

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2108687	(X3) Date Survey Completed 02/08/2022
Name of Provider or Supplier Hematology Oncology Care Of Northern Virginia, Pc	Street Address, City, State 1900 Opitz Boulevard Suites E & F, Woodbridge, 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 Hematology Oncology Care of Northern Virginia, PC on February 8, 2022 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:
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on a review of analyzer performance verification documentation, manufacturer's "DxH 520 Performance Verification Workbook" and interviews, the laboratory director (LD) failed to evaluate and verify the normal values (reference ranges) for Complete Blood Count (CBC) testing of a newly installed hematology analyzer from the installation date of September 28, 2021 to the date of the survey, February 8, 2022 while testing four hundred nineteen (419) patient specimens. Findings include: 1. During a tour of the laboratory on February 8, 2022 at approximately 9:15 AM, the inspector noted a Beckman Coulter DxH 520 Hematology Analyzer (Serial Number BE030119) installed by a Beckman Coulter Representative with an installation date of September 28, 2021. The Technical consultant stated the instrument was installed in September 2021 but the laboratory did not begin using the instrument until November 2021. 2. A review of the</p>

laboratory's analyzer performance verification documentation for the new Beckman Coulter DxH 520 Hematology Analyzer (Serial Number BE030119 installed on September 28, 2021) revealed no documentation of the verification of the new instrument's patient normal value ranges prior to patient testing. The surveyor requested to review the verification of the new instruments's patient normal value ranges. The laboratory provided no documentation of the normal range verification to review. 3. Review of the "DxH 520 Performance Verification Workbook" revealed the instructions "The laboratory director and/or the Medical Laboratory consultant need to validate the normal range studies." 4. Review of patient CBC test reports revealed 419 patient specimens were tested on the DxH 520 analyzer from November 12, 2021 until February 8, 2022. 5. In an interview with the Technical Consultant on February 8, 2022 at approximately 11:45 AM, the above findings were confirmed.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of patient test reports, and interviews, the laboratory failed to ensure the test report accurately indicated the laboratory name and address where testing was performed for four hundred nineteen (419) patient reports reviewed from November 12, 2021 until the date of the survey on February 8, 2022. Findings include: 1. During a tour of the laboratory on February 8, 2022 at approximately 9:15 AM, the inspector noted a Beckman Coulter DxH 520 Hematology Analyzer (Serial Number BE030119) installed by a Beckman Coulter Representative with an installation date of September 28, 2021. The Technical consultant stated the instrument was installed in September 2021 but the laboratory did not begin using the instrument for patient Complete Blood Count (CBC) testing until November 2021. 2. Review of patient test reports revealed from November 12, 2021 until the date of the survey on February 8, 2022, patient test reports did not contain the name and address of the laboratory where the testing was performed. 3. Review of patient CBC test reports revealed 419 patient specimens were tested on the DxH 520 analyzer from November 12, 2021 until February 8, 2022. 4. In an interview with the Technical Consultant on February 8, 2022 at approximately 11:45 AM, the above findings were confirmed.