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.

Inspector Instructions:

	• Sampling of blood type/group/antibody screen policies and procedures • Sampling of current package inserts • Sampling of QC records
	• Technologist performing testing (recording results at the time of testing)
	• What is your laboratory's course of action when ABO and Rh typing results are not in agreement with the patient's historical record? • How does your laboratory ensure that the direct antiglobulin test detects RBC-bound complement as well as IgG? • How do you confirm negative antiglobulin tests?
	• If there had been an instance when the ABO and Rh typing results were not in agreement with the patient's historical record, further evaluate the laboratory's responses, corrective actions and resolutions

IMM.40200 Package Inserts/Manufacturer's Instructions- Immunohematology Reagents Phase II

Current package inserts/manufacturer's instructions are available for immunohematology reagents.

NOTE: The laboratory must have a procedure that assures that:
- *The most current package inserts/manufacturer's instructions are in use.*
- *The relevant procedures are updated when changes to the instructions occur.*

Unless a manufacturer's package insert is being used as part of an approved procedure, laboratories are not required to retain discontinued package inserts; however, the laboratory must have a process to obtain expired package inserts from the manufacturer, if requested.

IMM.40250 Reagent Handling - Immunohematology Reagents Phase II

Immunohematology reagents are used according to manufacturer's instructions; or, if alternative procedures are used, validation records confirm that they perform as intended.

NOTE: Testing methods used for ABO, Rh and antibody screening that are different from the manufacturer's instructions are acceptable provided they are not prohibited by the manufacturer, have been demonstrated to be satisfactory, or, for laboratories subject to US regulations, have been approved by the Centers for Biologics Evaluation and Research (CBER).

Evidence of Compliance:
- ✓ Records of validation if instructions have been modified

REFERENCES
1) Food and Drug Administration. Guide to inspections of blood banks, Set 1994.
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1271(a)(1)].