Inspector Instructions:

	• Sampling of abnormal hemoglobin policies and procedures • Sampling of patient reports (confirmatory testing, comments) • Sampling of QC records
	• Hemoglobin separation patterns (appropriate separations and controls) • Examine a sampling of medium (media) used to identify hemoglobin variants including alkaline/acid electrophoresis, isoelectric focusing, HPLC or other method
	• What is your course of action when the primary screening method appears to show Hb S? • What is your course of action when the primary Hb screening method shows Hb variants migrating in non-A/non-S positions?

CBG.20165 Hb S Primary Screen **Phase II**

For samples that have screening results demonstrating the presence of a hemoglobin consistent with Hb S and suggesting a possible clinically significant condition, reporting of the screening results includes a recommendation that confirmatory testing be performed.

NOTE: For primary definitive diagnosis screening by electrophoresis or other separation methods, all samples with hemoglobins migrating in the "S" positions or peak must be tested for sickling hemoglobin(s). Known sickling and non-sickling controls both must be included with each run of patient specimens tested.

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1) Fairbanks VF. Hemoglobinopathies and thalassemias. Laboratory methods and case studies. New York, NY: BC Decker, 1980
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3) Cossu G, *et al*. Neonatal screening of betathalassemias by thin layer isoelectric focusing. *Am J Hematol*. 1982;13:149
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11) Adams JG III, Steinberg MH. Analysis of hemoglobins, In Hoffman R, *et al*, eds. Hematology: basic principles and practice. New York, NY: Churchill Livingstone, 1991:1815-1827
12) Mallory PA, *et al*. Comparison of isoelectric focusing and cellulose acetate electrophoresis for hemoglobin separation. *Clin Lab Sci*. 1994;7:348- 352
13) Awalt E, *et al*. Tandem mass spectrometry (MS) – A screening tool for hemoglobinopathies. *Clin Chem*. 2001;47(suppl):A165
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CBG.20170 Daily QC - Hgb Separation **Phase II**

Controls containing at least three known major hemoglobins, including Hb F and both a sickling and a nonsickling hemoglobin (eg, A, F and S) are applied with the patient specimen(s) and separations are satisfactory.

NOTE: There are written procedures for instruments with multiple electrophoretic chambers or capillaries to ensure that QC is performed on each individual chamber or capillary.

Evidence of Compliance:

- ✓ QC records reflecting the use of appropriate controls **AND**
- ✓ Data, tracings, or other appropriate testing results (eg, photographs, gels, cards with banding patterns) demonstrate appropriate controls and separation

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CBG.20175 Hemoglobin Variants — Phase II

All samples with hemoglobin variants not appearing to be Hb A, Hb F, or Hb S by the separation procedure in use, are reported with a recommendation to obtain confirmatory testing consistent with local screening program recommendations.

NOTE: The laboratory must have a defined process for the reporting of abnormal hemoglobin variants, developed in consultation with hematology advisors. The procedure must address the confirmatory testing recommendations, if confirmatory testing is not performed on-site.

Evidence of Compliance:

- ✓ Patient reports and records reflecting adherence to laboratory reporting procedures

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1) Giordino PC. Strategies for basic laboratory diagnostics of the hemoglobinopathies in multi-ethnic societies: interpretation of results and pitfalls. *Int J Hematol.* 2013;35:465-79.
2) Sabath DE. Molecular diagnosis of thalassemias and hemoglobinopathies: an ACLPS critical review. *Am J Clin Pathol.* 2017;148:6-15.
3) Greene DN, Vaughn CP, Crews BO, Agarwal AM. Advances in detection of hemoglobinopathies. *Clinica Chimica Acta.* 2015;15:439-50.
4) Troxler H, Kleinert P, Schmugge M, Speer O. Advances in hemoglobinopathy detection and identification. *Adv Clin Chem.* 2012;57:1-28.
5) Bain BJ. Haemaglobinopathy diagnosis: algorithms, lessons and pitfalls. *Blood Rev.* 2011;25(5):205-13.
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8) Bradley CA, Kelly A. Calibration verification of hemoglobins A, A2, S, and F with an automated chromatography system. *Clin Chem*. 2001;47(suppl):A173