FDT.02020 Conjugated Drug Controls **Phase I**

Conjugated drug controls are included in procedures where conjugates are hydrolyzed.

NOTE: This requirement may be satisfied with the use of purchased material or the use of pooled donor specimens.

FDT.02025 Internal Blind QC **Phase II**

An internal blind QC program is an integral part of the laboratory's QC system.

NOTE: An internal blind quality control program is required. Single-blind controls, known to the analyst to be controls, but blind as to content are acceptable. At least one specimen per screening batch and at least 1% of the screening samples must be blind controls. There is no requirement for positive internal screening blind controls to be confirmed. Criteria for acceptance and rejection of internal blind controls must be defined. The results of the blind control analysis must be reviewed and accepted before release of any positive or negative results. The internal blind QC samples should include at least 20% positive samples and include challenges from among the drugs being tested by the laboratory in a forensic drug test. The review of the internal blind QC program must be a part of the routine QC review responsibilities of the laboratory supervisory personnel and the laboratory director. An internal or external double blind QC program, where the analyst does not know the identity or content of the blind control, is encouraged but not mandatory.

Evidence of Compliance:

- ✓ Records of internal blind controls including review by laboratory personnel and laboratory director **AND**
- ✓ Records of certifying review including review of internal blind control records

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Toxicology and Drug Testing in the Medical Laboratory.* 3rd ed. CLSI guideline C52. Clinical and Laboratory Standards Institute, Wayne, PA; 2017.

FDT.02030 QC Acceptance Criteria - Controls **Phase II**

Criteria for acceptance and rejection of controls are defined and appropriate.

NOTE: The criteria for qualitative screening assays must be such that the positive control above the cut-off gives a positive response to be acceptable, and the control below the cut-off gives a negative result. The criteria for acceptance/rejection of quantitative QC results should at a minimum include the rejection of QC results that exceed a pre-determined range of the established control mean. It is commonly accepted that this range be no more than ± 20% for urine assays and no more than ± 30% for other specimen matrices.

FDT.02035 QC Acceptance Criteria - Internal Blind Controls **Phase II**

Criteria for acceptance and rejection of internal blind controls are defined and appropriate.

FDT.02045 Alternative Control Procedures **Phase II**

If the laboratory performs test procedures for which control materials are not commercially available, the laboratory performs and records alternative control procedures to detect immediate errors and monitor test system performance over time.

NOTE: "Performance" includes elements of accuracy, precision, and clinical discriminating power. The following are examples of alternative procedures: split sample testing with another

method or with another laboratory, the testing of previously tested specimens in duplicate, testing of specimens in duplicate, or other defined processes approved by the laboratory director.

Evidence of Compliance:
- ✓ Records of alternative control procedures

REFERENCES
1) 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): [42CFR493.1256(h)].

FDT.02060 Weekly QC Review **Phase II**

Quality control data are reviewed and assessed at least weekly by the laboratory director or designee to detect instrument malfunction or analytical system trends.

Evidence of Compliance:
- ✓ Records of QC review with follow-up for outliers, trends, or omissions

FDT.02080 Monthly QC Review **Phase II**

Quality control data are reviewed and assessed at least monthly by the laboratory director, including QC and blind QC records or summarized QC data to detect trends, and review of corrective actions taken by laboratory personnel.

NOTE: The laboratory director must be responsible for the overall QC program, which must include review at least monthly of QC analysis, QC evaluation and corrective actions taken, including appropriate records by laboratory personnel. The review of the quality control data must be recorded and include follow-up for outliers, trends, or omissions that were not previously addressed.

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

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

FDT.02150 Confirmation Assay Precision **Phase II**

The laboratory monitors the precision of each confirmation assay around the commonly accepted cut-offs.

NOTE: This may be accomplished by using the cut-off control to determine the assay's precision at the cut-off value.

Evidence of Compliance:
- ✓ Records of precision monitoring

FDT.02166 Error Detection **Phase II**

The laboratory has processes to detect significant clerical and analytical errors before reporting the results.

NOTE: The detection of errors (eg, wrong donor identification information, wrong client information, failure to report critical chain-of-custody errors, wrong tests performed, etc.) may have forensic implications, as may analytical errors. A documented procedure must be present that describes the laboratory's system to detect and prevent these clerical and analytical errors.

One common method is review of results by a qualified person (technologist, supervisor, pathologist, section director) before release from the laboratory, but there is no requirement for