Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2097970	08/11/2025
Name of Provider or Supplier	**Street Address, City, State**	
Hematology Oncology Care Of Northern Virginia	3022 Williams Drive - Suite 100, Fairfax, 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 on August 11, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, Hematology Quality Control (QC) records, lack of documentation and an interview, the laboratory failed to follow their established quality control policy and document corrective actions taken for "out of range" Hematology QC for twenty-two (22) of forty-six (46) testing days from April 1, 2025 until August 4, 2025. The findings include: 1. Review of the laboratory's policies and procedures revealed a policy, "Section 8-Quality Control and Calibration Policy and Procedures", with the following statements, "GENERAL GUIDELINES: 5. Remedial action (s) for all out-of-range QC values will be documented prior to testing patient samples or reporting patient results." and "Evaluation of QC Data- d. Corrective Actions: Document all problems identified on Action Log sheets for all problems identified in quality control testing." 2. Review of

	the laboratory's QC records for the Beckman Coulter DxH 520 Hematology Analyzer from April 1, 2025 until August 4, 2025 revealed the following days from April 2025 to August 2025 when the DxH 500 series Quality Control (lot numbers 3625171 exp 06/05/2025 and 3625173 exp 08/05/2025) was out of range with a lack of documentation of corrective actions performed: Lot number 3625171 exp 06/05/2025 04/09/2025 Abnormal (Abn) High (H) and Normal (N) QC Platelet (PLT)=low. 04/10 /2025 Abn H and N QC-PLT=low. 04/16/2025 Abn H QC-Red Blood Cell count (RBC)=high, Hematocrit (HCT)=high, PLT=low 04/23/2025 Abn H RBC-high, HCT=high, PLT=low. N QC HCT=high. 05/05/2025 N QC PLT=low, Neutrophil number (Neut #)=high. 05/08/2025 Abn H QC PLT=low. 05/12/2025 Abn H QC PLT=low. 05/14/2025 N QC PLT=low. 05/15/2025 N QC PLT=low. 05/19/2025 Abn H QC PLT=low. N QC PLT=low. 05/21/2025 N QC PLT=low. 05/22/2025 Abn H QC PLT=low. N QC PLT=low and Neut #=high. 05/28/2025 Abn H QC PLT=low. N QC PLT=low and Neut #=high. 05/29/2025 Abn H QC PLT=low. N QC PLT=low and Neut #=high. 06/04/2025 Abn H QC PLT=low. N QC PLT=low and Neut #=high. Lot number 3625173 exp 08/05/2025 06/11/2025 Abn H QC PLT=low. 06/18/2025 Abn H QC PLT=low. N QC PLT=low. 06/27/2025 Abn H QC PLT=low. 07/02/2025 Abn Low (L) QC Mean Platelet Volume (MPV)-low. 07/14/2025 Abn H QC PLT=low. 07/21/2025 Abn H QC PLT=low. 08/04/2025 Abn Low (L) QC Mean Platelet Volume (MPV)-low. Twenty two (22) of 46 days without corrective actions documented. The surveyor requested to review documentation of the QC corrective actions taken for the above listed out of range QC. The laboratory provided no documentation for review. 3. In an exit interview with the Technical Consultant and testing personnel on August 11, 2025, at 12:45 PM, the above findings were confirmed.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratorys established performance specifications; This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedures, Hematology quality control (QC) records, lack of documentation, policies, and interview, the technical consultant (TC) failed to ensure the policy for the documentation of corrections actions was followed. Cross Reference D5781.