

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0859560	(X3) Date Survey Completed 12/04/2023
Name of Provider or Supplier Meharry Sickle Cell Center Laboratory	Street Address, City, State 1005 Dr D B Todd Blvd, Nashville, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of laboratory policy, review of final patient test reports, and staff interview, the laboratory failed to follow its own policy for specimen rejection by reporting hemoglobinopathy results on one of five patient specimens greater than 7 days old. The findings include: 1. Observation of the laboratory on 12.04.23 at 08:05 am revealed the Bio-Rad Variant II Hemoglobin Testing System (SN 1405) and the PerkinElmer Migele Gel Electrophoresis Unit (SN 21180137) in use for patient hemoglobin and hemoglobin electrophoresis testing. 2. Review of the laboratory policy "Criteria for Specimen Rejection Policy" revealed "The following procedural actions are to be followed carefully in rejecting a blood specimen that is received in the laboratory for testing. Reject when the following occur: 5. Specimen collection date greater than 7 days" 3. Review of five final patient test reports revealed the following for Sample ID 108478: - Draw Date: 4/19/2023 at 10:37 am - Delivery Date: 4/28/2023 at 10:37 am - Run Date: 5/2/2023 at 3:15 pm - Report Date: 5/2/2023 at 4:23 pm 4. Interview with the Laboratory Director and Testing Person 2 on 12.04.23 at 12:45 pm confirmed that they failed to follow their own policy for specimen rejection for one of five specimens reviewed.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p>

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of manufacturer's operator's manuals, lack of documentation, and staff interview, the laboratory failed to monitor temperature and humidity in the area where the hemoglobin testing systems were in operation in 2021, 2022, and 2023. The findings include: 1. Observation of the laboratory on 12.04.23 at 08:05 am revealed the BioRad VARIANT II Hemoglobin Testing System (SN: 1405) and the Perkin Elmer Migele Gel Electrophoresis Unit (SN: 21180137) in use for patient hemoglobinopathy testing. 2. Review of the manufacturers' operating manuals revealed operating environment requirements of: - Bio-Rad VARIANT II system: Temperature 15-35 Celsius, Humidity 10-90% - Perkin Elmer Migele Gel Electrophoresis Unit: Temperature 18-30 Celsius, Humidity 20-80%. 3. Review of laboratory records revealed no documentation of room temperature or humidity. 4. Interview with the Laboratory Director and Testing Person 2 on 12.04.23 at 12:45 pm confirmed the laboratory did not monitor room temperature or humidity in 2021, 2022, and 2023 in the area where the Bio-Rad VARIANT II and PerkinElmer Migele test systems were located.

D5415

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)**

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of laboratory policy, and staff interviews, the laboratory failed to label two of two sets of reconstituted BioRad Hemoglobin A2 controls, Level 1 and Level 2 with Identity, date prepared, expiration date, and storage instructions. The findings include: 1. Observation of the laboratory on 12.04.23 at 8:05 am revealed two aliquots of reconstituted BioRad Lyphochek Hemoglobin A2 Control, Levels 1 and 2 (Lot: 54820 Exp: 2.28.25) in use for quality control of the Bio-Rad Variant II Hemoglobin Testing System (SN: 1405). The aliquots observed were not labeled with Identity, date prepared, expiration date, and storage instructions. 2. Review of the laboratory policy "Quality Assurance Program" revealed "All reagents prepared in the laboratory will be labeled with the following: Identification, Strength, titer or concentration, Date prepared, Expiration date, Storage instructions (e.g. temperature requirements if other than room temperature), Hazardous chemical Warning Label, if applicable, and Initials of preparer". 3.

Interview with the Laboratory Director and Testing Person 2 on 12.04.23 at 12:45 pm confirmed the aliquots of quality control material observed in the laboratory were not labeled with identity, date prepared, expiration date, and storage instructions.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CMS-209) and Clinical Laboratory Improvement Amendments Application for Certification (CMS-116), testing personnel competency assessment records, and staff interview, the laboratory's technical consultant (TC) failed to document all six required criteria for assessing personnel competency for 3 of 3 testing personnel (TP) performing hemoglobinopathy patient testing in 2021, 2022, and 2023. The findings include: 1. Review of the CMS-209 and CMS-116 provided by the laboratory on 12.04.23 revealed three TP who perform hemoglobin variant and hemoglobin electrophoresis testing. 2. Review of testing personnel competency assessment records for 2021, 2022, and 2023 revealed competency assessments completed annually for three of three TP failed to include documentation of the six required criteria of competency that include: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and, assessment of problem solving skills. 3. Interview with the Laboratory Director and Testing Person 2 on 12.04.23 at 12:45 pm confirmed the laboratory's TC failed to document the six required criteria for assessing personnel competency for three of three TP in 2021, 2022, and 2023.