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:

	• Sampling of GC policies and procedures • Sampling of GC control, calibration/standards records • Sampling of column verification records
	• 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

procedure that uses a single calibrator at an appropriate concentration is acceptable. Analyses based on a single point calibration must be controlled by appropriate quality control samples. In addition, inclusion of a negative control (reagent blank) is good laboratory practice.

Evidence of Compliance:
- ✓ Records of calibration/calibration verification

FDT.23330 Column Performance **Phase I**

The performance of the column is monitored on each day of use.

NOTE: Good laboratory practice dictates the use of a system to monitor the performance of the GC column. Unextracted standards and extracted calibrators or controls typically containing the target compound(s), may be analyzed on each day of use to monitor critical aspects of GC performance. Criteria for evaluating such parameters as retention time, relative retention time, separation of closely eluting compounds of interest, plates, and chromatography quality should be established and monitored. Records must be retained.

Evidence of Compliance:
- ✓ Records for column monitoring

FDT.23380 Extracted Calibrators **Phase II**

An appropriate extracted calibrator(s) is analyzed with each batch of samples.

NOTE: At least one extracted calibrator at the commonly accepted cutoff for single-point calibration, or multiple calibrators above and below the commonly accepted cutoff for multipoint calibration, must be analyzed with each run.

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

FDT.23430 Daily QC - GC **Phase II**

Appropriate controls are extracted and analyzed with each batch of samples.

NOTE: See General Quality Control section for specific controls required.

Evidence of Compliance:
- ✓ QC records

FDT.23530 Internal Standard **Phase II**

Internal standards are used as appropriate.

NOTE: An internal standard is not required for FDA-cleared/approved kits where an internal standard is not used. For a qualitative assay, the use of an internal standard is appropriate if sample preparation includes an extraction step(s), there is low or variable analyte recovery, and/or an accurate sample injection volume is important.

Evidence of Compliance:
- ✓ Records for use of internal standards **OR** written justification for not using an internal standard in assay

FDT.23730 Test Records **Phase II**