Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D1077539	12/17/2024
Name of Provider or Supplier	**Street Address, City, State**	
Howard University Center For Sickle Cell Disease	2041 Georgia Ave, Nw Room 5c28, Washington, DC	

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	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) 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. This STANDARD is not met as evidenced by: Based on observation of sample transportation coolers outside of the lab on the day of the survey 12/17/24 at 12:00 PM, review of the written procedure, and interview with the testing person (TP), the lab failed to validate coolers that transported Sickle Cell patient specimens. Findings: 1. The lab did not validate the four sample transportation coolers for temperature and optimal sample disposition when Sickle Cell samples were collected during the hospital blood drive once a month and transported to the lab for testing. 2. The TP stated on the day of the survey 12/17/24 at 12:00 PM that they have plastic and Styrofoam coolers that they give hospital personnel to transport Sickle Cell patient samples once they are collected during the blood drive once a month for testing in the lab. 3. The TP confirmed on the day of the survey 12/17/24 at 12:00 PM that the lab failed to validate the coolers that transported Sickle Cell patient specimens.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 review of the written procedure manual and interview with the testing person (TP), the lab failed to have written procedures for all areas of the laboratory when performing Sickle Cell patient testing. Findings: Repeat Deficiency 1. The laboratory did not have written procedures for the storage limit and deposition of patient Sickle Cell samples in the -80 Degree Celsius freezer when stored up to five years. 3. The TP stated on the day of the survey 12/17/24 at 1:30 PM that the lab saves special samples with rare diseases and that storage of the rare disease patient samples can be maintained at -80 Degree Celsius for up to five years. 4. The TP confirmed on the day of the survey 12/17/14 at 1:30 PM that the lab failed to have written procedures for all areas of the lab when performing Sickle Cell patient testing.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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: A. Based on observation of the specimen storage refrigerator on the day of the survey 12/17/24 at 12:00 PM and interview with the testing person (TP), the lab failed to document the temperature when samples were stored before nor after lab testing hours. Findings: 1. Observation of the specimen storage refrigerator outside of the lab on the day of the survey 12/17/24 at 12:00 PM showed that the temperature was not documented during the times Sickle Cell patient samples were stored after collection during scheduled community events at the hospital since the last survey on 12/8/2022. 2. The TP stated on the day of the survey 12/17/24 at 12:00 PM that patient samples are sometimes collected during special events at the hospital when the lab is closed and that collection personnel have been directed to store the samples in the refrigerator outside of the lab. 3. The TP confirmed on the day of the survey 12/17/24

	at 12:00 PM that the temperature for the specimen storage refrigerator outside of the lab was not documented each day samples were stored since the last survey on 12/8 /2022. B. Based on review of the written procedure, humidity logs, and interview with the testing person (TP), the lab failed to document the humidity level that included all areas of laboratory testing. Findings: 1. The lab did not document the humidity level required by the manufacturer for the vortex mixer since the last survey on 12/8/2022. 2. Review of the vortex mixer manufacturer instructions during the time of the survey on 12/17/24 at 1:30 PM showed that the humidity range is 20-85 %. 3. The TP stated on the day of the survey 12/17/24 at 1:30 PM that she was not aware that vortex mixer required a specific humidity range during patient testing. 4. The TP confirmed on the day of the survey 12/17/24 at 1:30 PM that the lab failed to document the humidity level that included all areas of laboratory testing since the last survey on 12/8/2022
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 on the day of the survey 12/17/24 at 2:00 PM, interview with the testing person (TP), and the laboratory director (LD), the lab failed to label all reagents used for Sickle Cell patient testing. Findings: 1. The lab did not label the one bottle of clear liquid with a white top that was observed on the day of the survey 12/17/24 at 2:00 PM on the counter without a label showing the name of the reagent, date of preparation, opened dated, received date, nor the expiration date. 2. The TP and the LD stated on the day of the survey 12/17/24 at 2:00 PM that they were unaware that the bottle of liquid did not have the required labeling that showed the contents and expiration date of the liquid. 3. The TP and the LD confirmed on the day of the survey 12/17/24 at 2:00 PM that the lab failed to label the one bottle of clear liquid used for Sickle Cell patient testing.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation of the laboratory on the day of the survey 12/17/24 at 2:00 PM, interview with the testing person (TP), and the laboratory director (LD), the lab failed to ensure that all areas of lab testing meet the laboratory's criteria of acceptability. Finding: 1. The lab did not dispose of one box of pipette tips that expired in May 2020. 2. The TP and the LD stated on the day of the survey 12/17/24 at 2:00 PM that they were unaware that the pipette tips had expired. 3. The TP and the LD confirmed on the day of the survey 12/17/24 at 2:00 PM that the lab failed to ensure that all areas of lab testing meet the laboratory's criteria of acceptability.

D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the patient final report, specimen sample run data, and interview with the testing person (TP), the lab failed to have a unique patient identifier on the patient's final report. Finding: 1. The lab receives Sickle Cell patient samples from the day clinic. 2. Samples arrive in the lab with the patient's first and last name and a sample number on the requisition. 3. The TP stated on the day of the survey 12/17/24 at 1:00 PM that during testing a unique injection number is added to each sample when loaded on the analyzer for testing. 4. Review of six patient analyzer printouts showed the unique identifier that is added by the TP during patient testing was printed on the sample analyzer printout once the testing had been completed. 5. Review of the same six patients showed that the unique identifier was not printed on the patient final report. 6. The TP confirmed during the time of the survey on 12/17/24 at 1:00 PM that the patient final report did not have a unique patient identifier printed on the final report.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Repeat Deficiency Based on review of the written procedure manual, review of quality assessment notes, interview with the testing person, and the laboratory director (LD), the LD failed to ensure that QA procedures were performed and maintained for all areas of the laboratory when performing Sickle Cell testing (Refer to D6094)
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the written procedure manual, review of quality assessment (QA) notes, interview with the testing person (TP), and the laboratory director (LD), the LD

	failed to ensure that QA procedures were performed and maintained for all areas of the laboratory when performing Sickle Cell testing. Findings: (Repeat Deficiency) Refer to D5311, D5403, D5413, D5415, D5417, and D5805 1. The LD failed to ensure that the TP documented humidity levels during the months of January and May 22, 2023 and the reason for not documenting humidity levels was because the lab was working on the installation of the humidity monitor. 2. The LD failed to ensure that the technical supervisor (TS) maintained the documentation of temperatures on laboratory temperature logs. 3. The LD failed to ensure that all problems that occured in the lab were documented on a problem log, corrected by the proper personnel, and discussed during QA meetings. 4. The LD confirmed on the day of the survey 12/17 /24 at 2:30 PM that QA procedures were not performed and maintained for all areas of the laboratory when performing Sickle Cell testing.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Repeat Deficiency Based on review of the manufacturers written procedure manual, competency procedures, interview with the testing person (TP), and the laboratory director, the technical supervisor failed to perform observational competency procedures with the TP when testing Sickle Cell specimens (Refer to D6121), and failed to perform annual competency procedures on the TP when performing Sickle Cell testing (Refer to D6128)
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on review of the manufacturers written procedure manual, competency procedures, interview with the testing person (TP), and the laboratory director (LD), the technical supervisor (TS) failed to perform observational competency procedures with the TP when testing Sickle Cell specimens. Findings: 1. The lab has one TP performing Sickle Cell testing. 2. The TS failed to perform observational competency procedures with the TP to ensure that the TP documented the Sickle Cell analyzer internal cartridge temperature when performing patient testing. 3. The manufacturer states that the analyzer temperature must be set to 33 Degrees Celsius and can be adjusted +/- 1 Degree Celsius for the cartridge when testing is performed. 4. The TP stated during the time of the survey on 12/17/24 at 2:00 PM that the analyzer temperature is shown on the computer screen during testing. She does not document the temperature. She does make a visual assessment to ensure that the temperature is in range for testing. 5. The TP and the LD confirmed during the survey on 12/17/24 at

	2:00 PM that the TS failed to perform observational competency procedures with the TP when testing Sickle Cell specimens to ensure that the TP documented the Sickle Cell analyzer internal temperature and cartridge adjustments.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of competency records, interview with the testing person (TP), and laboratory director (LD), the technical supervisor (TS) failed to perform annual competency procedures on the TP. Findings: 1. The lab has one TP performing Sickle Cell testing. 2. Review of training and competency records on the day of survey 12/17 /14 at 1:00 PM showed that the TP did not have annual competency procedures performed by the TS for performing Sickle Cell patient testing since the last survey in the year 2022. 3. The TP and the LD confirmed on the day of survey 12/17/14 at 1:00 PM that competency procedures were not performed on the TP for Sickle Cell testing since the last survey in the year 2022.