





# OOS Investigation & Repeat Testing Terms

OOS (Out of Specification) results\* call for responsible investigation by lab and quality assurance personnel. But OOS investigations sometimes tie up more time and resources than they should. Unnecessary expenditure of time and resources can stem from confusion around the four testing operations related to OOS: **reanalyzing, rediluting, retesting, and resampling**. Although these four terms are similar to one another, the operations they signify are quite different.

\*Examination, measurement or test results that do not comply with pre-established criteria.

**Understanding the differences between these four operations, and using the appropriate term for each when communicating with others, is key to efficient handling of OOS results.** It helps avoid the mistake of going further up the chain of sample sources than necessary, a mistake that results in unnecessary generation of data and misapplication of testing opportunities. Remember, every test produces new data that must be documented and acted upon—and the number of tests allowed before a batch must be rejected is finite.

Reanalyze	Redilute	Retest	Resample
			
Source: diluted sample	Source: sample preparation	Source: lab sample	Source: manufacturing production
Reanalyze original prepared, diluted solution	Redilute from original prepared sample, if applicable	Redo sample preparation using original lab sample from production	Obtain another sample of product from production
OOS Investigation			
Check for instrument problems	Check that proper dilution was used	Check sample preparation	Decide if original lab sample is suspect
Repeat Testing			
If you have determined the root cause of the OOS and believe the new test will produce a true result, perform whichever of the above operations applies			

Each available sample preparation offers its own opportunities for investigation and the generation of data.

Throwing out samples prematurely results in fewer investigation and testing options.

Proper investigation can prevent the need for repeat testing. Always perform a thorough initial investigation, checking for assignable causes beyond sample dilution or sample

preparation problems. In particular, be sure to check:

- that your calculations were correct
- that you used the correct test method

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