4) Fishleder AJ, Hoffman GC. A practical approach to the detection of hemoglobinopathies: part II. The sickle cell disorders. *Lab Med*. 1987;18:441-443
5) Fishleder AJ, Hoffman GC. A practical approach to the detection of hemoglobinopathies: part III. Nonsickling disorders and cord blood screening. *Lab Med*. 1987;18:513-518
6) Adams JG III, Steinberg MH. Analysis of hemoglobins, In Hoffman R, *et al*, eds. Hematology: basic principles and practice. New York, NY: Churchill Livingstone, 1991:18151-827
7) Mallory PA, *et al*. Comparison of isoelectric focusing and cellulose acetate electrophoresis for hemoglobin separation. *Clin Lab Sci*. 1994;7:348-352

ANTI-NUCLEAR ANTIBODY TESTING

Inspector Instructions:

READ

- Sampling of ANA result reports

CHM.33780 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.

HIV PRIMARY DIAGNOSTIC TESTING

Inspector Instructions:

READ

- Sampling of HIV diagnostic testing policies and procedures
- Sampling of HIV result reports

CHM.33790 HIV Primary Diagnostic Testing - Supplemental and Confirmatory Testing **Phase I**

The laboratory follows public health recommendations or guidelines for HIV primary diagnostic testing, including primary screening and additional (supplemental and/or confirmatory) testing.

NOTE: If additional testing after a primary screening test is recommended by public health authorities, the laboratory:

- *Performs additional testing reflexively if the specimen is suitable and the test is performed in house, or*
- *Sends additional testing to a referral laboratory if the specimen is suitable, or*
- *Provides guidance to providers on submission of additional specimens, if needed for supplemental or confirmatory testing.*

The US Centers for Disease Control and Prevention (CDC) and Association of Public Health Laboratories (APHL) provide recommendations for HIV testing. Guidelines and recommended algorithms can be found on the CDC and APHL websites.

Evidence of Compliance:

✓ Patient reports with initial screening results and reflexive testing results and/or guidance

REFERENCES

1) Centers for Disease Control and Prevention and Association of Public Health Laboratories. Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations. Available at http://stacks.cdc.gov/view/cdc/23447. Published June 27, 2014. Accessed 11/19/2019.
2) National Center for HIV/AIDS, Viral Hepatitis, and TB Prevention (US). Divisions of HIV/AIDS Prevention; Association of Public Health Laboratories. 2018 Quick reference guide: Recommended laboratory HIV testing algorithm for serum or plasma specimens. Available at: https://stacks.cdc.gov/view/cdc/50872. Published January 2018. Accessed 4/2/2023.
3) Association of Public Health Laboratories. Suggested Reporting Language for the HIV Laboratory Diagnostic Testing Algorithm. January 2019. Available at APHL Publications. Accessed 11/19/2019.

BLOOD GAS ANALYSIS

The Chemistry and Toxicology Checklist is intended for inspection of laboratory sections performing testing in a dedicated space (eg, main laboratory, respiratory therapy). Laboratories performing testing at or near the patient bedside (eg, portable instruments) must use the Point-of-Care Testing Checklist.

The number of checklists needed for test sites under the same CLIA number and CAP number is determined as follows:

- *Blood gas testing performed in more than one area under the **same supervision** use one Chemistry and Toxicology Checklist (eg, main laboratory and stat lab);*
- *Blood gas testing performed in more than one area under **different supervision** use separate Chemistry and Toxicology Checklists for each separately supervised site (eg, main laboratory and respiratory therapy department);*

Testing sites within an institution with different CLIA and CAP numbers must submit separate applications and have separate full inspections.

SPECIMEN COLLECTION AND HANDLING

Inspector Instructions:

	• Blood gas collection policy and procedure • Sampling of records for performance of collateral circulation tests
	• How are personnel that perform arterial punctures made aware of possible complications?