Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D1077539	12/08/2022
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
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 observation, the laboratory did not follow safety precautions to ensure that staff were not exposed to chemical and biohazard materials. Findings: 1. Inside the laboratory where patient testing was performed, staff kept food items and utensils used for eating. These items included: a) Napkins, plastic ware, silverware, a pot with water and a ceramic teapot; b) One microwave oven that was not labeled for laboratory use only; and c) Tea bags. 2. There was no signage stating that eating, drinking or application of cosmetics was prohibited in the laboratory. 3. The laboratory was cluttered with empty plastic jugs and the interior of the fume hood was also cluttered and contained a large Erlenmeyer flask with cloudy crystals on the bottom (no identifying information was on the flask), a charger cord, an exposed electrical box sitting out in the open, file folders, empty plastic boxes and cardboard boxes.
D3013	FACILITIES CFR(s): 493.1101(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation. This STANDARD is not met as evidenced by:

	Based on observation and interview, paper records were not securely stored to prevent tampering or unauthorized access by individuals not on staff. Findings; 1. Patient records were stored in an unlocked file cabinet in an entry room that was between a common passageway and the laboratory. On the day of survey, the door to this entry room was propped open with a box and the file cabinet containing patient records was not locked; as the surveyor was able to open each drawer and pull out patient records; and 2. The laboratory did not ensure that patient test records were securely stored to protect privacy and this was confirmed during interview with the laboratory director on the afternoon of the day of survey.
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: Based on review of instrument printouts and interview with the testing person (TP), the laboratory (lab) failed to retain patient final reports from each day Sickle Cell testing was performed. Findings: 1. Review of the analyzer printouts from August 2022-September 2022 showed that the lab did not retain the patient final test reports. 2. The TP stated that once the results are reported the final reports are locked in the General Supervisors office. 3. The lab was unable to retrieve copies of the final reports on the day of the survey. 4. The TP confirmed that patient final reports were not available on the day of the survey at 2:00 PM.
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: I. Based on review of the laboratory written procedure and interview with the

	laboratory director, the laboratory written procedures for high performance liquid chromatography were not specific and did not include step by step instructions for testing patient specimens and approving test results. Findings: 1. The laboratory written procedures referred to procedures that were no longer in use by the laboratory and these included: a) The written laboratory procedure identified as addendum referred to the trade marked system called Ultra Resolution, but the system used was the Variant II hemoglobin testing system; b) The written laboratory procedure referred to electrophoresis procedures that were no longer in use by the laboratory, and the title of the procedure was electrophoresis procedure c) The written laboratory procedure identified as overview was not current and stated that the primary screen is alkaline electrophoresis and the secondary test (used to rule out hemoglobin S) and patients with an apparent hemoglobin S and a negative solubility test is the patient is referred to the CDC for further testing. D) The retired procedures were not labeled as no lo longer in use with a discontinuance date and separated from the procedures currently in use. 44487 II. Based on review of the written procedure manual and interview with the testing person, the lab failed to have collection and storage procedures for performing Sickle Cell testing. Findings: Repeat Deficiency 1. The lab collects patient samples on a walk in basis on the first floor of the hospital when the Sickle Cell table is present and through appointments in the hospital clinic. 2. The testing person stated on the day of the survey at 1:00 PM that when patients walk in samples are labeled with the patient's name along with other identifiers and when patients are scheduled through the hospital clinic samples are labeled with an ID number. 3. The testing person confirmed on the day of the survey at 1:00 PM that the lab did not have collection procedures for performing Sickle Cell testing. 4. Once samples are collected, they are stored on the 6th floor in the refrigerator. 5. The lab failed to monitor and document the storage temperature of samples stored in the refrigerator on the 6th floor. 6. The testing person confirmed on the day of the survey at 1:00 PM that the storage temperature of collected samples were not monitored and documented.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on observation and record review, the laboratory did not label retired procedures as no longer in use and the date they were discontinued. Findings: 1. Trinity Biotech written procedures were in the standard operating procedure manual, they were with the current procedures and were not labeled with the date they were discontinued. 2. The written procedures also included instructions for electrophoresis procedures using cellulose acetate plates, that were discontinued, but not labeled with the date discontinued. 3. This findings were confirmed during interview with the laboratory director the afternoon of the day of survey.
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: Based on observation and interview, the laboratory did not take and did not record refrigerator or room temperature records to ensure proper storage of reagents and proper patient testing conditions for high performance liquid chromatography (HPLC). Findings: 1. It was observed that the laboratory did not have a thermometer in the room where testing was performed and did not have a thermometer in the refrigerator where reagents and patient specimens were stored; 2. Laboratory staff stated during interview in the afternoon of the day of survey that they were not aware that the manufacturer of the HPLC analyzer had temperature requirements for the room that the testing was performed and the laboratory did not take and record temperatures for the refrigerator used to store patient samples and patient test reagents. The manufacturer requires that the room temperature be between 15 to 30 degree Centigrade for testing and reagents were labeled with allowable temperature ranges for refrigerated storage.
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 and interview the laboratory did not label deionized water used for patient testing to show storage requirements, preparation or expiration date. Findings: 1. Deionized water is brought over from another laboratory. the water is collected in used plastic jugs that at one time held another type of reagent. One jug of the water was observed sitting on the testing bench, the jug containing the deionized water was not labeled to show when it was poured into the jug, and was not labeled with an expiration date. 2. The laboratory did not have a written procedure for preparing the jug for use as a storage container, where to obtain the reagent water, how to label the jug of water for when it was poured, and how to assign and label the jug of water with an expiration date or other pertinent information such as storage requirements. 3. One flask of clear liquid was sitting on the work bench and labeled wash fluid, it did not have a preparation or expiration date. 4. This was confirmed during interview with testing staff on the afternoon of the day of survey.
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 and interview, the laboratory did not ensure reagents were not used past expiration or deteriorated and substandard. for high performance liquid chromatography testing. Findings: 1. The laboratory stored expired reagents in the refrigerator, the expired reagents were not separate from reagents in use and were not labeled as expired and not for patient testing. The expired reagents include. a) 4 vials of Hgb A2F controls I and II lot 5560, expired 1/2017 b) 1 FASC Position Marker lot 6110, expired 1/2017 c) 2 vials of A2 + F control reagent lot number 9170, expired 9 /30/20 d) 1 vial of Lypho chek HgbA2 control lot 54750 expired 6/30/22 2. Two diluent reagents sitting on the bench top lot number 9249 expired 11/30/2020 3. The laboratory did not keep the manufacturer name, lot number and expiration dates of reagents, including controls used for patient testing. 4. This was confirmed with staff during interview the afternoon of the day of survey.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the Variant II Hemoglobin System maintenance log and interview with the testing person (TP), the laboratory (lab) failed to perform monthly maintenance procedures as required by the manufacturer when performing Sickle Cell testing. Findings: 1. Review of the analyzer maintenance log showed that the lab did not perform maintenance procedures for cleaning and flushing from August 4, 2022 to the present. 2. The TP confirmed on the day of the survey at 1:00 PM that maintenance logs were not completed.
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: Based on record review, hematology quality assurance procedures, interview with the laboratory director and testing person,the laboratory director failed to ensure that validation records for high performance liquid chromatography were reviewed (Refer to D6086); failed to ensure that quality assurance procedures were performed for sickle cell disease testing (Refer to D6094); and failed to ensure that monthly maintenance procedures were performed as required by the manufacturer when performing Sickle Cell testing (Refer to D6095). The cumulative effect of systemic problems resulted in the laboratory inability to ensure the quality of health care provided for patients receiving Sickle Cell testing.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)

	The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director, the laboratory did not have validation records or did not have the laboratory director approve validation records for high performance liquid chromatography. Findings: 1. The precision studies, carry over studies and accuracy studies for Hgb F and A2 were not reviewed, signed and dated by the laboratory director. 2. The laboratory did not have validation records for Hgb S, this was confirmed during interview with the laboratory director on the afternoon of the day of survey.
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 hematology quality assurance (QA) procedures and interview with the testing person, the laboratory director (LD) failed to ensure that quality assurance procedures were performed for sickle cell disease testing. Findings: Repeat Deficiency 1. The LD failed to perform QA procedures during the year 2021 for sickle cell disease testing. 2. The testing person confirmed on the day of the survey at 1:00 PM that QA procedures were not performed during the year 2020.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on review of the Variant II Hemoglobin System maintenance log and interview with the testing person (TP), the lab director failed to ensure that monthly maintenance procedures were performed as required by the manufacturer when performing Sickle Cell testing. Findings: Refer to D5429
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: Based on review of training documents and interview with the testing person, The

	technical supervisor failed to ensure that all persons performing patient testing was trained on the new analyzer. (Refer to D6120). The cumulative effect of systemic problems resulted in the laboratory inability to ensure the quality of health care provided for patients receiving Sickle Cell testing.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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 training documents and interview with the testing person, The technical supervisor (TS) failed to ensure that all persons performing patient testing was trained on the new analyzer. Findings: 1. The TS failed to ensure that all testing persons were trained on the Sickle Cell analyzer. 2 The lab performs Sickle Cell testing on the BIoRad Varient II installed in March 2022. 3. Training was performed by the manufacturer on March 16, 2022, for one of the two testing persons. 4. The testing person confirmed on the day of the survey at 11:30 AM that she was not trained by the manufacturer on the new Sickle Cell analyzer.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on review of the patient final reports and interview with the lab director (LD), the general supervisor (GS) failed to perform the second review required on the patient final report. Findings: 1. The lab performs Sickle Cell patient testing. 2. Review of patient final reports from October 2022 showed that the GS did not review and sign the final reports. 3. The reports have two required signatures at the bottom of the page. The technical supervisor (TS) and the GS. 4. The reports were reviewed and signed by the TS and were not reviewed and signed by the GS. 5. The LD confirmed on the day of the survey at 1:30 PM that the second required signature for the GS was not obtained prior to reporting of the patient results.