

IMM.34362 Monthly QC Review Phase II

The laboratory director or designee reviews and assesses quality control data at least monthly.

NOTE: The reviewer must record follow-up for outliers, trends, or omissions that were not previously addressed.

The QC data for tests performed less frequently than once per month may be reviewed when the tests are performed.

The review of quality control data for tests that have an IQCP approved by the laboratory director must include an assessment of whether further evaluation of the risk assessment and quality control plan is needed based on problems identified (eg, trending for repeat failures, etc.).

Evidence of Compliance:

- ✓ Records of QC review **AND**
- ✓ Records of corrective action taken when acceptability criteria are not met

IMM.34380 Numeric QC Data Phase II

For numeric QC data, quality control statistics (eg, SD and CV) are calculated monthly to define and monitor analytic imprecision.

NOTE: The laboratory must evaluate the imprecision statistics (eg, SD and CV, or other appropriate statistics) monthly to confirm that the test system is performing within acceptable limits. For whole blood methods, where stabilized whole blood or other suitable material is not available for QC, such statistics may be generated from previous patient/client samples using the SD of duplicate pairs or other patient data based statistical procedures.

This checklist requirement does not apply to external controls run only to verify new lots/shipments of test materials. However, the laboratory should have defined acceptable limits for such controls (either from the manufacturer or developed by the laboratory).

Evidence of Compliance:

- ✓ QC records showing monthly monitoring for imprecision

REFERENCES

- 1) Rifai N, Horvath AR, Wittwer CT, eds. *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics*. 6th ed. St. Louis, MO: Elsevier; 2018.
- 2) Clinical and Laboratory Standards Institute (CLSI). *Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions*. 4th ed. CLSI guideline C24. Clinical and Laboratory Standards Institute, Wayne, PA, 2016.
- 3) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):7146 [42CFR493.1256(d)(10)(i)]

IMM.34450 Fluorescent/Enzyme Antibody Stain QC Phase II

Positive and negative controls are included with each patient run for all fluorescent or enzyme antibody stains.

NOTE: When examining tissue specimens, internal antigens, when present, may serve as positive controls (eg, IgA in tubular casts, IgG in protein droplets, and C3 in blood vessels). Non-reactive elements in the tissue specimen may serve as a negative tissue control. A negative reagent control in which the patient tissue is processed in an identical manner to the test specimen but with the primary antibody omitted must be performed for each patient tissue specimen. If internal controls are not present (eg, ANA IFA), external positive and negative controls must be included with each patient run.

Evidence of Compliance:

- ✓ Records of fluorescent/enzyme antibody stain QC at defined frequency

REFERENCES