Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D2178404	03/08/2022
Name of Provider or Supplier	**Street Address, City, State**	
American Health Network - New Albany Oncology	4101 Technology Ave 2nd Floor, New Albany, IN	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to include calibration procedures in their procedure manual for one of one Hematology analyzer (Beckman Coulter DxH 520) in use. Findings include: 1) Review of the "CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION," CMS-116 on page 4, the laboratory indicated it was performing patient testing on the Beckman Coulter DxH 520 for complete blood counts (CBC) which includes; WBC (white blood count), RBC (red blood count), Hgb (Hemoglobin), Plt (platelet), and Hct (Hematocrit). 2) On 3/8/22 at 9:35 am, a

	Beckman Coulter Hematology Analyzer, model=DxH 520, was observed in use on the counter top in the laboratory. 3) Review of the operator's manual for the Beckman Coulter DxH520 read on page 11-1, "When to Verify Calibration * As dictated by your laboratory procedures and local or national guidelines." 4) Review of the laboratory's policies and procedures indicated there was no calibration procedure. 5) Medical record review indicated the following patients had hematology testing performed on the Beckman Coulter, DxH 520, without a calibration procedure: Patient # Date Result PT#1 2/22/22 WBC=8.56x10^3/uL PT#2 1/4/22 RBC=4. 75x10^6/uL PT#3 12/27/21 Hgb=15.27 g/dL PT#4 11/11/21 Plt=212.9x10^3/uL PT#5 10/4/21 Hct=41.7% PT#6 9/30/21 WBC=10.64x10^3/uL PT=patient WBC=White Blood Cell Count RBC=Red Blood Cell Count Hgb=Hemoglobin Plt=Platelet Hct=Hematocrit uL=Microliter g/dL=Grams per Deciliter 6) In interview on 3/8/22 at 12:30 pm, SP-1 (laboratory manger) confirmed the laboratory did not have a policy/procedure for performing calibrations on the Beckman Coulter, DxH 520. 7) Total annual CBC (complete blood count) testing volume is approximately, 4,500.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, document review, and interview, the laboratory failed to monitor and document humidity levels for six of six months reviewed (September, October, November, and December of 2021 and also, January and February of 2022). Findings include: 1) Review of the "CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION," CMS-116 on page 4, the laboratory indicated it was performing patient testing on the Beckman Coulter DxH520 for complete blood counts (CBC). 2) On 3/8/22 at 9:35 am, a Beckman Coulter Hematology Analyzer, model=DxH 520, was observed in use on the counter top in the laboratory. 3) Review of the operator's manual for the Beckman Coulter DxH 520 reads on page 1-7, "Humidity The instrument meets performance claims when operated at a maximum of 80% relative humidity (non-condensing) at 32 degrees C (89.6 degrees F)." C=Celcius and F=Fahrenheit. 4) Review of temperature and humidity logs for September, October, November, and December of 2021 and also, January and February of 2022, indicated no humidity readings were documented. 5) Review of American Health Network "IN-HOUSE TEST MENU (no effective date listed) 1) Hematology CBC INR," reads on page 14, "B. Humidity Some test systems are adversely affected by humidity. 1. Establish acceptable humidity ranges following the same procedure as above. 2. Document humidity daily, using a hygrometer..." 6) Medical record review indicated the following patients had hematology testing performed on the Beckman Coulter, DxH 520, without humidity levels being monitored nor documented: Patient # Date Result PT#1 2/22/22 WBC=8.56x10^3/uL PT#2 1/4/22 RBC=4.75x10^6/uL PT#3 12/27/21 Hgb=15.27 g/dL PT#4 11/11/21 Plt=212.9x10^3/uL PT#5 10/4/21 Hct=41.7% PT#6 9/30/21 WBC=10.64x10^3/uL

	PT=patient WBC=White Blood Cell Count RBC=Red Blood Cell Count Hgb=Hemoglobin Plt=Platelet Hct=Hematocrit uL=Microliter g/dL=Grams per Deciliter 7) In interview on 3/8/22 at 9:35 am, SP-1 (laboratory manager) confirmed the laboratory staff were not documenting humidity levels as required by their policy and manufacturer's instructions. 8) Total annual CBC (complete blood count) testing volume is approximately, 4,500.