Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2097970	02/09/2022
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 initial survey was conducted at Hematology Oncology Care of Northern Virginia, PC on February 9, 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:
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, Beckman Coulter DxH 520 instrument worklists, lack of documentation, and interviews, the laboratory failed to establish and follow a policy to ensure positive identification and integrity of patient Complete Blood Count (CBC) specimens analyzed on Beckman Coulter DxH 520 Hematology Analyzer from September 16, 2021 until the date of the survey, February 9, 2022, while analyzing one-thousand three-hundred and thirty-eight patient (1338) specimens. Findings include: 1. Review of the Beckman Coulter DxH 520 instrument worklists from September 16, 2021 to February 9, 2022 revealed a lack of a second identifier listed for 1338 patient CBCs analyzed on the DxH 520. For 1338 patients, the only patient identifier listed in the instrument worklists was the patient's last name. In an interview with Testing Personnel A at approximately 11:15 AM on February 9, 2022, the surveyor asked Testing Personnel A (TP A) to describe the process once the CBC specimen is received in the laboratory. TP A stated, "We mix the sample and enter the patient's last name from the label in the instrument as the "Specimen ID" and test the specimen." 2. Review of the laboratory's policy and procedure manual revealed a lack of a policy to ensure the positive identification and

	integrity of patient CBC specimens from time of collection to completion of analysis on the DxH 520 Hematology Analyzer. 3. In an interview with the Technical Consultant and Laboratory Director at approximately 11:30 AM on February 9, 2022, the above findings were confirmed.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of procedures, and interviews, the laboratory failed to follow their policy for specimen labeling for six (6) of 6 collected Complete Blood Count (CBC) patient specimens observed in the laboratory on February 9, 2022 at approximately 11:00 AM. Findings include: 1. At approximately 11:00 AM on February 9, 2022, the surveyor observed 6 patient CBC specimens in a specimen rack, each labeled with the patient's first and last name and date of birth. 2. Review of the laboratory procedure manual revealed a policy, "Order Entry/Requisition/Collection Process" which stated, "b. Specimens will be collected by medical assistants, nurses, or physicians in the exam room or in the infusion room and MUST be received labeled with 2 identifiers, to include date/time of collection and initials of collector. c. Under NO circumstances will the laboratory accept unlabeled specimens. d. Once received in the lab for testing, a printed label will be affixed to the specimen tube." 3. In an interview with Testing Personnel A at approximately 11:15 AM on February 9, 2022, TP A stated, "We label our specimens with the patient's first and last name and date of birth. Our label printer has been broken and we have not had it fixed yet." 4. In an exit interview with the Technical Consultant and Laboratory Director at approximately 11:30 AM on February 9, 2022, the above findings were confirmed.