Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0672570	(X3) Date Survey Completed 02/10/2020
Name of Provider or Supplier Norton Children's Medical Group-Iroquois	**Street Address, City, State** 5109 New Cut 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
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 February 10, 2020, the laboratory failed to document corrective action for temperatures that were out of range in the laboratory refrigerator from February 3, 2019 through November 29, 2019. Findings include: 1. The stated range for the laboratory's refrigerator was listed as two (2) to eight (8) degrees Celsius. 2. Review of temperature log revealed there were seventeen (17) days the temperature was out of the acceptable range with no corrective action documented from February 1, 2019 through November 29, 2019. 3. Testing personnel acknowledged in an interview at 9:14 AM on February 10, 2020, the laboratory failed to have a system in place to ensure the corrective action was taken when the temperature was out of the acceptable range.