

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 \pm 20% for urine assays and no more than \pm 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