

Summary - Explanation of Repeat Testing and Retesting Utilized During Microbiological OOS Investigation

Microbiological repeat testing may be defined as additional laboratory testing performed to replace original invalid data when a laboratory assignable cause has been identified.

The repeat test result is intended to replace the original invalidated OOS test result. Microbiological repeat testing is very similar to repeat testing conducted during analytical laboratory investigations. If an assignable cause is clearly identified, the initial OOS test result is invalidated and the original testing is repeated to generate a valid result

Unlike microbiological testing, some analytical test methods consist of multiple analyses per test sample.

Retesting may be performed only to corroborate or confirm the original OOS test result. If the retest results *do confirm* the initial OOS test result, this data can be used to support the case that the initial OOS test result is valid and not due to laboratory contamination. A confirmed OOS test result will cause the rejection of the test article (unless approved for reprocessing).

Retest results alone cannot be used to invalidate the initial OOS test result. Only a clearly identified assignable cause can invalidate the initial OOS test result.

Microbiological retesting is significantly different to the retesting conducted during analytical method laboratory investigations.

Analytical laboratory investigation retest results can be utilized to overcome the initial OOS test result after evaluation by Q.A. management. Microbiological retest results are only used to corroborate or confirm the initial OOS test result.

Microbiological OOS retesting differs significantly from analytical method OOS retesting with regards to testing requirements and data interpretation.

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