Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D1077539	09/20/2018
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 the review of the laboratory's policies and procedures manual and confirmation by interview with Testing Personnel, the laboratory failed to establish written procedures for assessing the competency of the Technical Supervisor and the General Supervisor. Findings include: 1. Review of the laboratory's policies and procedures manual failed to provide a written procedure for assessing the General Supervisor and the Technical Supervisor. 2. Interview with the Testing Personnel on 9 /20/18 at approximately 2:30 PM, the laboratory did not have written procedures for assessing the competency of the General Supervisor and the Technical Supervisor.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policies and procedures and confirmation by LD and the laboratory staff on September 20, 2018 at approximately 11:45 AM. The current Laboratory Director (LD) failed to approve, sign and date the laboratory's policies and procedures for one (1) of the one (1) laboratory test procedure used to

	screen for hemoglobinopathy (High Performance Liquid Chromatography). The findings included: 1. Review of the laboratory's procedure and quality Assurance manual for the High Performance Liquid Chromatography (HPLC) procedure revealed that the procedure was last reviewed and signed on 9/1/2016. It should be noted that the LD that signed the procedure on 9/1/2016 was replaced by another director on 11/1/2016 who was again replaced by the current director on 5/31/2017. There was no documentation that the current director or the director who was on board on 11/1/2016 had approved and singed the procedure. 2. 2. Interview with the current LD and the laboratory staff on 9/20/18 at approximately 12:00 Noon confirmed the lack of signature by the current laboratory director. It should be further noted that this is a repeat deficiency from the 8/22/2016 recertification survey.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on the review of records (pipette maintenance and the laboratory's policies and procedures) and interview with the Testing Personnel, the laboratory failed to develop a maintenance protocol that specify the frequency of pipette calibration. The findings included: 1. Review of the laboratory's procedure revealed a protocol for performing pipette calibration. However, the protocol did not specify how often each pipette should be calibrated. 2. Review of pipette maintenance performed by an outside pipette servicing company revealed that the pipettes have been calibrated every two (2) years the last calibration was done on 9/6/18. 3. Review of the manual pipette calibration log revealed that the staff calibrated the pipettes on 7/16/18 and 8/16/18. 4. Interview with the Testing Personnel on 9/20/18 at approximately 3:00 PM confirmed that the laboratory's procedure for calibrating pipettes did not include information indicating how often each pipette should be calibrated.