

*The original article was published on the NimaSensor.com website prior to being acquired by Medline and rebranded as Nima Partners. Shireen Yates is the founder of Nima Sensor, but she sold her interest in the company to Medline in 2020. I have provided this PDF archive of the article for my readers.*

## **Response to Recommendations Against the Nima Gluten Sensor by Gluten Free Watchdog (GFWD)**

by Shireen Yates | Sep 7, 2018 | News

Gluten Free Watchdog's view of our recently published validation is incomplete and misleading. Here's why:

- All the studies show Nima is highly sensitive across a range of both low and high levels of gluten.
- The Nima third party data accurately reported gluten found at 20 ppm and above between 93.3% for food as prepared (a food item that is spiked with an intended quantity of gluten) and 97.2% for food as quantified by an ELISA lab kit (used to determine the exact ppm of gluten in the food).
- The Nima peer reviewed study published in the [Food Chemistry Journal](#) reported gluten found at 20 ppm and above at 96.9% accuracy.
- The statement that, "Nima will fail to detect gluten at 20 ppm 20% of the time" is almost entirely driven by 1 specific food out of 13 tested. That sample, when quantified, was actually below 20 ppm.
- In real life, people get glutened at many different ppm levels, not just 20 ppm. Nima has been shown to detect gluten at levels below, at and above 20 ppm across a variety of foods in a number of studies.

Critics believe you are putting yourself at risk by using a Nima, while we believe the data shows you are improving your chances of staying healthy.

If you want to learn more, keep reading.

### **What is the difference between food as prepared and food as quantified?**

In the independent study, gluten free foods were first prepared, and then small amounts of wheat flour were added to each batch of food to achieve the desired ppm level, for example, 20ppm. This is referred to as "food as prepared." Each of these samples was then tested with Nima, and separately with an ELISA to confirm how much gluten was in each sample. This is referred to as "food as quantified." In the webinar, we showed the results of the ELISA for the foods as prepared at 20 ppm.

## Results for 20ppm, quantified by ELISA

Sample	Intended Gluten Level (ppm) Food as prepared	Neogen R5 - ELISA mean + SD (ppm)	Romer G12- ELISA mean + SD (ppm)
Bread A	20	11.3 ± 1.7	19.9 ± 1.1
Bread B	20	12.0 ± 2.2	32.9 ± 3.8
Bread C	20	14.6 ± 2.8	22.1 ± 1.1
Chocolate	20	14.7 ± 0.7	15.4 ± 2.0
Corn Puffs	20	18.7 ± 2.1	15.0 ± 0.6
Ice Cream	20	15.8 ± 1.7	22.4 ± 1.8
Meatballs	20	11.3 ± 0.3	17.5 ± 0.5
Muffin	20	16.0 ± 0.9	31.3 ± 2.9
Oatmeal	20	9.4 ± 0.3	16.5 ± 1.5
Pasta A	20	8.0 ± 1.9	19.2 ± 0.8
Pasta B	20	11.3 ± 1.3	20.8 ± 3.2
Pasta C	20	13.2 ± 0.5	27.6 ± 2.6
Salad dressing	20	11.2 ± 1.8	15.0 ± 1.3

As you can see, there is high variability in the quantification of the different foods. Nima's perceived "failure" to detect 20 ppm in the Pasta A sample, which is used to calculate accuracy, was not based on a food that contained 20 ppm of gluten according to ELISA. Nima's true positive rate (the amount of times Nima correctly identifies gluten) for food as quantified is 97.2% at 20 ppm and above when compared to the ELISA results.



	Nima 447 tests • 57 foods	Independent Lab A (ISO accredited) 390 tests • 13 foods	Independent Lab A (ISO accredited) 282 tests • 13 foods
<b>True Positive (Sensitivity)</b>	99.0%	92.6%	97.5%
<b>True Negative (Specificity)</b>	92.2%	96.2%	96.2%
<b>False Positive</b>	7.8%	3.9%	3.9%
<b>False Negative</b>	1.0%	7.4%	2.5%
<b>Accuracy</b>	96.9%	93.3%	97.2%

Combination food as prepared and quantified by ELISA

As prepared

As quantified by Neogen R5 ELISA

All results are based on gluten levels 0 ppm or 20 ppm and above for approved test samples

### Why is focusing on 20 ppm a problem outside of the lab?

At mealtime, you are not thinking about ppm. Getting “glutened” is about having gluten at many levels and is highly variable for each individual. Every individual body is sensitive to gluten at all different levels. A crumb can affect one in the same way that a piece of bread can affect another. We understand the lab focus on 20 ppm since that is the number set by the FDA, but in reality, gluten levels in the wild can vary greatly and show up at significantly higher levels than 20 ppm outside of the lab. [Through studies](#), we know people on gluten-free diets are getting consistently exposed to gluten. Food labelled gluten-free, especially at restaurants, are at all ranges of ppm levels, including above 20 ppm, [as this study shows](#).

The difference between a quantitative lab test and a Nima test is that you can't use a lab test on your vacation or on a date. Nima wants to protect you from accidentally consuming gluten at any level – not just 20 ppm – and at any occasion. A quantitative lab test is meant to provide the food manufacturer with data to support labeling food as gluten-free. Each has their place.

### Gluten found

The GFWD reports “Based on third party testing data this gadget is reporting gluten found approximately 35% of the time when the level of gluten is 5 ppm and approximately 56% of the time when the level of gluten is 10 ppm.”

Critics reported these findings as a mark against Nima's dependability, however, while 20 ppm is the standard for gluten-free in some countries (and it's even lower in others), it doesn't change the fact that those who avoid gluten, ideally, wouldn't want ANY gluten in their food. If it's detected at any level in the sample, it's extremely likely to be littered throughout the dish and thus, not a meal people avoiding gluten would want to eat.

### **Variability**

The GFWD statement "in a sample from less than 2 ppm up to a level of gluten between 30 ppm and 40 ppm, the result displayed on the Nima Sensor may be either smiley face or gluten found" is also misleading in that it implies an equal chance of finding a gluten found or smiley face result throughout that range. That is not true. Nima will absolutely detect gluten more consistently at 20 ppm and above opposed to the low end of 2 ppm as evidenced in the validation data.

### **Conclusion**

The purpose of the Nima Gluten Sensor is to provide another layer of information in your decision making process. It's meant to give you information beyond best intentions of the person cooking the food, beyond conversations with waitstaff, beyond menu labeling, and beyond hard to understand food packaging. Ultimately, nothing is 100% guaranteed.

All we can do is continue to work together to have an open dialogue. Our mission is to serve and empower you with the data to make more informed choices and live your healthiest life. If you are looking to continue the conversation, please don't hesitate to reach out to us through [customerservice@medline.com](mailto:customerservice@medline.com).

-The Nima Team