Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0320482	06/22/2018
Name of Provider or Supplier	**Street Address, City, State**	
Norton Children's Medical Group - Prospect	9217 Us Highway 42, Prospect, KY	

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 staff interview and record review on 06/22/18, it was determined the facility failed to monitor and document the percent humidity for the laboratory where the testing was performed. Percent humidity was not recorded from May 3, 2016 through June 21, 2018. Findings include: Review of the Manufacturer's Operation Manual for the ACT-diff Hematology Analyzer, revealed the operating range for percent humidity should be between twenty percent (20%) and eighty-five percent (85%). Review of the Maintenance Log, revealed there was no documented evidence the percent humidity had been monitored from May 3, 2016 through June 21, 2018. Testing personnel acknowledged in an interview, on 06/22/18 at 10:30 AM, the laboratory failed to have a system in place to ensure the percent humidity was monitored and documented daily.
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 staff interview, and review of the Procedure Manual for the ACT-Diff Hematology Analyzer on 06/22/18, it was determined that the laboratory failed to perform and document calibration procedures in accordance with manufacturer's instructions. Findings include: Review of the Procedure Manual for the ACT-Diff Hematology Analyzer, revealed calibration verification should be performed at least every six (6) months. However, there was no documented evidence the laboratory performed calibration verification between July 16, 2016, through May 8, 2018. Testing personnel acknowledged in an interview on 6/22/18 at 10:28 AM, the laboratory failed to have a system in place to ensure calibration of the ACT-Diff Hematology analyzer be performed and documented in accordance with manufacturer's requirements.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on staff interview and record review on 06/22/18, it was determined the laboratory failed to ensure normal values were available to the authorized person for six (6) of six (6) patient test reports. Findings include: A Complete Blood Count (CBC) was reported on Patient #1 on 03/16/16; however, the report failed to include reference ranges for each analyte. A CBC was reported on Patient #2 on 04/19/16; however, the report failed to include reference ranges for each analyte. A CBC was reported on Patient #3 on 05/16/16; however, the report failed to include reference ranges for each analyte. A CBC was reported on Patient #4 on 10/10/17; however, the report failed to include reference ranges for each analyte. A CBC was reported on Patient #5 on 11/14/17; however, the report failed to include reference ranges for each analyte. A CBC was reported on Patient #6 on 01/17/18; however, the report failed to include reference ranges for each analyte. Testing personnel acknowledged in an interview on 06/22/18 at 11:15 AM, the laboratory failed to have a system in place to ensure normal values were available and reported on patient test reports.