Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2032845	11/04/2020
Name of Provider or Supplier	**Street Address, City, State**	
Birmingham Hematology Oncology	2728 10th Avenue South, Suite 330, Birmingham, AL	

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
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 a review of the environmental logs and an interview with the Technical consultant, the surveyor determined the laboratory failed to ensure room temperatures were within acceptable ranges for reliable test system operation. This was noted on 130 days on the 2019-2020 temperature logs reviewed by the surveyor. The findings include: 1. A review of the 2019-2020 environmental logs revealed acceptable ranges of 20 - 25 degrees Celsius (C) for room temperature where Folate testing was performed. However, the surveyor noted 130 days when the room temperature was documented as less than 20 degrees C. 2. During an interview conducted on 11/04 /2020 at 3:20 PM, the Technical Consultant reviewed the above noted findings, confirmed the laboratory performed Folate testing on these days and the room temperature should be between 20 - 25 degrees Celsius. .
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the

	manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of the Hematology calibration records, a review of the Beckman Coulter DxH 600 Operator's Manual, and an interview with the General Supervisor, the laboratory failed to follow the manufacturer's instructions to perform quality controls after calibration, and before running patient samples. This was noted on one of four 2019-2020 calibrations reviewed. The findings include: 1. A review of Hematology records revealed the Beckman Coulter DxH 600 was calibrated on 01/03/2019 at 6:59 AM, however three levels of quality control were not performed until 1:35 PM. 2. A review of the Beckman Coulter DxH 600 Operator's Manual revealed, "Chapter 11 Quality Assurance Calibration" "... 12 Verify your calibration with controls. ..." 3. During an interview on 11/04/2020 at 12:45 PM, the General Supervisor confirmed the above noted findings, stating 76 patient CBC's (Complete Blood Counts) were performed on 01/03/2019 after the calibration was run and before the quality controls were performed at 01:35 PM. .
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records and an interview with the Technical Consultant, the laboratory failed to ensure two levels of QC for Cancer Antigen 27.29 were within acceptable ranges before patient testing. This was noted on one day in the 2020 records. The findings include: 1. A review of the TOSOH QC records revealed on 08/03/2020 Level 1 QC for Cancer Antigen 27.29 was outside the acceptable range. Testing personnel repeated Level 1, however the QC was still out of range. 2. During an interview on 11/04/2020 at 3:15 PM, the Technical Consultant confirmed that quality control was not acceptable for 08/03/2020 and 29 patient's samples were performed that day. SURVEYOR ID #32558 Licensure and Certification Surveyor