Evidence of Compliance:

- ✓ Records of defined cut-off values for all screening and confirmatory tests

LABORATORY SAFETY

The inspector should review relevant requirements from the Safety section of the Laboratory General checklist, to assure that the forensic drug testing laboratory is in compliance. Please elaborate upon the location and the details of each deficiency in the Inspector's Summation Report.

QUALITY MANAGEMENT

Inspector Instructions:

	• Records of quality monitoring, including pre-analytic (correct collection, effects of excessive sample dilution or potential adulteration), analytic and post-analytic and corrective action when indicators do not meet threshold
	• What is your course of action when a false positive result is reported?
	• Further evaluate the responses and root-cause analysis for any false positive result reported

FDT.01200 Specimen Collection QM **Phase I**

There is evidence that the laboratory is involved in influencing the correct collection of client samples.

NOTE: This must include the monitoring of collection problems, chain-of-custody problems, transportation delays, etc. A system must be in place to inform and influence the improvement of these processes. The laboratory must discuss with each client the issues of potential adulteration or excessive dilution of samples and how these affect the analytical methods used by the laboratory. The laboratory must be able to perform ancillary tests that may aid in the detection of excessive dilute or potentially adulterated samples, eg, pH, specific gravity, or creatinine.

Evidence of Compliance:

- ✓ Records of collection monitoring with client communication or consultation

FDT.01400 Interpretive Consultations **Phase I**

There is evidence that the laboratory is actively involved in consultation with clients about interpretive problems.

Evidence of Compliance:

- ✓ Records of external communication such as memos, laboratory newsletters/communications or consultation log

FDT.01666 Root Cause Analysis for False Positives **Phase II**

The laboratory's QM program requires completion of a root-cause analysis with review by the laboratory director within 30 days of discovery for any false positive result reported.

NOTE: The laboratory's written QM plan must include procedures for analyzing and determining the root-cause of any false positive confirmed drug result reported by the laboratory on donor or proficiency testing specimens. (This does not apply to screening tests and those pending confirmation.) This procedure also applies to falsely reported specimen adulteration or substitution. Elements of this procedure must include investigation of pre-analytic, analytic, and post-analytic components. The results of the investigation must be recorded and include corrective action (eg, retraining) to prevent recurrence.

QUALITY CONTROL/STANDARD OPERATING PROCEDURES (SOP)

The laboratory director must be responsible for the quality control (QC) program. There must be records of initial and biennial review of the policy and approval of any changes by the laboratory director. The overall QC program must be defined clearly, recorded (paper or electronic), and readily available to the technical and supervisory staff. It should include delegation of responsibilities, general policies, procedures, and analytic details. The records should be organized with a defined system to permit regular review by appropriate supervisory personnel and the laboratory director.

The records should reflect the system described in the QC procedures. QC results should be recorded or plotted in a fashion that allows for continuous review. Out-of-control results should be clearly identified and associated with the corrective actions taken along with evidence of review by supervisory personnel, laboratory director, or designee.

GENERAL QUALITY CONTROL

Inspector Instructions:

READ	• Sampling of QC policies and procedures • QC records for each analytic procedure for the past year (includes weekly and monthly review) • Sampling of internal blind QC records
ASK	• How do you determine when quality control is unacceptable and when corrective actions are needed? • How does your laboratory verify or establish acceptable quality control ranges? • How do you monitor the precision of your confirmatory testing?