Evidence of Compliance:
- ✓ Records of concentration technique verification at defined frequency

RADIOIMMUNOASSAYS

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

IMM.35965 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

IMM.35975 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

IMM.35995 Counting Times **Phase II**

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

ANALYTICAL BALANCES

COLORIMETERS, SPECTROPHOTOMETERS, AND FLUORIMETERS

The following requirements apply to stand-alone instruments; they are not applicable to instruments embedded in automated equipment for which the manufacturer's instructions must be followed.

Inspector Instructions:

READ	• Sampling of colorimeter/spectrophotometer policies and procedures • Sampling of manufacturer required system checks
ASK	• How does your laboratory verify calibration curves?

IMM.39500 Absorbance/Linearity **Phase II**

Absorbance and/or fluorescence linearity is checked and recorded at least annually or as often as specified by the manufacturer, with filters or standard solutions.

Evidence of Compliance:
- ✓ Records of absorbance and linearity checks at required frequency

IMM.39520 Spectrophotometer Checks **Phase II**

Spectrophotometer (including ELISA plate readers) wavelength calibration, absorbance and linearity are checked at least annually (or as often as specified by the manufacturer), with appropriate solutions, filters or emission line source lamps, and the results recorded.

NOTE: Some spectrophotometer designs, eg, diode array, have no moving parts that can alter wavelength accuracy and do not require routine verification. The manufacturer's instructions must be followed.

Evidence of Compliance:
- ✓ Records of spectrophotometer checks at required frequency

IMM.39530 Stray Light **Phase II**

Stray light is checked at least annually with extinction filters or appropriate solutions, if required by the instrument manufacturer.

Evidence of Compliance:
- ✓ Records of stray light checks, as applicable

IMM.39540 Calibration Curves **Phase II**

For procedures using calibration curves, all the curves are rerun at defined intervals and/or verified after servicing or recalibration of instruments.

NOTE: Calibration curves must be run following manufacturer's instructions, at minimum, and as defined in laboratory procedure.

Evidence of Compliance:
- ✓ Records of calibration curve rerun and/or verification at defined frequency

PROCEDURES AND TEST SYSTEMS

ANTI-NUCLEAR ANTIBODY TESTING

Inspector Instructions:

- Sampling of ANA result reports

IMM.39700 Anti-Nuclear Antibody Reporting **Phase I**

The method used for detecting anti-nuclear antibodies (ANA) is included on the report.

NOTE: Indirect immunofluorescence is traditionally used to detect antibodies with affinity for HEp-2 cells, and the pattern of ANA immunofluorescence is reported. Other methods (such as enzyme-linked immunoassay or multiplexed bead immunoassay) may not detect all of the same autoantibodies as the HEp-2 methodology, and these differences may be clinically significant. The ANA results report must include a brief description of the method used for ANA screening if the methodology is not explicit in the test name.

Evidence of Compliance:

✓ Records of ANA reports indicating method used

REFERENCES

1) Meroni PL, Schur PH. ANA screening: an old test with new recommendations. *Ann Rheum Dis.* 2010;69:1420-1422.
2) American College of Rheumatology Position Statement: Methodology of Testing for Antinuclear Antibodies. American College of Rheumatology. August 2015.

TUMOR MARKER TESTING

Inspector Instructions:

- Sampling of tumor marker result reports
- Test reference guide or other communication to ordering providers

IMM.39800 Tumor Marker Result Reporting **Phase I**

The following information is available to clinicians for the reporting of tumor marker results:

- **Manufacturer and methodology of the tumor marker assay**
- **A statement indicating that patient results determined by assays using different manufacturers or methods may not be comparable.**

NOTE: As used in this checklist, a tumor marker is defined as any analyte that is serially measured over time primarily as an indicator of tumor burden.

Tumor marker results obtained can vary due to differences in assay methods and reagent specificity. If there is an assay change while monitoring a patient, the CAP recommends (but does not require) that the laboratory run parallel measurements with both assays.

The required information does not need to be reported with the test result if it is readily available elsewhere (eg, test reference guide).

Evidence of Compliance:

✓ Patient reports with required elements **OR**

✓ Test reference guide or other mechanism for providing ordering and interpretation information

REFERENCES

1) National Academy of Clinical Biochemistry. Sturgeon, CM, Diamandis, EP. (Eds.). *Laboratory Medicine Practice Guidelines. Use of tumor markers in clinical practice: quality requirements.* American Association for Clinical Chemistry; 2009.

BLOOD TYPE, GROUP, AND/OR ANTIBODY SCREENS

If the laboratory performs transfusion-related testing or any immunohematology tests other than blood group typing (ABO and Rh) antibody screens, or direct antiglobulin testing (DAT), the Transfusion Medicine Checklist must be used for inspection.