IMMUNOASSAYS

Inspector Instructions:

	• Sampling of immunoassay policies and procedures (includes re-analysis and secondary screening information) • Validation data for modifications, if applicable • Sampling of calibration data
	• Multi-well plate procedure
	• How are you assured your automatic pipetting systems exhibit no carryover effects?

FDT.20980 **Pipette Carryover** **Phase II**

The laboratory evaluates its automatic pipetting systems for carryover.

NOTE: One suggested method to study carryover is to run known high samples (calibrators, standards, reference material, assayed controls), followed by known low samples to see if the results of the low-level material are affected. If carryover is detected, the laboratory must determine the level beyond which low-level samples are affected and this must be defined in the procedure. Results of each analytical run must be reviewed to ensure that no results exceed this level. If results that exceed the defined level are detected, then the appropriate course of action must be defined (repeat analysis of subsequent samples, for example).

Evidence of Compliance:

- ✓ Records of carryover studies **AND**
- ✓ Records of reassessment of samples with potential carryover

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *General Laboratory Equipment Performance Qualification, Use, and Maintenance.* 2nd ed. CLSI guideline QMS23. Clinical and Laboratory Standards Institute, Wayne, PA, 2019.

FDT.20996 **Multi-Well Plate** **Phase II**

If a multi-well plate procedure is used, the laboratory has taken appropriate steps to prevent cross-contamination.

NOTE: The laboratory must have a written procedure to prevent contamination into or between wells of multi-well plates.

FDT.21030 **Calibration Materials** **Phase II**

Appropriate calibrators are used.

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:

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