Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0859560	09/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
Meharry Sickle Cell Center Laboratory	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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observations, a review of the laboratory procedure manual, a lack of documentation, and staff interviews, the laboratory failed to follow the safety plan procedure for eyewash station and fire extinguisher inspections in 2024 and 2025. The findings include: 1. Observation of the laboratory on 09/09/2025 at 11:00 revealed the following: An eyewash station with a bottle labeled "Buffered Eye-Lert Emergency Eye & Skin Flush" with a handwritten expiration date of 07/31/2025. A fire extinguisher with a "Monthly Inspection Record Tag" with dates recorded as follows: 02/12, 03/05, 04/09, 05/08, 06/16, 07/07. The tag did not include the year of inspection. 2. A review of the laboratory procedure titled "Chemical Hygiene and Hazard Communication Safety Plan," section "Engineering Controls," revealed that "Eyewash stations shall be inspected at least quarterly and the inspection records maintained by the Safety Officer" and "Fire extinguishers shall be visually inspected on a monthly basis by laboratory personnel and serviced annually by an outside company licensed to perform such inspections." 2. On the date of the survey (09/09 /2025), documentation of the quarterly eyewash station inspections and monthly or annual fire extinguisher inspection records for 2024 and 2025 was unavailable. 3. The survey findings were confirmed in an interview with the laboratory general supervisor and testing person two on 09/09/2025 at 3:00 p.m.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)

	Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on laboratory observation, review of laboratory calibration records, lack of records, and staff interviews, the laboratory failed to retain the manufacturer's assay information sheets (two of three reviewed) for the calibrators used for the Bio-Rad Variant II Hemoglobin Testing System in 2024 and 2025. The findings include: 1. Observation of the laboratory on 09/09/2025 at 11:00 a.m. revealed the Bio-Rad Variant II (Serial Number: 14085) instrument used for patient normal and abnormal hemoglobin detection. 2. A review of the laboratory's calibration records revealed the following: Calibrator Lot 64581947 performed on 08/02/2024 Calibrator Lot 64631585 performed on 03/12/2025 3. The manufacturer's assay information sheets, which provided the expected values for the calibrators, were unavailable on the survey date (09/09/2025). 4. The survey findings were confirmed in an interview with the laboratory general supervisor and testing person two on 09/09/2025 at 3:00 p.m.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of laboratory procedures, a lack of records, and staff interviews, the laboratory failed to follow the established procedure when it did not perform calibration verification assays for the Bio-Rad Variant II Hemoglobin Testing System in 2024 or 2025. The findings include: 1. Observation of the laboratory on 09/09/2025 at 11:00 a.m. revealed the Bio-Rad Variant II (Serial Number: 14085) instrument used to detect normal and abnormal hemoglobin in patients. 2. A review of the laboratory procedure titled "Meharry Sickle Cell Center Reference Laboratory Quality Assurance Program" in the section "Calibration and Calibration Verification Policy and Procedure" revealed that calibration verification

	assays were required "at least every 6 months" with "at least 3 levels that cover the high, low, and mid-points of the reportable range". 3. Calibration verification assay records for 2024 or 2025 were not available on the survey date (09/09/2025). 4. The survey findings were confirmed in an interview with the laboratory general supervisor and testing person two on 09/09/2025 at 3:00 p.m.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation of the laboratory, a review of the manufacturer's package inserts, laboratory policy, and staff interview, the laboratory failed to store quality control material according to the manufacturer's requirements for the Bio-Rad Hemoglobin A2 controls (Level 1 and Level 2) used for the Bio-Rad Variant II Hemoglobin Testing System. The findings include: 1. Observation of the laboratory on 09/09/2025 at 11:00 a.m. revealed the following: Bio-Rad Variant II (Serial Number: 14085) instrument used for patient normal and abnormal hemoglobin detection. Bio-Rad Lyphochek Hemoglobin A2 quality control aliquots (lots 54851 and 54852) that were reconstituted and stored in a freezer for use. 2. A review of the Bio-Rad Lyphochek Hemoglobin A2 quality control package insert revealed that the storage requirements for reconstituted controls were 2-8C. 3. A review of the laboratory policy titled "Meharry Sickle Cell Center Laboratory Quality Control-Quality Control Policy" revealed "The controls are to be stored at the recommended temperature." 4. An interview with the laboratory general supervisor and testing person two on 09/09/2025 at 3:00 p.m. confirmed the survey findings. Word Key: - degrees C- Celsius