



- Review a sampling of QC data over the previous two-year period. Select several occurrences in which QC is out of range and follow records to determine if the steps taken follow the laboratory procedure for corrective action

FDT.02002 QC Confirmation of Acceptability

Phase II

Personnel review control results for acceptability before reporting donor results.

Evidence of Compliance:

- ✓ Records of control result approval

FDT.02005 QC - Screening Tests

Phase II

Appropriate controls are used for all screening tests.

NOTE: The laboratory must include appropriate controls based upon the methodology/technology used and the AMR of the test. The following controls should be used for all commonly used screening cutoffs to challenge the cutoffs:

1. Drug-free
2. Approximately 25% below screening cutoff
3. Approximately 25% above screening cutoff
4. Blind, at least 1% of batch and at least one per batch
5. Controls must comprise at least 10% of the samples in a batch, and
6. At least one fortified control must be at the end of the batch

A control 25% below cutoff may not be practical for some drugs/matrices and some cutoffs, eg, cannabinoids at 20 ng/mL and some benzodiazepines at 100 ng/mL. The laboratory must have written criteria for the required controls for all screening tests and all matrices being tested. The blind controls may be internal blind controls, known by the analyst to be blind controls, but blind as to content.

FDT.02010 QC - Confirmation Tests - Single Point Calibration

Phase II

Appropriate matrix-matched controls are used for all confirmation tests using single point calibration.

NOTE: The following controls must be used for all confirmation tests using single point calibration, for the most common cut-offs in use:

1. Drug-free
2. Approximately 25% below confirmation cut-off(s), or near the limits of quantitation (LOQ)
3. Approximately 25% above confirmation cut-off(s), and
4. Controls must comprise at least 10% of the samples in a batch

FDT.02015 QC - Confirmation Tests - Multiple Point Calibration

Phase II

Appropriate matrix-matched controls are used for all confirmation tests using multiple point calibration.

NOTE: The following controls must be used for all confirmation tests using multiple point calibration, for the most common cut-offs in use:

1. Drug-free
2. Positive, at a concentration to challenge the cutoff(s) in use, and
3. Controls must comprise at least 10% of the samples in a batch