

AQR: Competency Test Results Inconsistencies

Sources of inconsistencies

Inconsistencies between the test manufacturer's target results and the analyst's results may occur for several reasons, including:

- test defects
 - the test was poorly designed
 - the test sample was improperly made or had deteriorated
 - analyst error
 - the analyst did not understand the instructions
 - the analyst utilized inadequate or improper analytical procedures
 - the analyst erred in interpreting the analytical data resulting in inaccurate or inappropriate conclusions
 - an experienced analyst new to the laboratory was unfamiliar with Laboratory of Forensic Services procedures
 - system error
 - training protocols were inadequate
 - available written procedures were inadequate or faulty
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Addressing test defects

A test that is poorly designed, improperly made, or contains items subject to rapid degradation may result in the analyst being unable to obtain the anticipated results.

A test may be declared defective by the external provider or the Quality Manager. The Quality Manager will consult with the unit supervisor, the DNA Technical Lead (if applicable), or the appropriate peer group before making this determination. The Quality Manager will provide a written justification for declaring a test to be defective. External provider statements and internal justifications become part of the test file.

If a test is declared defective, it will be cancelled and a new test will be issued.

Exception: If a test is judged only partly defective, the Quality Manager may decide, in consultation with the unit supervisor, that the acceptable portion of the test is sufficient for testing purposes and no new test will be issued.

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Addressing analyst and system errors

5.2.6.2.1

Inconsistencies from expected results may occur because of

- a lack of understanding, insufficient training, or poor judgment on the part of the analyst, leading to analytical or reporting errors
- technical problems not identified during the review process or inadequate or faulty procedures resulting in false or misleading data and reporting errors
- a combination of both factors

If an inconsistency occurs that cannot be attributed to a defective test, the Quality Manager will inform the unit supervisor, the trainer, and the DNA Technical Lead (if applicable) of the situation.

The Quality Manager will consult with the supervisor, the DNA Technical Lead (if applicable), the analysts involved in the production and verification of the test, and/or the testing analyst, as required, to determine the cause and appropriate corrective action for the error.

Depending upon the nature and extent of an identified *analyst error*, corrective actions may include, but are not limited to, one or more of the following:

- counseling the analyst
- requesting the analyst to re-evaluate test data or reanalyze test items
- retraining the analyst in specified areas
 - training plans must be documented and attached to the test file
- issuing a new test
 - a new test is required after retraining

Depending upon the nature and extent of an identified *system error*, corrective actions may include, but are not limited to, one or more of the following:

- counseling or retraining the technical reviewer
- modifying existing or writing new technical procedures
- issuing a new test

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Dispute resolution

There may be times when agreement as to the form or extent of corrective action cannot be reached.

Disputes that cannot be settled are brought by the Quality Manager to the Laboratory Director for resolution.

Corrective action requests

Corrective actions resulting from analyst or system errors will be recorded on a *Corrective Action Request* form. This form contains information on the nature of the inconsistency and the recommended corrective action.

Corrective actions are given a maximum 90-day due date from the initiation date.

Once the corrective action has been successfully completed, the Laboratory Director will sign the completion line of the form and attach it to the test file. See *DPC: Corrective Action* for more information on how this form is filled out.

Note on disciplinary action

Analyst errors resulting in inconsistencies will not result in disciplinary action on the initial attempt to complete a competency test.

It is anticipated that consultation, re-training or additional testing will resolve most problems.

If analyst or system error persists in the attempt to establish competency, the matter will be submitted to the Laboratory Director for review and recommendation.
