

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2159814	(X3) Date Survey Completed 03/22/2023
Name of Provider or Supplier Northern Virginia Hematology Oncology Associates	Street Address, City, State 125 Hospital Center Drive, Suite 317, Stafford, 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	<p>An announced CLIA recertification survey was conducted at Northern Virginia Hematology-Oncology Associates, PC-Stafford on March 22, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows and includes a Condition under 42 CFR part 493 CLIA Regulation: D6063 -42 CFR. 493.1421 Condition Testing Personnel.</p>
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), hematology proficiency testing (PT) records, procedures, and an interview, the laboratory failed to rotate PT testing among all personnel performing Complete Blood Count (CBC) testing in calendar year 2022. Findings include: 1. Review of the CMS 209 laboratory personnel form revealed that the laboratory director identified four (4) testing personnel (TP) as qualified performing patient hematology CBC testing during the twenty-three month review timeframe of April 2021 to the date of the inspection, on March 22, 2023. 2. Review of the laboratory's American Proficiency Institute (API) hematology PT records for calendar year 2022 revealed that one (1) of 4 TP signed attestations as performing all CBC events (#1, #2, and #3). The inspector noted that TP A performed three (3) of 3 2022 PT modules (See Personnel Code Sheet). 3. Review of the laboratory procedures revealed a protocol (under section 7, titled: Proficiency Testing Policy and Procedures) that stated, "Each person that performs laboratory testing MUST participate in at least one testing event for all tests that they are authorized to perform</p>

each calendar year. A rotation schedule will be monitored by the Technical Consultant to ensure all personnel participate appropriately; no single individual should be designated for proficiency testing." 4. An interview with the technical consultant at approximately 1 PM on 3/22/23 confirmed the above findings.

D5413

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)**

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on a review of procedures, manufacturer's user guide/package inserts, daily temperature/environment logs, lack of documentation, and interview, the laboratory failed to monitor humidity and room/refrigerator temperatures to ensure manufacturer's operating and storage requirements were followed for the Medonic analyzer and hematology quality control (QC) materials utilized for Complete Blood Count (CBC) patient testing for nineteen (19) of fifty-four (54) days during a review timeframe of April 4, 2022 through December 31, 2022. Findings include: 1. Review of the laboratory's procedures revealed a protocol (under section 3, titled: Laboratory Environmental Monitoring) that outlined daily monitoring of environmental conditions that included laboratory room temperature/ humidity and refrigerator temperatures. The protocol stated, "The laboratory will ensure that temperature and humidity requirements for all instruments and test systems are met and do not exceed manufacturer's recommendations for optimal test performance. Storage conditions for reagents, controls, calibrators MUST be maintained within the temperature range as specified by the manufacturer. Testing personnel are responsible to record temperatures daily for room temperature and humidity, refrigerator." 2. Review of hematology manufacturer's guidelines/package inserts revealed the following requirements: Medonic analyzer user guide - "Environmental Specifications: relative humidity range is 80% maximum"; CDS Boule Con-Diff Tri-Level QC package insert - "Store 2-10 C"; CDS Boule Calibrator and Reportable Range Verification Kit package insert - "Store 2-10 C". 3. Review of 54 randomly selected temperature log dates during an eight month timeframe (4/4/22 to 12/31/22) revealed no record of laboratory room temperature/humidity or refrigerator temperature monitoring for the following 19 patient CBC testing days: 4/27, 8/19, 8/26, 9/1, 9/3, 9/8, 9/9, 9/10, 9/13, 9/15, 9/17, 9/20, 9/22, 9/24, 9/27, 12/2, 12/9, 12/14, 12/16. The inspector requested to review documentation of the environmental monitoring to manufacturer's specifications for the patient testing dates outlined above. No records were available for review. 4. An interview with the technical consultant at approximately 1 PM on 3/22/23 confirmed the above findings.

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:

A. Based on a review of manufacturer's operations manual, hematology analyzer maintenance records, lack of documentation, and an interview, the laboratory failed to document performance of required monthly instrument preventative maintenance for five (5) of twenty-three (23) months reviewed during timeframe of April 2021 to March 22, 2023. Findings include: 1. Review of the Medonic M Series Operations Manual revealed manufacturer's instructions (under heading Preventative Maintenance) to "perform monthly cleaning procedures utilizing the Boule Cleaning Kit, document on the maintenance log, save records for minimum of 2 years." 2. Review of the laboratory's available Medonic hematology maintenance logs from April 2021 to the date of the inspection on 03/22/23, revealed no documentation of the required monthly cleaning maintenance outlined above during the following months: November 2021, December 2021, January 2022, September 2022, and November 2022. The inspector requested to review documentation of the monthly cleaning maintenance for the two months in calendar year 2021 and three months in 2022 outlined above. No records were available for the 5 months requested. 3. An interview with the technical consultant at approximately 1 PM on 3/22/23 confirmed the above findings. B. Based on a review of manufacturer's operations manual, hematology analyzer maintenance records, lack of documentation, and an interview, the laboratory failed to document performance of required daily instrument maintenance on sixteen (16) days in three months selected for review (August 2022 through October 2022). Findings include: 1. Review of the Medonic M Series Operations Manual revealed manufacturer's instructions (under heading Preventative Maintenance, page 63) to "perform daily cleaning procedures according to detailed instructions found in this manual and on reverse side of the laminated Daily Start Up Sheet, document on the maintenance log, save records for minimum of 2 years." 2. Review of the laboratory's available Medonic hematology maintenance logs revealed the following maintenance tasks marked to perform daily: check reagent levels, check printer paper, verify background count, verify controls, clean probe with alcohol. The inspector selected three months to review daily maintenance in calendar year 2022 (August, September, October) and noted there was no documentation of daily maintenance recorded on the following dates: 8/19, 8/26, 9/1, 9/3, 9/6, 9/8, 9/10, 9/13, 9/15, 9/17, 9/20, 9/22, 9/24, 9/27, 9/29 and 10/26. The inspector requested to review documentation of the daily maintenance tasks for the 16 days in calendar year 2022 outlined above. No records were available. 3. An interview with the technical consultant at approximately 1 PM on 3/22/23 confirmed the above findings.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), testing personnel (TP) records, procedures, and an interview, the technical consultant (TC) failed to document performance of semi-annual competency assessments for two (2) of 2 new TP in calendar year 2022.

Findings include: 1. Review of the laboratory's CMS 209 personnel form revealed that the laboratory director (LD) identified one (1) TC and 4 TP as responsible for patient hematology Complete Blood Count (CBC) testing during the inspection timeframe of April 2021 to March 22, 2023. 2. Review of personnel records revealed that TP A and TP B were each initially trained and started performing patient CBC testing on 3/23/22. The record review also revealed no semi-annual competency assessment for TP A or B (See Personnel Code Sheet). The inspector requested to view semi-annual competency assessments for the 2 TP outlined above. No records were available. 3. Review of the laboratory's procedures revealed a policy (section 2, titled: Staff Training and Competency Testing) that stated: "Competency assessment will be performed by the technical consultant for each newly hired testing individuals after successful completion of initial training for each test/instrument/test system, at 6 months and annually thereafter." 4. An interview with the TC at approximately 1 PM on 3/22/23 confirmed the above findings.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form, testing personnel records, lack of documentation, and interview, the laboratory failed to retain documentation of education qualification for one of four testing personnel responsible for reporting moderate complexity hematology patient test results during the timeframe of April 2023 to the date of the inspection on March 22, 2023. See D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), personnel records, lack of documentation, and an interview, the laboratory failed to retain documentation of education qualifications for hematology testing personnel (TP A) from March 23, 2022 to the date of the inspection on March 22, 2023 (See Personnel Code Sheet). Findings include: 1.

Review of the CMS 209 form revealed the LD identified one (1) Technical Consultant (TC) and four (4) testing personnel as qualified/responsible to perform moderate complexity patient hematology Completed Blood Count (CBC) testing. 2. Review of the 4 laboratory personnel files for evaluation of education documentation revealed no records of education for one (1) of the 4 TP. The inspector requested to review documentation of education for TP A. No education record for TP A was available for review. The inspector noted that TP A was initially trained and started performing CBC testing on 3/23/22. 3. An interview with the TC at approximately 1 PM on 3/22 /23 confirmed the above findings.