Out-of-Specification Results (OOS):

Tips to Regroup Successfully

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Receiving test results that are not what you expected, it can be frustrating. What do you do next? You may not know who to ask or how to investigate unusual results. Out-of-specification (OOS) results are always challenging because it requires expertise and understanding of what goes on in a lab to figure out what might have gone wrong. And, what if you determine the results are correct—what do you do then?

After years of building and operating ISO 17025-accredited testing labs, we have seen anything and everything go wrong with lab tests. Labs make mistakes and some errors are very common BUT it is not always a lab error that causes an OOS result. What if the wrong test was requested and run? What if the testing method was not appropriate for the material? What if the material or product is sub-potent?

With so many "what if's" having a resource to call, ask questions and help you dig into OOS results on the certificate of analysis (COA) can save you a time and headaches. We can evaluate the data, work on root cause, and develop corrective actions. Using a risk-based approach, we can help write justifications for removing testing due to method interferences or even contact lab and vendors to help resolve the issue completely. We can help you regroup and do it quickly.

This doesn't have to be a mystery. There is always an answer to the problem—it just takes asking the right questions to find the solution. You must know what questions to ask, and that's our specialty.

Here are some examples:

1. A result come back from a third-party lab that was almost exactly half the result that was expected. The customers' OOS procedure had them pull a fresh sample and retest in duplicate to gather more data points. The new results passed and were above the specification. We talked with the testing lab and went through the original raw data to help determine the root cause of the original result. A lab error was found, and these original results were thrown out as invalid.
2. A complex supplement finished product was tested, and the results came back higher than expected. The OOS high result needed to be investigated. The customer pulled a fresh sample and retested it in duplicate. The new tests showed two different results. One was extremely low and the other was close to the specification. After asking the lab to perform a spike study test, along with reviewing the method, we concluded that the method they used was not appropriate for the material. The method was a pH-based titration and the co-ingredients in the blend were causing a large pH change that interfered with the method performance. This method was written for a single raw material or simple finished product and was not appropriate for this

complex blend. By collecting all the test results, we were able to have enough data to write a justification to exempt this testing in the future.

3. A mineral test did not meet the specifications for label claims on the finished product. After following the OOS procedure, we found that all the results were below specifications. After a thorough laboratory notebook review, we requested that the contract manufacturer also perform a review of the batch records. They found a mistake was made during production, and the blend needed to be re-worked to add the correct formulation of raw material to get the product to test in compliance.

4. When investigating low-calcium results for a supplement product, we found that the lab tested calcium potency on ICP-MS. This sample preparation, running on mass-spec low-detection equipment, created just enough uncertainty from the serial dilutions for the results to show OOS. When we tested the same sample using ICP-OES technology, without the need for multiple dilutions, it tested above specification. We were able to help the customer determine the correct piece of equipment to test their high-potency mineral formulas and found the root cause for the low original results.

These are just a few examples of investigations that have helped solve customer issues with their products. OOS results are complicated and require scientific knowledge and a team approach to resolve. Instead of letting OOS results overwhelm you or not knowing how to address product testing problems, call us to review the data and help you regroup—without the headache.

About Execute To Achieve

After spending years in the food and supplement industry, it was clear that resources need to be dedicated to education, training, and guidance on how industries and brands alike need to comply with FDA requirements. Our team of experienced managers will assist your company in building a quality food safety mindset, maintain compliance with ISO and FDA regulations, and train employees for strong retention. Employees want to be part of a team when they are empowered, knowledgeable, and confident in their job.

Contact us at solutions@executetoachieve.com and let us give guidance to your organization too!