









#### GET THE MOST OUT OF YOUR ALLERGEN TESTS: HOW TO MINIMIZE HUMAN ERROR AND MAXIMIZE ACCURACY IN QUALITY CONTROL

There are many variables to consider when bringing a new test into your quality control program: What is the testing method? How has the kit been validated? How specific is it? How sensitive? Will it work with your product matrices? Does it require special storage?

Even if a kit seems well-suited to your needs on paper, there is still one big way it can let you down: human error. Here at Emport LLC, people sometimes ask us how good our rapid kits are. The answer? They're as good as the people running the tests.

Read on to learn the top five most common ways human error can impact your test kits' accuracy – and the ways to avoid these mistakes in your own QA practice.

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#### NISTAKE #1: NOT TAKING YOUR TIME

There isn't a lot of down time in the manufacturing day. People are waiting for your clearance to move on with production: is the ingredient glutenfree? Has the surface been adequately cleaned of peanut residue? As tempting as it can be to rush through steps to get to the results...don't!

Remember: Kit validation includes validation of the kit manual. If you don't follow the instructions, you aren't using a validated test method.

**Example**: A GlutenTox Pro test requires a wait time of 10 minutes before you can declare a sample to be negative for gluten. Often, positive results will show up much quicker – but not always, and not in the case of gluten concentrations right around the detection limit. If you only wait 5 minutes because the test "seems" negative, you might be missing an important warning.

### MISTAKE #2: GUESSING, NOT COUNTING

It may sound obvious, but if a kit calls for one gram of sample, you should use one gram of sample. A digital scale that can measure to the tenth or hundredth of a gram costs less than \$25 and can eliminate any guesswork.

The same is true of any other numbers: if you need to use 10 drops of solution, count to 10 out loud to make sure you get the right number. If you need to shake something for two minutes, set a timer instead of going by your best guess or the clock on the wall.

**Example:** A cookie dough client was confused: they were getting positive results with GlutenTox Pro at a 5ppm LOD – but when they sent samples off to the lab, the ELISA Sandwich results were negative at the same LOD. A closer look revealed that their doughs were exceptionally heavy; instead of using one gram of sample, they were using almost two. This had the impact of making GlutenTox Pro "think" the sample had twice as much gluten as it really did: instead of 3-4ppm, the kit reported 6-8ppm. Had the client been using too little sample, the opposite could have happened and the kit could report less gluten than was truly in the dough.

# NOT LABELING YOUR SAMPLES

If you only ever run one test at a time, it can be easy to remember what you're testing. But how often does that really happen? When you're running multiple tests in a day it's absolutely imperative that you develop and maintain a system of careful labeling and recording: relying on memory is asking for things to go wrong.

Assign each sample an ID, and use that ID on every single component of the test: the test strip, the vials, the results log, etc. It might seem like extra work, but we promise it's worth the time. After the first few times it will be second nature. Our recommended best practices for sample organization are available on our website, but there's no one right way to do it.

**Example**: Imagine you are using AlerTox Peanut to verify that three different lots of an incoming spice blend are peanut-free. You set things up in order of the lot number. Easy, right? Sure – until you get called into a quick meeting or someone comes by and offers to help you shake the samples. Now was that left to right or right to left? Are you sure you remember which vial of solution contains which lot? If only you'd labeled the samples, vials of solutions, and test strips in a clearly identifiable way!

### MISTAKE #4: FORGETTING YOUR ENVIRONMENT

If a test gives you an answer you don't expect, it can be tempting to blame the test itself. Certainly it's a good idea to ask your kit supplier questions, but there's another important step. Take a look around you: could anything else be going on?

Pathogens and allergens alike have a tricky habit of showing up absolutely everywhere. Are you sure your hands were clean? Will you get the same results if you wear gloves? Is there an air vent blowing into your QA room from your production room – and if so, what is that air blowing onto your tests? Are you certain that your testing equipment was clean? What possible sources of contamination might be present in your facility that you haven't accounted for?



**Example**: A client was confused. An area of their largest room was dedicated to gluten-free production on dedicated equipment. They only ran gluten-free at times when they were not running anything else, and they gave all the equipment a thorough cleaning before starting production. Even so, their surface tests were often coming back positive for gluten: what was going on?

Eventually we found the culprit: the stack of rags they used to wipe everything down was stored in this very same shared room. Even freshly laundered, unused rags were covered in a light dusting of flour, and the rags themselves tested positive for gluten. Instead of cleaning, the team was actually contaminating! Luckily there was a quick fix: dedicated rags for the gluten-free area were purchased, washed separately, and stored in a sealed container outside of the production floor.

#### MISTAKE #5: TRUSTING YOUR MEMORY

Most of the time everything works as it should and the tests you hope will be negative are indeed negative. But what do you do when you get a positive? It's common practice (and good practice) to repeat the test, and to test to other thresholds if that makes sense with your particular test. It might also make sense to test other lots, to see if you can establish a pattern of contamination.

While you're in the thick of it, all these steps can seem like common sense. It might seem impossible to forget exactly what you tested and what the results were – but trust us, it's very possible. In order for us to help you figure out what's going on – and in order for you to identify and correct any problems with your vendors or your production team – you need to be able to explain exactly what you tested, how, and to what results.

**Example:** Careful recording of test results might indicate that it's only tests run by a certain person, or at a certain time, that are showing up positive. Might that person require retraining on the kits, or might there be something happening at that time that could explain the results? Or in a different scenario: imagine a discrepancy between your rapid tests and your third party lab verifications. Are you certain you tested identical products? Not just from the same lot or the same day, but from the same 100–500 g reserved sample? If you aren't comparing apples to apples, it can be tricky to figure out next steps.





### IN CONCLUSION

Keeping your products up to safety and quality standards is tough enough as it is. As many variables as you can eliminate, you should; monitoring your process for human error is the best way to ensure that you keep unexpected surprises to a minimum.

An Emport LLC team member will be more than happy to walk you through the many best practices we suggest for gluten and allergen testing – just ask! Our website is also a wonderful resource, whether you are new to gluten and allergen detection or simply looking to improve your facility's Allergen Control Plan.

#### ABOUT OUR PRODUCTS:

Whether testing foods, beverages, surfaces or rinsewater for gluten or allergens, our test kits help you minimize the risk and cost of allergen recalls.

## GlutenTox

GlutenTox test kits are specially designed to help keep gluten-free items free of contamination. The test is robust, and has been validated against a wide range of matrices. GlutenTox Pro holds AOAC-RI Certification for both foods and surfaces and can test down to 5ppm.

## **AlerTox**

AlerTox Sticks test kits detect traces of common allergens: soy, milk, egg, fish, peanut and more! AlerTox is a great tool for validating your suppliers against food adulteration and maintaining FSMA compliance. The kits are easy to use on both foods and surfaces.

For information on quantifiable options including many ELISA kits, contact our sales team.

