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?