result was  $< 20$  ppm in 13 of 13 matrices with the Veratox for Gliadin R5 ELISA and in 7 of 13 matrices with the AgraQuant Gluten G12 ELISA. Processing and preparation may affect gluten recovery. Although the AgraQuant Gluten G12 ELISA kit seemed to uniformly detect higher levels of gluten in the various food matrices, the gluten spiking levels were initially determined by using the Veratox for Gliadin R5 ELISA, and disparities may exist in kit standards, calibrations, and other factors.

With these 13 food matrices, false-positive results occurred at a very low rate (3.6%) with the gluten-sensing device (Table 2). The device did detect gluten in several of the food matrices when the gluten was incurred at levels below 20 ppm, including 21 of 78 subsamples at 5 ppm and 44 of 78 subsamples at 10 ppm.

## DISCUSSION

Adherence to gluten-free diets is critical to the health of individuals with celiac disease, dermatitis herpetiformis, and other forms of gluten sensitivity (16). Additionally, consumers with IgE-mediated allergies to wheat, barley, or rye also likely rely on gluten-free dietary options, even though they often only need to avoid one of those gluten-containing grains (23). The individual tolerance levels for gluten among gluten-sensitive consumers are likely variable, although the extent of variability is not well established.

Based upon several pivotal clinical studies (1, 5, 7), many countries, including the United States, have defined gluten-free as  $< 20$  ppm of gluten in food products as consumed (9, 24). This accepted threshold concentration for gluten of  $< 20$  ppm provides a safety margin for consumers with celiac disease. A key clinical study indicated that patients with celiac disease can likely tolerate foods containing  $\leq 10$  mg of gluten (1, 5, 7). A food having 20 ppm of gluten will contain 5 mg of gluten in a large 250-g serving. Thus, foods having  $< 20$  mg of gluten are rather unlikely to provoke adverse reactions in consumers with celiac disease on the basis of this key clinical challenge study (5). Another study indicated that patients with celiac disease did not suffer intestinal damage when allowed to consume foods having 100 ppm of gluten, although the study did not monitor how frequently patients might have actually consumed such foods (7). With respect to consumers with IgE-mediated wheat allergy, a reference dose for wheat protein of 1 mg was established by the Allergen Bureau of Australia and New Zealand based upon oral clinical challenges of wheat-allergic individuals (22). This reference dose represents the 95% lower confidence interval of the eliciting dose predicted to induce an objective adverse reaction in the 5% most sensitive wheat-allergic subjects. Thus, clinical challenge evidence suggests that subjects with IgE-mediated wheat allergy may be more sensitive to wheat protein than individuals with celiac disease, although additional challenges of patients with celiac disease are desirable to create greater certainty about this difference.

In recent years, many gluten-free products have appeared as packaged foods and as menu options in restaurants. Although this variety of options offers a major benefit to gluten-sensitive consumers, reliable, sensitive, rugged, and economical ways to evaluate the veracity of these gluten-free label claims did not exist. The portable gluten sensor evaluated in this study represents the first device intended for use by gluten-sensitive consumers. Based upon the results presented in Table 1, the Nima gluten sensor is able to detect gluten at the desired levels of 20 ppm and above in a range of different food matrices.

Food formulations and processing may affect the reliability of the Nima device to some extent. At the critical level of 20 ppm, the Nima device failed to detect gluten in any of six samples of pasta brand A, in three of six samples of bread brand A, and in three of six samples of corn puffs. Although the Nima device failed to detect gluten in pasta brand A, the device performed well with other pasta formulations and in pasta brand A at 30 ppm of incurred gluten. The disparity in performance with the three different types of pasta cannot be readily explained beyond noting that the pastas had differing formulations that may have affected extraction in the Nima device. The formulations of the three different types of bread were also variable with bread brand A containing sorghum flour as the principal ingredient, while bread brands B and C had white rice flour and garbanzo bean flour, respectively. With corn puffs, extrusion processing may represent the harshest processing condition among all of these foods. With bread brand A and corn puffs, the Nima device performed well at 30 ppm of

TABLE 1. *Gluten detection in food products with Nima device and commercial ELISA methods*

Food	Intended gluten level (ppm)	Neogen Veratox for Gliadin R5 ELISA (ppm)	Romer Laboratories	Nima device (no. detected/no. tested)	
			AgraQuant Gluten G12 ELISA (ppm)	As is	Ground
Bread (brand A)	5	BLQ <sup>a</sup>	6.4 ± 0.3	1/6	1/3
	10	6.1 ± 0.8	11.7 ± 0.4	3/6	0/3
	20	11.3 ± 1.7	19.9 ± 1.1	3/6	2/3
	30	18.3 ± 1.5	43.2 ± 1.6	6/6	3/3
	40	30.3 ± 5.7	57.8 ± 3.4	6/6	3/3
	100	91.3 ± 10.9	193 ± 7	6/6	3/3
Bread (brand B)	5	BLQ	5.6 ± 0.2	0/6	0/3
	10	6.3 ± 1.6	13.6 ± 1.0	6/6	2/3
	20	12.0 ± 2.2	32.9 ± 3.8	5/6	3/3
	30	19.6 ± 3.0	42.6 ± 3.2	6/6	3/3
	40	33.4 ± 5.1	62.6 ± 1.3	6/6	3/3
	100	90.0 ± 1.9	192 ± 4	6/6	3/3
Bread (brand C)	5	BLQ	6.9 ± 0.5	3/6	1/3
	10	6.5 ± 1.3	11.9 ± 0.8	3/6	3/3
	20	14.6 ± 2.8	22.1 ± 1.1	6/6	3/3
	30	21.0 ± 4.9	45.9 ± 1.2	4/6	3/3
	40	41.8 ± 18.4	58 ± 1.3	6/6	3/3
	100	111 ± 16	146 ± 9	6/6	3/3
Chocolate	5	BLQ	BLQ	2/6	1/3
	10	6.6 ± 1.4	8.3 ± 2.0	5/6	3/3
	20	14.7 ± 0.7	15.4 ± 2.0	5/6	3/3
	30	23.4 ± 7.4	27.2 ± 4.6	6/6	3/3
	40	28.5 ± 2.5	33.1 ± 3.1	6/6	3/3
	100	122 ± 11	102 ± 14	6/6	3/3
Corn puffs	5	5.1 ± 1.0	4.2 ± 0.3	2/6	1/3
	10	11.7 ± 2.2	9.2 ± 0.5	1/6	1/3
	20	18.7 ± 2.1	15.0 ± 0.6	3/6	3/3
	30	31.2 ± 0.5	24.6 ± 1.2	6/6	3/3
	40	41.3 ± 6.7	37.6 ± 1.6	5/6	3/3
	100	108 ± 4	116 ± 4	6/6	3/3
Ice cream	5	BLQ	5.2 ± 0.5	6/6	NA <sup>b</sup>
	10	8.9 ± 0.7	12.8 ± 0.7	6/6	NA
	20	15.8 ± 1.7	22.4 ± 1.8	6/6	NA
	30	22.0 ± 0.8	44.4 ± 0.7	6/6	NA
	40	30.3 ± 0.8	54.9 ± 0.4	6/6	NA
	100	75.5 ± 6.2	153 ± 4	6/6	NA
Meatballs	5	BLQ	4.1 ± 0.4	1/6	0/3
	10	6.4 ± 0.1	10.8 ± 0.9	3/6	3/3
	20	11.3 ± 0.3	17.5 ± 0.5	6/6	2/3
	30	20.2 ± 1.9	35.9 ± 1.8	6/6	3/3
	40	25.6 ± 2.7	47.3 ± 2.6	6/6	3/3
	100	66.0 ± 3.5	171 ± 1	6/6	3/3
Muffins	5	BLQ	7.7 ± 1.0	5/6	2/3
	10	6.0 ± 0.2	14.4 ± 0.5	5/6	3/3
	20	16.0 ± 0.9	31.3 ± 2.9	6/6	3/3
	30	21.1 ± 3.1	50.1 ± 1.7	6/6	3/3
	40	36.8 ± 3.3	68.5 ± 1.9	6/6	3/3
	100	104 ± 7	202 ± 10	6/6	3/3
Oatmeal	5	BLQ	5.0 ± 0.3	0/6	1/3
	10	6.8 ± 0.3	13.6 ± 0.8	4/6	3/3
	20	9.4 ± 0.3	16.5 ± 1.5	6/6	2/3
	30	14.0 ± 1.0	28.7 ± 2.3	6/6	3/3
	40	23.5 ± 2.2	50.4 ± 3.5	6/6	3/3
	100	64.7 ± 8.7	192 ± 18	6/6	3/3

TABLE 1. *Continued*

Food	Intended gluten level (ppm)	Neogen Veratox for Gliadin R5 ELISA (ppm)	Romer Laboratories AgraQuant Gluten G12 ELISA (ppm)	Nima device (no. detected/no. tested)	
				As is	Ground
Pasta (brand A)	5	BLQ	7.8 ± 0.4	0/6	1/3
	10	6.6 ± 0.6	13.8 ± 0.4	0/6	1/3
	20	8.0 ± 1.9	19.2 ± 0.8	0/6	2/3
	30	17.2 ± 0.2	29.2 ± 3.6	4/6	1/3
	40	25.4 ± 3.5	32.4 ± 14.0	6/6	2/3
	100	55.5 ± 6.0	176 ± 1.9	5/6	3/3
Pasta (brand B)	5	BLQ	8.8 ± 0.7	1/6	1/3
	10	6.1 ± 0.5	11.9 ± 0.5	1/6	0/3
	20	11.3 ± 1.3	20.8 ± 3.2	5/6	3/3
	30	20.6 ± 1.5	32.3 ± 2.5	6/6	3/3
	40	27.5 ± 5.0	44.5 ± 0.9	6/6	3/3
	100	59.6 ± 8.8	159 ± 5	6/6	3/3
Pasta (brand C)	5	BLQ	8.5 ± 0.7	0/6	0/3
	10	6.8 ± 0.7	15.1 ± 0.8	1/6	0/3
	20	13.2 ± 0.5	27.6 ± 2.6	5/6	2/3
	30	20.3 ± 5.3	37.9 ± 1.4	5/6	3/3
	40	23.8 ± 0.8	53.4 ± 4.3	6/6	3/3
	100	63.5 ± 5.4	180 ± 3	6/6	3/3
Salad dressing	5	BLQ	BLQ	6/6	NA
	10	BLQ	5.6 ± 0.4	6/6	NA
	20	11.2 ± 1.8	15.0 ± 1.3	6/6	NA
	30	15.6 ± 2.9	18.8 ± 0.6	6/6	NA
	40	23.0 ± 1.8	23.0 ± 2.5	6/6	NA
	100	79.1 ± 9.0	109 ± 5	6/6	NA

<sup>a</sup> BLQ, below limit of quantification.

<sup>b</sup> NA, not applicable.

incurred gluten. Further research would be needed to determine the basis for the reliability issues with the Nima device at an incurred gluten level of 20 ppm.

Although the Nima device is the first portable gluten detection sensor available to consumers, the EZ Gluten kit, a lateral flow device, has been available to consumers for home use for several years. We did not compare the Nima device to the EZ Gluten kit in this study. Although the EZ Gluten kit has AOAC International certification (2), the method uses the Skerritt antibody that weakly detects barley gluten (10) and requires 20 to 25 min for test completion, which is quite long for use in restaurant settings.

We conclude that the portable, handheld Nima gluten sensor functions reliably detect gluten residues at appropriate levels in a range of different foods. The foods were deliberately chosen to represent the wide range of products that might be available as gluten-free options. In our opinion, use of the Nima device will protect the health of gluten-sensitive consumers, if properly used on foods with reasonably uniform gluten distribution. The Nima device did perform poorly in detection of the critical 20 ppm on certain categories of foods, including bread, pasta, and corn puffs (47% detection). However, in those categories, detection improved to 88% at 30 ppm of gluten and 97.5% at 40 ppm of gluten. In the other five food categories, the Nima device detected 20 ppm of gluten in 96.5% of occasions. Gluten-sensitive consumers could improve the reliability of the

device by testing duplicate samples in the case of bread, pasta, and extruded snacks.

The Nima device has some limitations. Admittedly, we evaluated this device while carefully adhering to the instructions for its proper use. We made no attempt to evaluate its performance when used improperly and would encourage consumers to follow the use instructions if they want to achieve similarly reliable results. The sample volume taken into the Nima device is a small pea-sized portion. Based upon the results, the small sample provides reliable results when the gluten is well distributed in the tested food. However, the presence of gluten-containing particulates could be missed with this sampling device. The sampling problem with particulates is a key issue with the Nima device. Consumers would need to take multiple samples to increase reliability when particulates are suspected. Commercial gluten ELISAs also rely upon a small sample size of 0.25 g, but larger samples are typically taken and ground before the smaller subsample is taken for analysis. Another acknowledged limitation of the gluten-sensing device is that it detects intact gluten but may not detect gluten residues in fermented and hydrolyzed products, such as beer, soy sauce, and others. Finally, we did not evaluate the performance of the Nima device with respect to the hook effect that would occur when testing foods with high concentrations of gluten.

TABLE 2. False-positive results obtained with the Nima device

Food	Ground	No. of samples	% positive
Bread (brand A)	No	0/6	0
	Yes	0/3	0
Bread (brand B)	No	0/6	0
	Yes	0/3	0
Bread (brand C)	No	0/6	0
	Yes	0/3	0
Chocolate	No	0/6	0
	Yes	0/3	0
Corn puffs	No	2/6	33
	Yes	0/3	0
Ice cream	No	0/6	0
Meatballs	No	0/6	0
	Yes	0/3	0
Muffins	No	0/6	0
	Yes	0/3	0
Oatmeal	No	1/6	17
	Yes	1/3	33
Pasta (brand A)	No	0/6	0
	Yes	0/3	0
Pasta (brand B)	No	0/6	0
	Yes	0/3	0
Pasta (brand C)	No	0/6	0
	Yes	0/3	0
Salad dressing	No	0/6	0
Summary	Not Ground	78 (3 positive)	3.8
	Ground	33 (1 positive)	3.0
	Total	111 (4 positive)	3.6

## ACKNOWLEDGMENT

The research described in the article was sponsored by Nima. Nima also provided the portable testing devices and the testing capsules needed to perform the research.

## REFERENCES

- Akobeng, A. K., and A. G. Thomas. 2008. Systematic review: tolerable amount of gluten for people with coeliac disease. *Aliment. Pharmacol. Ther.* 27:1044–1052.
- Allred, L. K., and E. S. Park. 2012. EZ Gluten for the qualitative detection of gluten in foods, beverages, and environmental surfaces. *J. AOAC Int.* 95:1106–1117.
- Biesiekierski, J. R., E. D. Newnham, P. M. Irving, J. S. Barrett, M. Haines, J. D. Doecke, S. J. Shepherd, J. G. Muir, and P. R. Gibson. 2011. Gluten causes gastrointestinal symptoms in subjects without celiac disease: a double-blind randomized placebo-controlled trial. *Am. J. Gastroenterol.* 106:508–514.
- Bolotin, D., and V. Petronic-Rosic. 2011. Dermatitis herpetiformis. Part I. Epidemiology, pathogenesis, and clinical presentation. *J. Am. Acad. Dermatol.* 64:1017–1024.
- Catassi, C., E. Fabiani, G. Iacono, C. D'Agate, R. Francavilla, F. Biagi, U. Volta, S. Accomando, A. Picarelli, I. De Vitis, G. Pianelli, R. Gesuita, F. Carle, A. Mandolesi, I. Bearzi, and A. Fasano. 2007. A prospective, double-blind, placebo-controlled trial to establish a safe gluten threshold for patients with celiac disease. *Am. J. Clin. Nutr.* 85:160–166.

- Cianferoni, A. 2016. Wheat allergy: diagnosis and management. *J. Asthma Allergy* 9:13–25.
- Collin, P. 2007. Safe gluten threshold for patients with celiac disease: some patients are more tolerant than others. *Am. J. Clin. Nutr.* 86:260–261.
- Collyer, E. M., and B. S. Kaplan. 2016. Nonceliac gluten sensitivity: an approach to diagnosis and management. *Curr. Opin. Pediatr.* 28:638–643.
- Diaz-Amigo, C., and B. Popping. 2012. Gluten and gluten-free: issues and considerations of labeling regulations, detection methods, and assay validation. *J. AOAC Int.* 95:337–348.
- Diaz-Amigo, C., and B. Popping. 2013. Accuracy of ELISA detection methods for gluten and reference materials: a realistic assessment. *J. Agric. Food Chem.* 61:5681–5688.
- Fasano, A., I. Berti, T. Gerarduzzi, T. Not, R. B. Colletti, S. Drago, Y. Elitsur, P. H. Green, S. Guandalini, I. D. Hill, M. Pietzak, A. Ventura, M. Thorpe, D. Kryszak, F. Fornaroli, S. S. Wasserman, J. A. Murray, and K. Horvath. 2003. Prevalence of celiac disease in at-risk and not-at-risk groups in the United States: a large multicenter study. *Arch. Intern. Med.* 163:286–292.
- Green, P. H. R., B. Lebowohl, and R. Greywoode. 2015. Celiac disease. *J. Allergy Clin. Immunol.* 135:1099–1106.
- Järvinen, K.-M., M. Turpeinen, and H. Suomalainen. 2003. Concurrent cereal allergy in children with cow's milk allergy manifested with atopic dermatitis. *Clin. Exp. Allergy* 33:1060–1066.
- Jones, S. M., C. F. Magnolfi, S. K. Cooke, and H. A. Sampson. 1995. Immunologic cross-reactivity among cereal grains and grasses in children with food hypersensitivity. *J. Allergy Clin. Immunol.* 96:341–351.
- Lexhaller, B., C. Tompos, and K. A. Scherf. 2017. Fundamental study on reactivities of gluten protein types from wheat, rye and barley with five sandwich ELISA test kits. *Food Chem.* 237:320–330.
- Ludvigsson, J. F., J. C. Bai, F. Biagi, T. R. Card, C. Ciacci, P. J. Ciclitira, P. H. Green, M. Hadjivassiliou, A. Holdaway, D. A. van Heel, K. Kaukinen, D. A. Leffler, J. N. Leonard, K. E. Lundin, N. McGough, M. Davidson, J. A. Murray, G. L. Swift, M. M. Walker, F. Zingone, D. S. Sanders, BSG Coeliac Disease Guidelines Development Group, and British Society of Gastroenterology. 2014. Diagnosis and management of adult coeliac disease: guidelines from the British Society of Gastroenterology. *Gut* 63:1210–1228.
- Murray, J. A. 1999. The widening spectrum of celiac disease. *Am. J. Clin. Nutr.* 69:354–365.
- Sampson, H. A., and C. C. McCaskill. 1985. Food hypersensitivity and atopic dermatitis: evaluation of 113 patients. *J. Pediatr.* 107:669–675.
- Scherf, K. A., K. Brockow, T. Biedermann, P. Koehler, and H. Wieser. 2016. Wheat-dependent exercise-induced anaphylaxis. *Clin. Exp. Allergy* 46:10–20.
- Shewry, P. R., M. J. Miles, and A. S. Tatham. 1994. The prolamin storage proteins of wheat and related cereals. *Prog. Biophys. Mol. Biol.* 61:37–59.
- Slot, I. D. B., M. Bremer, I. van der Fels-Klerx, and R. J. Hamer. 2015. Evaluating the performance of gluten ELISA test kits: the numbers do not tell the tale. *Cereal Chem.* 92:513–521.
- Taylor, S. L., J. L. Baumert, A. G. Kruizinga, B. C. Remington, R. W. R. Crevel, S. Brooke-Taylor, K. J. Allen, Allergen Bureau of Australia & New Zealand, and G. Houben. 2014. Establishment of reference doses for residues of allergenic foods: report of the VITAL Expert Panel. *Food Chem. Toxicol.* 63:9–17.
- Taylor, S. L., S. L. Hefle, and A. Muñoz-Furlong. 1999. Food allergies and avoidance diets. *Nutr. Today* 34:15–22.
- U.S. Food and Drug Administration. 2013. Food labeling: gluten-free labeling of foods. Final rule. *Fed. Regist.* 78:47154–47179.