

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2159820	(X3) Date Survey Completed 04/29/2019
Name of Provider or Supplier Northern Virginia Hematology Oncology Associates	Street Address, City, State 8140 Ashton Ave Suite 210, Manassas, VA	
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
D0000	An announced CLIA initial survey was conducted at Northern Virginia Hematology Oncology Associates-Manassas on April 29, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the tour of the laboratory, manufacturer's quality control package insert (PI) and interview with testing personnel B (TP B) and lab consultant, the laboratory failed to label three (3) of three (3) hematology quality control (QC) materials with an open-vial expiration date according to the manufacturer's PI on the date of survey. Findings include: 1. A tour of the laboratory revealed that the laboratory utilizes the Boule Con-Diff Tri Level hematology QC materials. The current vials in use (lot numbers 21902-31, 21902-32 and 21902-33 exp 06/24/19) did not have an open-vial date nor a revised expiration date recorded. 2. Review of the Boule Con-Diff Tri Level PI revealed the following statement: "Storage- Open vial stability 14 days after opening when returned to refrigerator after each use." 3. In an interview at approximately 12:45 PM, the surveyor asked the TP B when the vials of hematology QC were opened and how did they track the dates of use according to the manufacturer's PI. TP B did not know when the vials were opened and did not realize QC material was only stable 14 days from the date of opening. 4. In an exit interview with TP B and the lab consultant at approximately 1:00 PM, TP B confirmed the findings.</p>

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 a review of manufacturer's User Manual, maintenance logs, and interview with Testing Personnel B (TP B), the laboratory failed to follow manufacturer's instructions for performing and documenting the performance of the Medonic M Series Hematology Analyzer's daily maintenance for two (2) of sixteen (16) days reviewed and monthly maintenance for one (1) of four (4) months reviewed from January 2019 to April 2019. Findings include: 1. Review of the laboratory's Medonic M series User's Manual and maintenance log revealed the following required maintenance procedures: Daily-Check Reagent Levels, Check Printer Paper, Background Count, Quality Control, Clean Probe(s) with alcohol; Monthly-Monthly Cleaning (Hypochlorite), Clot Prevention (Enzymatic). 2. Review of the Medonic M series maintenance logs from January 2, 2019 to the date of the survey on April 29, 2019 revealed the following days lacked documentation of daily maintenance: 2/27/19 and 3/27/19. The surveyor requested documentation of the performance of the daily maintenance for the dates listed above. The laboratory provided no documentation for review. 3. Review of the Medonic M series maintenance logs from January 2, 2019 to the date of the survey on April 29, 2019 revealed the following month lacked documentation of monthly maintenance: March 2019. The surveyor requested documentation of the performance of the monthly maintenance for March 2019. The laboratory provided no documentation for review. 4. In an exit interview with TP B and the lab consultant at approximately 1:00 PM, TP B confirmed the findings.

D5779

CORRECTIVE ACTIONS

CFR(s): 493.1282(a)

Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's policy manual, Hematology Quality Control (QC) records, patient logs, problem logs, and an interview with Testing Personnel B (TP B), the laboratory failed to follow their corrective action policy for Hematology QC that was "out of range" for eight (8) of thirty-four (34) days reviewed from January 2, 2019 to April 29, 2019. Findings include: 1. Review of the laboratory's Medonic M Series Procedure Manual revealed a QC policy which stated, "Troubleshooting out-of-range QC Results: If only one level of QC provides unacceptable results and the other two levels are acceptable, patient samples may be tested and results reported. The out-of-range control should be examined in comparison to the remaining (acceptable) controls to see if a pattern is indicated, and if so, the issued should be resolved before testing continues. If two or more controls are out-or-range, repeat the controls no more than one time each to see if the issue can be resolved. If one or both controls continue to produce out-pf-range results, refer to the "Troubleshooting" section of the Medonic M Series User's Manual and/or call

Technical Service for telephone support or onsite visit. Do not report any patient until the problem has been resolved." 2. Review of the laboratory's QC records and patient logs from January 2, 2019 until April 29, 2019 revealed the following days when the Medonic M series QC was "out-of-range": 1/21/19 CDS Boule Con-Diff Normal lot number 21811-32 - Hemoglobin (HGB) low. 39 patients reported; 2/18/19 CDS Boule Con-Diff High lot number 21811-33 - HGB low. Forty-four (44) patients reported; 3/11/19 CDS Boule Con-Diff Normal lot number 21811-32- HGB low. Forty-seven (47) patients reported; 3/13/19 CDS Boule Con-Diff Normal lot number 21811-32- HGB low. Forty-five (45) patents reported; 3/25/19 CDS Boule Con-Diff Normal lot number 21902-32- HGB low. Forty-five (45) patients reported; 4/01/19 CDS Boule Con-Diff Normal lot number 21902-32- HGB low. Fifty-two (52) patients reported; 4/15/19 CDS Boule Con-Diff High lot number 21902-33 HGB high. Forty-eight (48) patients reported; 4/17/18 CDS Boule Con-Diff Normal lot number 21902-32 Red Blood Cell (RBC) high. Eighteen (18) patients reported. A total of 8 days with "out-of-range" QC and three hundred thirty-eight (338) patients reported 3. Review of the laboratory's problem logs from January 2, 2019 until April 29, 2019 revealed no documentation of troubleshooting performed for the above listed dates when the Hematology QC was 'out-of-range". The surveyor requested to review the troubleshooting /corrective action documentation for the "out of range" QC for the dates listed above. The laboratory provided no documentation of the troubleshooting /corrective actions taken. 4. In an exit interview with TP B and the lab consultant at approximately 1:00 PM, TP B confirmed the findings.