| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br><br>49D2159820 | (X3) Date Survey Completed<br><br>01/18/2023 |
|---|---|---|
| **Name of Provider or Supplier**<br><br>Northern Virginia Hematology Oncology Associates | **Street Address, City, State**<br><br>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 recertification survey was conducted at Northern Virginia Hematology Oncology Associates on January 18, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The deficiencies cited are as follows: . |
| **D5415** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(c)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on tour of the laboratory, review of the laboratory's policy and procedures, manufacturer's package insert and interview, the laboratory failed to label three of three Sysmex XN-L Check hematology quality control (QC) vials with date placed in service and expiration date as described in the policies and procedures on the date of the survey on January 18, 2023. Findings include: 1. A tour of the laboratory area on January 18, 2023 at approximately 9:00 AM revealed a cup with the Sysmex XN-L Check hematology QC materials. Three vials of the hematology QC with the lot numbers 23221401, 23221402, and 23221403 were in the small cup. The three vials lacked documentation of date placed in service and expiration date. 2. Review of the laboratory's policies and procedures revealed a policy, "Section 8-Quality Control Policy and Procedures, Part 1: Quality Control Policy and Procedure", with the following statement, "QC Material Expiration-1. The QC material used in the laboratory is stable until the expiration date printed on the packaging (box). 2. Once opened, QC material is stable for 14 calendar days. Testing personnel will write the open date (OD) and new expiration date (ED) on the vial when opened and their |

| | |
|---|---|
| | initials to indicate they are observing this recalculation of the expiration date of the opened QC Material." 3. Review of the Sysmex XN-L Check QC package insert revealed the following statement, "Storage and shelf life after first opening- open vials and vials which have been sampled by cap piercing will retain stability for 15 days if stored after recapping." 4. In an exit interview with the Technical Consultant on January 18, 2023 at approximately 11:45 AM, the above findings were confirmed. |
| **D6029** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(11)<br><br>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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, the laboratory's policies and procedures, lack of documentation and interviews, the laboratory director failed to follow the laboratory's established policy to ensure that one of one new TP had documented training and competency assessments prior to performing patient testing procedures for hematology at the date of survey on January 18, 2023. Findings include: 1. Review of CLIA CMS-209 form revealed TP A listed as performing patient testing. (See attached TP Code Sheet.) 2. Review of TP records and an interview with the Technical Consult (TC) on January 18, 2023 at approximately 9:45 AM revealed that TP A was hired and began patient testing in August 2022. The inspector requested to review training and initial competency assessment documents for TP A. The laboratory provided no documentation for review. 3. Review of the laboratory's policies and procedures revealed a policy, "Section 2-Staff Training & Competency Testing", which the following statement, "e. New testing personnel are required to be signed off as completed all instrument training by qualified lab trainer/technical consultant, and complete initial competency assessments by the lab technical consultant, prior to testing patient samples. Documentation of completion of all competency assessment evaluations will be retained in the Lab Personnel Binder." 4. In an exit interview with the Technical Consultant on January 18, 2023 at approximately 11:45 AM, the above findings were confirmed. |