

CBG.18050 Electrophoresis Separations Phase II

Electrophoresis separations are satisfactory.

CBG.18075 Acceptable Limits - Controls Phase II

Acceptable limits are set for controls of procedures where the electrophoretic bands are quantified.

Evidence of Compliance:

- ✓ Records of defined acceptable limits for control range verification of each lot

RADIOIMMUNOASSAYS

Refer to the Laboratory General Checklist for requirements for use and storage of radioactive materials.

Inspector Instructions:

	<ul style="list-style-type: none">• Sampling of radioimmunoassay policies and procedures• Sampling of calibration records• Sampling of background radioactivity records
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CBG.18080 Gamma Counter Calibration Phase II

Gamma counters and/or scintillation counters are calibrated, with the results recorded and compared to previous values each day of use.

Evidence of Compliance:

- ✓ Records of calibration

CBG.18085 Background Radioactivity Phase II

The background radioactivity is determined each day of use, including the background in each well of a multi-well counter, with defined upper limits of acceptability.

Evidence of Compliance:

- ✓ Records of background radioactivity determinations at defined frequency

CBG.18090 Counting Times Phase II

The laboratory defines counting times for quantitative procedures that are sufficiently long for statistical accuracy and precision.

NEWBORN SCREENING SPECIMEN COLLECTION, HANDLING AND TESTING

This section applies to laboratories that perform testing on newborns from whole blood heel stick samples collected on filter paper collection devices for the routine screening of congenital disorders. Additional specimen collection requirements for newborn screening specimens are found in the Laboratory General Checklist.