Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D1077539	03/16/2021
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the testing person, the laboratory did not perform annual competency assessments for the technical supervisor (TS) and the general supervisor (GS) when performing hematology testing. Findings: Repeat deficiency 1. The laboratory "annual review general supervisor and technical supervisor" sheet was presigned with the signature of the laboratory director and dated 10/08/2018. 2. Competency procedures for sickle cell disease testing were not performed for the years 2019 and 2020 for the GS and the TS. 3. The testing person confirmed that annual competency procedures were not performed for the GS and TS.
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, the laboratory director (LD) failed to have written procedures for the collection, labeling, and storage requirements of hematology specimens used for performing sickle cell disease testing. Findings: 1. The laboratory did not have procedures for collecting capillary tubes of patient blood, labeling, and storage prior to performing sickle cell disease testing. 2. The testing person stated the person that collects the specimens is on another floor. When specimens are ready for pickup the collection person will alert her. 3. Once alerted the testing person will sign out the specimens from the upstairs refrigerator. 4. The testing person stated that specimen collection procedures were not in the laboratory.
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on observation of the laboratory at 11:00 AM and interview with the testing person, the laboratory director failed to ensure the safety of the laboratory environment each day of patient testing. Findings: Observation of the laboratory floor showed cracked and loose tiles. The tiles were no longer glued to the floor and moved each time someone walked over them. The surface of the tiles were slippery. The surveyor tripped over the loose and cracked tiles. The testing person apologized.
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 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: 1. The LD failed to perform QA procedures during the year 2020 for sickle cell disease testing. 2. The laboratory has a "QA Quarterly Review" sheet that is presigned with the LD signature

	and dated 10/08/18 at the bottom of the sheet. 3. The "QA Quarterly Review" sheet that was presigned with the LD signature and dated 10/08/18 was used to perform QA procedures on 10/11/19, 4/2/19, and 1/7/19 without an original signature and date from the LD. 4. The testing person confirmed that QA procedures were not performed during the year 2020.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the testing person, the laboratory director failed to perform annual competency assessments for the technical supervisor (TS) and the general supervisor (GS) when performing hematology testing. Findings: Refer to D5209 Competency procedures for sickle cell disease testing were not performed for the years 2019 and 2020 for the GS and the TS.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the patient final reports and interview with the testing person, the laboratory director (LD) failed to specify in writing delegation requirements for review and signing the patient final reports when the lab supervisor was unavailable. Findings: 1. Review of seven Center for Sickle Cell Disease patient final reports showed two of the seven reports were not reviewed and signed by the lab supervisor. 2. The patient final report has the printed name of the laboratory supervisor at the bottom of the page. The lab supervisor is suppose to review and sign the final report once the test results are completed. 3. Two patient reports were reviewed and signed by the laboratory deputy director according to the testing person. 4. The testing person stated that when the lab supervisor is unavailable the deputy director or director will sign the patient final report. 5. The testing person confirmed that a written policy was not available establishing delegation of duty requirements when reviewing and signing patient final reports.
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 evaluations and interview with the testing person, the technical supervisor (TS), failed to perform competency assessments procedures for all laboratory personal performing sickle cell disease testing. Findings: 1. The laboratory has two testing persons (TP) performing sickle cell disease testing. 2. Only one of the two TP had competency evaluations performed in the year 2020 and 2021. 3. Review of the "Staff Competency Assessment Hemoglobin HPLC" was not used by the TS to perform competency assessments for all TP performing specimen testing. 4. The TP confirmed that the "Staff Competency Assessment Hemoglobin HPLC" was not used by the TS to perform competency assessments for all TP performing specimen testing.