

Specimen run order, chromatographic peak shape and retention time for calibrators, controls, and unknowns are recorded and maintained for review.

FDT.22930 Analytical Data Phase I

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

FDT.23030 Carryover Detection Phase II



The laboratory has a process to detect and evaluate potential carryover.

NOTE: No matter what type of injection is used, the process must address criteria for the evaluation of potential carryover from a preceding elevated (high concentration) sample to the following sample in each analytical batch analysis.

Evidence of Compliance:

- ✓ Records for reassessment of samples with potential carryover

FDT.23080 Reinjection/Reanalysis Phase II



The laboratory defines situations when reinjection or reanalysis are indicated.

GAS CHROMATOGRAPHY (GC)

This section covers GC instruments with various detectors, including mass spectrometers. The program allows the use of flame ionization detection for testing of ethanol only. All other drugs must be confirmed by mass spectrometric methods.

Inspector Instructions:

	<ul style="list-style-type: none"> • Sampling of GC policies and procedures • Sampling of GC control, calibration/standards records • Sampling of column verification records
	<ul style="list-style-type: none"> • How does your laboratory evaluate potential carryover? • When are reinjection or reanalysis procedures required?

FDT.23250 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 verified by periodic multipoint calibration verification and AMR verification protocols, a calibration