DISCOVER

- If problems are identified during the review of method validation studies, or when asking questions, further evaluate the laboratory's responses, corrective actions and resolutions
- Select a recent method validation and review all records

FDT.19930 Initial Validation **Phase II**

There is a written procedure for method validation.

FDT.20030 Method Validation Evaluation **Phase II**

The laboratory validates the method performance specifications for each analytical method used for forensic drug testing and retains records of approval.

NOTE: The specifications must include the following elements:

1. *Accuracy (comparison to reference methods or reference standards)*
2. *Precision (determined at the cutoff value(s))*
3. *Analytical sensitivity (LOD) must be determined for confirmation procedures*
4. *Analytical specificity (ie, relevant interferences)*
5. *Linearity for quantitative methods including LOQ, which must be determined*
6. *Carryover potential*

Evidence of Compliance:

✓ Records of validation and approval of all analytical methods

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb28):7164 [42CFR493.1213]
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Medicare, Medicaid and CLIA programs; CLIA fee collection; correction and final rule. *Fed Register.* 1993(Jan 19):5230-5231 [42CFR493.1202, 493.1203, 493.1213]

FDT.20130 Method Validation Records **Phase II**

The records for method performance validation are complete for all forensic drug testing analytical methods and sample types.

FDT.20163 Method Performance Annual Verification **Phase II**

The laboratory verifies confirmation method performance at least annually and records are retained.

NOTE: The verifications must, at least, include the following elements:

1. *Precision (determined at the cutoff value(s))*
2. *Analytical sensitivity (LOD)*
3. *Linearity including LOQ*
4. *Carryover potential*

Evidence of Compliance:

✓ Records of verification of confirmation method performance

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb28):7164 [42CFR493.1213]
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Medicare, Medicaid and CLIA programs; CLIA fee collection; correction and final rule. *Fed Register.* 1993(Jan 19):5230-5231 [42CFR493.1202, 493.1203, 493.1213]