Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0219030	09/29/2021
Name of Provider or Supplier	**Street Address, City, State**	
Hillcrest Clinic Inc	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**
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the patient testing log and proficiency testing (PT) records and interview with the testing person (TP), the laboratory failed to log the PT samples with the regular patient workload. Findings: 1. The laboratory utilized a "Patient Lab Log" to record the name of each patient tested for Rhesus (Rh) factor, the test results, and the results interpretation. 2. The PT records for eight events from 2019-2021 were reviewed. 3. For each PT event, the results were recorded on a separate worksheet titled "Quality Assurance Rh Testing UNKNOWN SAMPLES FROM PROFICIENCY TESTING." 4. Review of the PT testing dates in the "Patient Lab Log" determined that the PT samples were not logged into the "Patient Lab Log" with the regular patient workload. 5. During the survey on 09/29/2021 at 2:15 PM, the TP confirmed that the Rh factor PT samples were not logged into the "Patient Lab Log" with the regular patient workload.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	Based on review of the quality control (QC) records and interview with the testing person (TP), the laboratory failed to document the results of anti-D QC testing. Findings: 1. The laboratory listed all the reagent lot numbers, expiration dates, and QC results for Rhesus factor testing on the back of each "Patient Lab Log", which is documented on a tablet and printed daily. 2. The daily logs did not include the anti-D reagent and QC testing. 3. During the survey on 09/29/2021 at 2:05 PM, the TP confirmed that the anti-D QC was performed every time the bottle was opened, but it was not being recorded on the daily logs.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records and interview with the testing person (TP), the laboratory director (LD) failed to ensure that the PT results evaluation reports for Rhesus (Rh) factor testing were reviewed to evaluate the laboratory's PT performance. Findings: 1. Records for the Rh factor PT 2019 2nd - 3rd events, 2020 1st - 3rd events, and 2021 1st - 2nd events were reviewed. 2. The PT provider's results evaluation reports from the 2019 2nd and 3rd events and the 2020 1st and 2nd events were not signed by the LD or a LD designee. 3. The PT provider's results evaluation reports from the 2020 3rd event and the 2021 2nd event were missing from the PT records. 4. During the survey on 02/29/2021 at 2:15 PM, the TP confirmed that the PT provider's results evaluation reports were either missing or not signed by the LD or a LD designee.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the procedure manual and laboratory records and interview with the testing person (TP), the laboratory director failed to implement and document quality assurance (QA) activities defined in the procedure manual. Findings: 1. Section "5. Test comparison" of the "Quality Assurance Plan for Laboratory" stated that "Every six months, laboratory personnel(s) must evaluate procedures for obtaining a sample of blood from the patient when running Rh [Rhesus] factor typing (proficiency testing samples can be used to determine results). It will be performed by

	venipuncture and lancet (finger stick). Results must be evaluated and compared to determine both methods to produce equal results." The laboratory did not have records that Rh factor test comparison of venipuncture versus lancet specimens was being performed every six months. During the survey at 2:10 PM, the TP confirmed that the test comparison of venipuncture versus lancet specimens was not performed. 2. Section "e. Laboratory Quality Assurance Committee" of the "Quality Assurance Plan for Laboratory" stated that "The QA committee will meet at least quarterly to discuss matters relating to QA" and "Minutes of each meeting will be forwarded to the Medical Director and Technical Consultant for review and approval." The procedure included a form titled "Meeting Minutes" to document the attendance and topics of discussion for each meeting. The laboratory did not have records of the quarterly QA meetings and the TP was not aware of the designated form to record the QA meeting minutes. 3. The procedure titled "Policy: Quality Control Review and Approval" stated that "On a monthly basis, the Laboratory Director/ Technical Consultant will review all quality control documentation performed by the testing personnel" and "Upon review, the Laboratory Director/ Technical Consultant will sign off and date the quality control review form designated for this purpose." The laboratory did not have records of monthly QC review and approval and the TP was not aware of a designated form to document the monthly QC review. 4. The procedure titled "Worksheet Review" stated that "On a quarterly review (every three months), the Laboratory Director/ Technical Consultant will review the daily worksheet used for documenting laboratory test results" and "Upon review, the Laboratory Director/ Technical Consultant will sign off and date the worksheet review form designated specifically for this purpose." The laboratory did not have records of quarterly review of the daily worksheets and the TP was not aware of a designated form for the quarterly worksheet review. 5. During the survey on 09/29/2021 at 2:10 PM, the TP stated that the LD reviewed the daily worksheets and the QC results, but that the reviews were not documented.