| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 49D2159814 | 05/29/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Northern Virginia Hematology Oncology Associates | 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 initial survey was conducted at Northern Virginia Hematology Oncology Associates on May 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 deficiency is as follows: |
| **D5779** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>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 A (TP A), the laboratory failed to follow their corrective action policy for Hematology QC that was "out of range" for five (5) of fifty-seven (57) days reviewed from January 14, 2019 to May 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-of-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-of-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 14, 2019 until May 29, 2019 revealed the following days when the Medonic M series QC was "out- |

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| | of-range": 4/01/19 CDS Boule Con-Diff Low lot number 20902-31 - White Blood Cell (WBC) low. Two (2) patients reported; 4/05/19 CDS Boule Con-Diff Normal lot number 20902-32 - WBC low. Seventeen (17) patients reported; 4/12/19 CDS Boule Con-Diff High lot number 21902-33- Hemoglobin (HGB) low. Ten (10) patients reported; 4/17/19 CDS Boule Con-Diff High lot number 21902-33 HGB low. Seven (7) patients reported; 4/26/18 CDS Boule Con-Diff High lot number 21902-33 HGB low. Seventeen (17) patients reported. A total of 5 days with "out-of-range" QC and fifty-three (53) patients reported 3. Review of the laboratory's problem logs from January 14, 2019 until May 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 on the dates listed above. The laboratory provided no documentation of the troubleshooting/corrective actions taken. 4. In an exit interview with TP A at approximately 12:00 PM, TP A confirmed the findings. |