| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br><br>49D2159814 | (X3) Date Survey Completed<br><br>01/08/2025 |
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| **Name of Provider or Supplier**<br><br>Northern Virginia Hematology Oncology Associates | **Street Address, City, State**<br><br>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 |
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| **D0000** | An announced CLIA recertification survey was conducted at Northern Virginia Hematology-Oncology Associates, PC (Stafford) on January 8, 2025 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 the Conditions under 42 CFR part 493 CLIA Regulation: D5400 -42 CFR. 493.1250 Analytic Systems. |
| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250<br><br>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on a review of the laboratory's policies and procedures, maintenance records, and lack of documentation, the laboratory failed to document performance of the required six-month cleaning procedures for the Medonic M Series Hematology analyzer (see D5429). **Repeat Deficiency** |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. |

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| | This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory's policies and procedures, Medonic M Series Hematology analyzer's maintenance instructions and log, lack of documentation, and an interview, the laboratory failed to follow their established policy to document the performance of the required monthly instrument preventative maintenance for five (5) of twenty (20) months reviewed from April 2023 until January 2025. **REPEAT DEFICIENCY** The findings include: 1. Review of the laboratory's "Medonic M Series Hematology Analyzer" procedure revealed the following statements, "Instrument maintenance is performed monthly and semi-annually according to the manufacturer's instructions, utilizing the the Boule Cleaning Kit...All maintenance should be documented (a maintenance log is recommended), and the documentation saved for a minimum of 2 years." 2. Review of the laboratory's "Medonic M-Series Hematology Analyzer" log sheets from April 2023 until January 2025 revealed a lack of documentation of the required "Monthly Maintenance" during the following months: June 2023, July 2023, October 2024, November 2024 and December 2024. The surveyor requested to review documentation of the monthly cleaning maintenance for the five months listed above. The laboratory provided no documentation to review. 3. In an exit interview with the Technical Consultant (TC) on January 8, 2025 at 11:30 AM, the findings were confirmed. |