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.