Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0321467	08/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
Norton Children's Medical Group-Windy	4884 Brownsboro Rd, Louisville, 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
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on staff interview and record review of proficiency testing results from American Academy of Family Practice (AAFP) on 8/17/2021, the laboratory director failed to ensure proficiency test results were reviewed for one (1) out of one (1) event for 2019, and one (1) out of three (3) events for 2020. Findings include: 1. The laboratory scored a ninety-seven percent (97%) for AAFP Event C 2019 for Hematology. Record review revealed that the laboratory failed to document any corrective action for that event. 2. The laboratory scored a ninety-six percent (96%) for AAFP Event A 2020 for Hematology. Record review revealed that the laboratory failed to document any corrective action for that event. 3. The testing staff acknowledged in an interview at 1515 hrs. on 8/17/2021, that the laboratory director failed to establish a system to ensure proficiency testing results were evaluated.
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 8/17/2021, the laboratory failed to monitor and document the humidity and temperature in the laboratory from 12/4/2019 through 11/4/2020. Findings include: 1. Temperatures were not recorded for 12/4 through 12/5/2019. 2. Temperature was not recorded for 10/8/2020. 3. Temperature was not recorded for 11/4/2020. 4. Humidity readings were not recorded for 1/6/2020 through 1/7/2020. 5. Laboratory staff acknowledged in an interview at 1500 hrs. on 8 /17/2021, the laboratory failed to have a system in place to ensure the temperature and humidity was monitored and documented daily, using the manufacturer's recommended range.