

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

REFERENCES

- 1) Fairbanks VF. Hemoglobinopathies and thalassemias. Laboratory methods and case studies. New York, NY: BC Decker, 1980
- 2) Beuzard Y, et al. Isoelectric focusing of human hemoglobins, In Hanash, Brewer, eds. Advances in hemoglobin analysis. New York, NY: Alan R. Liss, 1981:177-195
- 3) Cossu G, et al. Neonatal screening of betathalassemias by thin layer isoelectric focusing. *Am J Hematol.* 1982;13:149
- 4) Bunn HF, Forget BG. Hemoglobin: molecular, genetic and clinical aspects. Philadelphia, PA: WB Saunders, 1986
- 5) Honig GR, Adams JG III. Human hemoglobin genetics. Vienna, Austria: SpringerVerlag, 1986
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- 9) 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
- 10) Armbruster DA. Neonatal hemoglobinopathy screening. *Lab Med.* 1990;21:815-822
- 11) Adams JG III, Steinberg MH. Analysis of hemoglobins, In Hoffman R, et al, eds. Hematology: basic principles and practice. New York, NY: ChurchillLivingstone, 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
- 14) Bradley CA, Kelly A. Comparison of high performance liquid chromatography with electrophoresis for measurement of hemoglobins A, A2, S, F, and C. *Clin Chem.* 2001;47(suppl):A172
- 15) Bradley CA, Kelly A. Calibration verification of hemoglobins A, A2, S, and F with an automated chromatography system. *Clin Chem.* 2001;47(suppl):A17315

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

REFERENCES

- 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. Haemoglobinopathy diagnosis: algorithms, lessons and pitfalls. *Blood Rev.* 2011;25(5):205-13.
- 6) Awalt E, et al. Tandem mass spectrometry (MS) – A screening tool for hemoglobinopathies. *Clin Chem.* 2001;47(suppl):A165
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