

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0219030	(X3) Date Survey Completed 04/13/2023
Name of Provider or Supplier Hillcrest Clinic Inc	Street Address, City, State 5602 Baltimore National Pike 600, Baltimore, MD	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the testing person(TP), the laboratory failed to provide written instructions for entering the quality control (QC) results into the excel spreadsheet, printing the worksheet, documenting the cleaning of the equipment, and initialing the worksheet each day of testing. Findings: During the survey on 04/13/2023 at 1:15 PM, the TP confirmed that the procedure manual failed to include written instructions for entering the QC results into the excel</p>

spreadsheet, printing the worksheet at the end of each day, documenting the cleaning of the equipment on the daily worksheet, and initialing the printed worksheet after each day of testing.

D6022

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

I. Based on review of the "Rho(D) Typing" and "Spectrogen Trio Anti-D Control" procedures and interview with the testing person (TP), the laboratory director (LD) failed to ensure that the procedures included instructions for recording the patient and quality control (QC) results into the excel spreadsheet. Findings: 1. The last sentence of the "Rho(D) Typing" procedure states: "7. Record Results." There are no instructions for where and how to record the patient test results. 2. The "Spectrogen Trio Anti-D Control" procedure explains how to perform the test and the expected QC results but there are no instructions for where and how to record the QC test results. 3. The TP stated that the patient and QC results are entered into an excel spreadsheet each day of testing. The worksheet is printed at the end of the testing day and initialed by the TP performing the testing that day. After approximately 30 day the existing spreadsheets are deleted. 4. During the survey on 04/13/2023 at 1:15 PM, the TP confirmed that the procedure manual failed to include written instructions for where and how to enter patient and QC results into the excel spreadsheet, printing the spreadsheet each day of testing and the frequency of deleting the spreadsheets. II. Based on review of the "MLE [Medical Laboratory Evaluation] Proficiency Testing Instructions", PT records, review of the patient lab logs, and interview with the TP, the LD failed to ensure that the proficiency testing (PT) results were documented as required. Findings: 1. The "MLE Proficiency Testing Instructions" require the "1. One the day the testing is completed, the results must be documented into the lab log for that day. 2. Each specimen should be added to the lab log in the patient column. Record the results for each specimen in addition to the worksheet in the MLE survey notebook." 2. PT records from the third event of 2021 through the first event of 2023 (5 events) were reviewed. Review of the patient lab logs on the day of PT testing showed that the PT sample results were not recorded along with the patient test results as required by the procedure manual. 3. During the survey on 04/13/2023 at 1:15 PM, the TP confirmed that the PT results were documented along with the patients as required. III. Based on review of the quarterly quality assessment (QA) records and interview with the TP, the LD failed to ensure that all the QA records were signed and dated at the time of the review. Findings: 1. The "OSHA [Occupational Safety and Health Act] Bloodborne Pathogen Regulation: Monitor of Universal Precautions Personal Protective Equipment and Biohazardous Waste Disposal" worksheets from 2022 and 2023 (4 quarters) were reviewed. The worksheets for July to September and October to December of 2022 did not include documentation of the signature and date of review. 2. The TP stated that the LD would perform the "10 Observations of Employees" during the monthly visits of each three month quarter. None of the records included the dates of the actual observations and the signature of the LD. 3.

During the survey on 04/13/2023 at 1:15 PM, the TP confirmed that the OSHA QA records failed to include the dates of the actual observations and the signature of the LD showing that the LD performed the observations and when the observations were performed.