

NOTE: Appropriate calibrators for screening assays should consist of at least one positive calibrator. If only one calibrator is used, it must be at the declared cutoff value(s).

Laboratories may use historical calibrations; however, controls must be run with each batch to verify the calibration. In addition, the laboratory must have validated the stability of the calibration, and have a record of the validation.

Evidence of Compliance:

- ✓ Records of calibration

FDT.21130 Analytical Data

Phase II

The analytical data are presented to permit scientific review of the data for calibrators, controls and unknowns by the analyst.

FDT.21430 Spectrophotometer Calibration

Phase II



Spectrophotometers, if part of an immunoanalyzer, are calibrated at the frequency and as directed by the instrument manufacturer, and results recorded.

Evidence of Compliance:

- ✓ Records of calibration at defined frequency

FDT.21680 Reanalysis/Secondary Screening

Phase II



The laboratory defines situations when reanalysis and secondary screening are indicated.

LIQUID CHROMATOGRAPHY (LC)

This section covers the LC inlet system of LC/MS and LC/MS/MS instruments.

Inspector Instructions:

	<ul style="list-style-type: none"> • Sampling of LC policies and procedures • Sampling of LC control, calibration/standards records • Sampling of column verification records
	<ul style="list-style-type: none"> • How does your laboratory ensure appropriate extracted calibrator(s) are analyzed? • How does your laboratory evaluate potential carryover? • When are reinjection or reanalysis procedures required?

FDT.22150 Calibration and Calibration Verification

Phase II



Appropriate calibration or calibration verification is performed on each day of testing or following the manufacturer's instructions.

NOTE: For qualitative assays, an appropriate calibrator should be run at normal and abnormal levels. For quantitative assays, a multipoint calibration may be required if the measurement has a non-linear response. For some assays, a level near the assay's limit of detection (LOD) or at critical decision point(s) is needed. For measurement systems that have a linear response