Dietitian Experiences Using a Novel Portable Personal Testing Gadget For Gluten

By Tricia Thompson, MS, RD; Nancee Jaffe, MS, RDN; Amy Keller, MS, RD, LD; Janelle Smith, MS, RDN, CEDRD

This article was sponsored by the Dietitians in Gluten and Gastrointestinal Disorders (DIGID) and had been approved for 0.5 continuing professional education units (CPEU), see Editor's Corner for details.

Abstract

Key Words: Celiac disease, gluten-free diet, cross-contact, personal testing gadgets

Introduction: Portable gadgets that allow consumers to test food for gluten and various allergens are beginning to enter the marketplace. The Nima Sensor (Nima Labs, Inc., San Francisco, CA) for gluten is one such gadget marketed to gluten-free consumers as a tool that allows the testing of gluten anytime and anywhere. Dietitians participated in a dinner hosted by Gluten Free Watchdog, LLC, to evaluate how a portable testing sensor for gluten is perceived and used. *Procedure:* Seventeen dietitians received brief instruction on use of the Nima Sensor and were encouraged to read the instructions provided by the manufacturer. They described their (delete testing) experience in writing, including the test result, the food they chose to test and why, how they felt while waiting for the result, and how they felt seeing the result. *Results:* The most frequently cited reason for testing a food was to check for cross-contact with gluten, followed by checking sauces for gluten. Of emotions noted during the waiting and result process, 79% were negative. Of the 24 tests conducted, 9 (38%) resulted in an error message. *Conclusion:* While there was a lot of general anxiety, there was also curiosity about the device, and after the testing experience was complete some participants expressed relief. However, the frequency of unexplained error messages along with obstacles, such as cartridges not closing tightly, difficulty determining proper sample size, and delay in receiving results, contributed to an overall sense of frustration.

Learning Objectives

Upon completion of this article, the reader should be able to:

1. Identify pros and cons to consumer use of a portable gadget intended to detect gluten in prepared foods
2. Understand both the consumer experience and the dietitian experience of using such devices
3. Be prepared to counsel patients on the use of portable gadgets for detecting gluten in prepared foods

Portable gadgets that allow consumers to test food for gluten and various allergens are beginning to enter the marketplace. These gadgets are marketed to consumers to allow them to "test your food for gluten anytime, anywhere" (1). Such gadgets are appealing to the gluten-free and allergic communities to help ensure that food prepared outside the home (e.g., restaurants) is free from gluten or the allergen of interest, especially when there is concern about cross-contact.

The Nima Sensor (Nima Labs, Inc., San Francisco, CA) for gluten and the Nima Sensor for peanut are currently available for purchase. The Allergy

Amulet (Allergy Amulet, LLC, Madison, WI) is in development. Because of the complicated nature of testing food for allergens and gluten, these gadgets are receiving scrutiny from the analytical community. The focus of this scrutiny has largely been on the Nima Sensor for gluten because this was the first commercially available portable sensor for consumer use (2,3). The Nima Sensor is a lateral flow device that is marketed as "usable right at the dinner table" (1). The first generation of the Nima Sensor is a triangular handheld device with a slot for a single-use testing capsule. The capsule has a screw top that the user opens to place a pea-sized amount of food inside. The screw top is then replaced and the capsule is placed inside the device. A button is pressed to start the testing process. After a few minutes, the display will show either a result—smile; low gluten; high gluten; or a test error message. Updated firmware and second-generation devices may vary.

The Nima Sensor for gluten was recently evaluated in the peer-reviewed scientific literature (4). In this evaluation, researchers stated that the sensor "worked with greater reliability as the gluten levels in the foods increased." In a webinar about the evaluation, it was reported that the gadget detected gluten in samples at the 20 parts per million (ppm) level 79.5% of the time (5). Under the gluten-free rule of the Food and Drug Administration (FDA), foods labeled gluten-free must contain less than 20 ppm of gluten. The AOAC International has published a stakeholders' guidance document for consumer analytical devices with a focus on gluten and food allergens that is intended to help inform future development and improvement of these products (2). "These guidelines cover areas such as kit validation, user sampling instructions, kit performance, and interpretation of results" (2).

To help understand how a portable testing sensor for gluten is perceived and used, dietitians knowledgeable about the gluten-free diet were invited to attend a dinner where the Nima Sensor for gluten was available for use. Dietitians knew in advance that their testing experience would help form the basis of a case study on using this sensor to test restaurant food designated as gluten-free. The purpose of this evaluation was not to assess the accuracy of the sensor but rather to assess the user experience.

Description of Evaluation

Dietitians working with patients with gluten-related disorders, most of whom were attending the annual Academy of Nutrition and Dietetics Food & Nutrition Conference & Expo, were invited to attend a dinner and use a consumer gadget designed to test food for gluten. The consumer advocacy group and consumer food testing service Gluten Free Watchdog, LLC, hosted the dinner.

The dinner was held at a restaurant with gluten-free menu items. Dishes were ordered in advance and served buffet style in a separate area of the restaurant removed from the other patrons. The restaurant knew in advance that the food was to

be prepared gluten-free and that the dinner was for dietitians knowledgeable about the gluten-free diet. Menu items included chicken lettuce wraps, Pad Thai with fried tofu, spinach with garlic, coconut curry with tofu and vegetables, beef with broccoli, and white rice.

Seventeen dietitians attended the dinner and tested food for gluten. Two testing sensors and 24 single-use testing capsules were available on the table for testing. Manufacturer instructions for the sensors also were placed on the table. Before the dinner, participants were provided with brief oral instructions on how to use the sensor, including the amount to test (a pea-sized amount as recommended by the device manufacturer) and were advised not to overfill the capsules, which would lead to incomplete closure.

Participants were told that if they chose to test food for gluten using the sensor, two main points regarding testing were important to keep in mind. First, gluten contamination can be very heterogeneous (e.g., spotty) and not evenly spread throughout a dish, and second, the limit of detection for the particular sensor they would be using could be very low. At the 5-ppm level, the device reports gluten found 34.6% of the time and at 10 ppm, the device reports gluten found 56.4% of the time (4,5). As a consequence, a "gluten found" result does not necessarily mean the sample contains gluten at or above 20 ppm (the threshold level of gluten allowed under the FDA's gluten-free labeling rule). Participants were also advised to read instructions; photograph (using their phone) the portion of the plate from where the sample to be tested was taken; photograph the result; provide information on what food(s) they tested and why; and provide information on how they felt while waiting for the result and how they felt when they saw the result.

Table 1. Handheld Testing Gadget: Ingredients Tested, Stated Reasons for Testing, and Results

Menu Item	Ingredients Tested	Stated Reason (s) for Testing	Total Number Tests	Number Smiles	Number High Gluten	Number Low Gluten	Number Errors	Number Missed
Chicken lettuce wrap	Chicken	Small size; favorite dish; checking for contamination	2	1	0	0	0	1
	Combination: chicken/water chestnut/noodle	Wanted to test a mashed up composite sample	1	1	0	0	0	0
Pad Thai with fried tofu	Noodles	Checking for cross-contact with wheat-based noodles	4	1	0	0	3	0
	Fried tofu	Checking for cross-contact due to possible use of shared fryer; Checking for use of (or cross-contact with) gluten-containing soy sauce	4	2	0	0	2	0
Spinach with garlic	N/A		0	0	0	0	0	0
Soy sauce	Soy sauce (not gluten-free)	Wondered whether the device could detect gluten protein fragments from wheat	1	1	0	0	0	0
Coconut curry with tofu and vegetables	Broccoli	Wanted to test simple, nonhomogenized food; Confirming first test result	2	1	0	1	0	0
	Combination: peanut/green onion	No reason provided	1	0	0	0	1	0
	Tofu	Checking to see if device could test soy	1	0	0	0	1	0
	Mushroom	Wanted to test a food no one else had tested	1	1	0	0	0	0
White rice	White rice	Checking for cross-contact during cooking	1	1	0	0	0	0
Beef with broccoli	Beef	Favorite dish; making sure the sauce coating the beef was gluten-free	3	1	0	0	2	0
	Broccoli	Making sure the sauce coating the broccoli was gluten-free	1	1	0	0	0	0
	Sauce	Wanted to test homogenized product of several ingredients; checking to make sure soy sauce used was gluten-free	2	2	0	0	0	0
		TOTAL	**24**	**13**	**0**	**1**	**9**	**1**

Lesson Learned

Test Results

As shown in Table 1, of the 24 tests conducted, 9 (37.5%) resulted in error messages. One test result was missed because it was not read before the display clearing. Of the 14 tests with a result (58%), 13 were smiles and 1 was low gluten. The manufacturer states that "A smiley face will be displayed on the screen if Nima doesn't find gluten in a sample at 20 ppm or higher." (6). A low gluten/gluten found result includes any nonzero result in parts per million detected by the sensor (7).

The low-gluten result was received when a sample of broccoli was tested. When the same participant tested a second sample of broccoli, the result was a smile. Error messages were received three of five (60%), three of four (75%), and two of three (66%) times when tofu, noodles, and beef were tested, respectively. The two most frequently stated reasons why particular samples were chosen for testing were checking for cross-contact with gluten and checking to see if a sauce was gluten-free.

Obstacles and Limitations to Testing

Participants were asked to provide answers to open-ended questions, including how they felt during and after the testing process. As illustrated in Table 2, 10 (62.5%) of 16 participants noted various obstacles or limitations in their responses. Obstacles and limitations were mentioned for both the sensor and the testing capsules. Some participants also noted a general lack of confidence in this form of testing. The most bothersome aspect of the testing process reported by participants was the length of time it took to receive the result. The next two most reported difficulties/limitations were determining sample size and fitting the sample into the capsule, and the sample size not accurately representing the entire dish (Figure).

Table 2. Obstacles and Limitations Noted by Participants (N=16)

Obstacle/Limitation Noted	Number of Participants Noting	Number of Times Noted
Gadget limitations		
Results slow to receive	7 (44%)	13
Generally difficult to use	3 (19%)	4
Wasteful of resources (i.e., money, cartridges)	2 (13%)	2
Hard to use in a darkened restaurant	1 (6%)	1
Result missed because display cleared	1 (6%)	1
Cartridge-specific obstacles		
Difficulty fitting sample into cartridge/determining sample size	4 (25%)	6
Cartridge difficult to close all the way	2 (13%)	2
Cartridge wrapper difficult to open	1 (6%)	1
Difficulty fitting cartridge into device	1 (6%)	1
Lack of confidence in form of testing		
Sample size not representative of entire dish	4 (25%)	5
Does not work on hydrolyzed or fermented foods	2 (13%)	3
Not reliable, "not worth it"	2 (13%)	2
	TOTAL	**41**
Number of participants reporting an obstacle	10 (62.5%)	
Number of participants with no obstacle noted	6 (37.5%)	

Table 3. Emotions Reported by Study Participants During Gadget Testing Process (n=16)

	Emotion Described by Participants	Number of Participants Experiencing Emotion	Number of Times Noted
Negative emotions	Afraid/fearful	2	2
	Annoyed	1	2
	Anxious/nervous	4	5
	Blamed self for error message	1	1
	Burdensome	1	1
	Concerned	2	4
	Confused	1	1
	Curious (negative)	2	2
	Disappointed	1	3
	Distracted	1	1
	Doubtful	1	1
	Felt bad/sorry	1	2
	Frustrated	4	5
	Guilty	2	2
	Impatient	2	3
	Indifferent	1	1
	Skeptical	1	1
	Stressed	1	2
	Unsettled/unnerved	2	2
	Unsure	2	2
	Worried	1	1
Positive emotions	Comforted	1	1
	Confident	1	1
	Curious (positive)	2	2
	Elated	1	1
	Excited	1	1
	Optimistic	1	1
	Relaxed	1	1
	Relieved	4	4
Number of NEGATIVE *types* of emotions expressed	21	Number of POSITIVE *types* of emotions expressed	8
Number of *times*	44	Number of *times*	12
NEGATIVE emotions expressed		POSITIVE emotions expressed	

Emotions During Testing Process

Participants also reported feeling a number of emotions, both positive and negative during the testing process. As shown in Table 3, of the 29 different types of emotions reported, 72% were negative. Of the 56 times that emotions were expressed by participants, 79% were negative emotions. Emotions reported by the greatest number of participants included anxiety, frustration, and relief.

sometimes used in the extraction process to help prevent false positives or false negatives. When products are tested with the Nima Sensor, the manufacturer instructions call for an unweighed pea-sized amount of food to be placed inside a testing capsule (9). If the food is dense or dry, instructions provided with the device suggest using "a little bit less." If the food is airy or puffed, instructions suggest using "a little bit more." When testing products with the Nima Sensor, the instructions state "put a pea-sized sample of liquid or solid food in a one-time use capsule" (9). Although a consumer could use a blender at home to homogenize a representative sample of product (subsamples taken from the top, middle, and bottom of a container, for example) before testing a pea-sized amount, this is not a practical solution in a restaurant setting. It seems unlikely that testing such a small amount of nonhomogenized food from a restaurant meal would capture gluten that may be in the plate of food because of cross-contact (e.g., using the same food preparation tools for gluten-free and gluten-containing foods).

Discussion

Checking Restaurant Food for Cross-Contact with Gluten

Checking for cross-contact was one of the reasons most frequently cited by participants for choosing to test a particular sample of food. However, gluten, when present unintentionally in a food (versus being added intentionally as an ingredient), is not necessarily evenly distributed throughout a product. This is one reason why laboratories homogenize a representative amount of sample (grinding it to a powder) before testing smaller extractions (8). When products are tested with a scientifically validated enzyme-linked immunosorbent assay (ELISA), such as the sandwich R5 ELISA, manufacturer instructions call for the homogenization (thorough grinding to a powder) of at least 5 g and up to 200 g of sample depending on the food tested (8). Extractions from 0.25 g up to 1 g (in the case of oats) are tested with manufacturer recommendations calling for samples to be tested in duplicates. Because of the matrix effects caused by the composition of some foods, a milk additive is

Checking Restaurant Sauces for Gluten

Assessing sauces for gluten was the other reason most frequently cited by participants for choosing to test a particular sample of food. Restaurant sauces, particularly at Asian-style restaurants may contain hydrolyzed wheat protein in the form of soy sauce. The Nima Sensor instructions state that the device cannot accurately test soy sauce or other fermented or hydrolyzed foods (this limitation would also apply to sauces containing barley malt ingredients) (10).

One participant tested regular soy sauce containing wheat to confirm whether or not the sensor would detect gluten peptide fragments. The result was a smile. Because of this limitation, it is impossible to know whether a sauce does or does not contain hydrolyzed wheat or barley protein from ingredients such as soy sauce or barley malt unless the consumer has access to the ingredients list.

Negative Emotions During the Testing Process

Although all of the dietitian participants have an

active interest in the gluten-free diet, some are more directly affected by this diet than others because they either have celiac disease or have a family member with celiac disease. Only the dietitians who could be considered among the target consumer group for this sensor (e.g., they have celiac disease, family member has celiac disease) reported feeling fearful during the testing process.

Negativity bias is well established (e.g., human beings are prone to remember the bad more than the good) (11); it is nonetheless striking that of the 56 times that emotions were expressed by participants in their responses, 79% were negative emotions. Here is a representative sample of the statements provided by participants (identifying information redacted):

- “I felt impatient while waiting for my result and thought it was taking too long. When I got the error result I was very disappointed, and also blamed myself for the error. I worried about wasting the resource/money and felt guilty for that as well.”
- “I felt annoyed by the process—the container was hard to close and figuring out what a "pea-sized" amount was a challenge. The noise of the machine was unsettling and made me feel anxious. The wait is also anxiety provoking as I was already consuming my meal.”
- “It was nice to see the smiley face to confirm that [restaurant name] does know what they are doing, although I know that this tiny bit of tofu getting a smiley face isn't necessarily confirmation of that either. But it did inspire some additional confidence even though I understand the limitations.”
- “While waiting for the result I was excited to see if it would work (rather than getting an error). I was also optimistic that gluten would not be found in my gluten-free chicken lettuce wrap. Mostly because [dinner host—name withheld] appeared to trust that it was gluten-free and did not seem nervous about the possibility of anyone finding it to contain gluten.”

- "While the sauce response was welcomed and did relieve some anxiety about the meal, the tofu result was unnerving (it was an error message). It would be frustrating to see an error result—now you have a dilemma—do you test again? Do you proceed and assume it is okay—it is almost worse than having either a positive or negative result."

Number of Error Messages

The number of error messages received by study participants is concerning. An error message was received 37.5% of the time. These errors could have been caused by the placement of too much food into a capsule and/or the inability to completely close the capsule. In an effort to help determine what might be happening, one of the study authors well versed in testing food using the Nima Sensor tested a very small amount of food in one of the sensors. The result was an error message. To make sure the sensor was functioning properly, another participant used the sensor to test a sample of food. The result was a smile. The samples with errors could all be considered to have textures that were gummy (noodle, tofu), hard (peanut), or tough (beef).

One consideration that should not be overlooked with this percentage of error messages is expense. Each single-use testing capsule costs approximately $5 to $6 depending on the purchase plan (automatic refills or single 12-pack purchase).

Summary

The Nima Sensor for gluten is intended to give consumers the ability to test food at the point of service to help determine whether a meal or dish is safe to consume. Dietitians involved in this user evaluation most often tested samples to check either for cross-contact with gluten or whether sauces contained gluten. These testing choices were made despite participants being advised before the testing process, either verbally or in writing, that gluten contamination can be spotty and that hydrolyzed wheat protein as may be found in Asian style sauces cannot be accurately tested with the device.

During the testing process, dietitians experienced more negative emotions than positive. Although there was a lot of general anxiety, there was also curiosity about the device, and after the testing experience was complete, some participants expressed relief. However, the frequency of unexplained error messages, along with obstacles such as cartridges not closing tightly, difficulty determining proper sample size, and delay in receiving results contributed to an overall sense of frustration. Many felt that the sensor would not be accurate, and expressed worry about the confusion and stress it could cause their patients.

References

1. Nima. Nima Gluten Sensor. https://nimasensor.com/gluten/. Accessed March 10, 2019.
2. Popping B, Allred L, Bourdichon F, et al. Stakeholders' guidance document for consumer analytical devices with a focus on gluten and food allergens. *J AOAC Int*. 2018;101:185-189. doi: 10.5740/jaoacint.17-0425.
3. Rogers A. Personal allergen testing devices: can they be trusted? Food Matters Live. Available at: https://www.foodsmatter.com/allergy_intolerance/allergy_testing/articles/personal-allergen-testing-rogers-01-18.html. Accessed March 10, 2019.
4. Taylor SL, Nordlee JA, Jayasena S, Baumert JL. Evaluation of a handheld gluten detection device. *J Food Prot.* 2018;81:1723-1728. doi: 10.4315/0362-028X.JFP-18-184.
5. Nima. The science behind Nima. Available at: https://nimasensor.com/science-nima-understanding-device/. Accessed March 10, 2019.
6. Boise S. What do the symbols on Nima's screen mean? Available at: https://help.nimasensor.com/hc/en-us/articles/115009668347-What-do-the-symbols-on-Nima-s-screen-mean-. Accessed March 10, 2019.
7. Sliwinski H. Gluten levels in food: the 20 ppm debate. Available at: https://nimasensor.com/2017/03/24/gluten-levels-in-food-20-ppm-debate/. Accessed March 10, 2019.
8. R-Biopharm. Ridascreen gliadin instructions. Available at: https://food.r-biopharm.com/wp-content/uploads/sites/2/2016/05/R7001-Gliadin-15-10-09.pdf. Accessed March 10, 2019.
9. Boise S. How do I use Nima? Available at: https://help.nimasensor.com/hc/en-us/articles/115009668207-How-do-I-use-Nima-. Accessed March 10, 2019.
10. Boise S. what kinds of foods or beverages cannot be tested with Nima? https://help.nimasensor.com/hc/en-us/articles/115009840348-What-kinds-of-foods-or-beverages-cannot-be-tested-with-Nima-. Accessed March 10, 2019.
11. Vaish A, Grossmann T, Woodward A. Not all emotions are created equal: the negativity bias in social emotional development. *Psychol Bull*. 2008;134:383-403. doi: 10.1111/bjdp.12093.

Funding

No funding was received for the analysis of the data or writing of the article. The meals for testing the sensor were paid for by Gluten Free Watchdog, LLC. Gluten Free Watchdog, LLC, purchased the testing sensor and testing capsules.

Acknowledgments

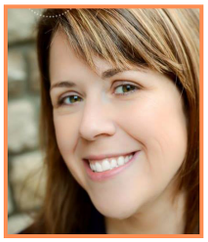
We would like to thank Trisha B. Lyons for her help and guidance in developing and formatting the tables. We would like to thank the dietitians who participated in this evaluation.

Figure. A dietitian participant at the dinner placing a food sample into a testing capsule.

About the Authors

Tricia Thompson is the owner/founder of Gluten Free Watchdog, LLC.

Nancee Jaffe, MS, RDN, is head of the Digestive Health and Nutrition Clinic at UCLA. Nancee joined the UCLA Division of Digestive Diseases in 2012, where she is involved with direct individual nutrition counseling sessions on such disease states as irritable bowel syndrome, inflammatory bowel disease, celiac disease, short bowel syndrome and idiopathic or functional bowel. Nancee is also a sought-after speaker on nutrition and digestive disorders for conferences and webinars and is involved in research with Dr. Lin Chang of the G. Oppenheimer Center for the Neurobiology of Stress and Resilience.



Amy Keller, MS, RDN, LD, has been a registered dietitian for 17 years, working primarily in community hospitals. She has a special interest in celiac disease, and is the current chair of the Medical Nutrition Practice Group, for the Academy of Nutrition and Dietetics. She founded and leads the Logan County Celiac Support group in Bellefontaine, Ohio. She is a preceptor for dietetic interns from Bowling Green State University, Bluffton University, and Rutgers University. She is a popular speaker, presenting regularly at regional and national celiac disease events. She is a frequent contributor to Gluten Free Living *magazine and serves on the magazine's dietetic advisory board. Amy holds a bachelor's degree in nutrition from West Virginia Wesleyan College, and a master's degree from Ball State University. She has also completed additional training in celiac disease at the University of Chicago.*

Janelle Smith, MS, RDN, CEDRD, is the current chair of the Dietitians in Gluten and Gastrointestinal Disorders subunit of the Medical Nutrition Practice Group. She practices as a registered dietitian nutritionist with expertise in both eating disorders and gastrointestinal disorders. Janelle treats adults with gastrointestinal disorders and disordered eating at UCLA Division of Digestive Diseases. Janelle's expertise has been featured with the Academy of Nutrition and Dietetics Behavioral Health Nutrition network, the Celiac Disease Foundation, Children's National Hospital, and the National Eating Disorder Association of America. She is a certified eating disorder dietitian through the International Association of Eating Disorder Professionals. She has no conflicts of interest to declare and has not received any funding to write the article.

HANDGRIP STRENGTH ASSESSMENT: A SKILL TO ENHANCE THE DIAGNOSIS OF DISEASE RELATED MALNUTRITION

Did you know that we have a complimentary malnutrition tool kit, with 3 CPEUs, available to all members? You can access it on our website, mnpgdpg.org, resources, Handgrip Toolkit

(https://www.mnpgdpg.org/members/page/handgrip-toolkit).