

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0954692	(X3) Date Survey Completed 06/06/2018
Name of Provider or Supplier Norton Children's Medical Group-Stonestreet	Street Address, City, State 9702 Stonestreet, Suite 100, 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	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and record review on 06/06/2018, the laboratory failed to monitor and document the humidity of the laboratory where the testing was performed. Humidity was not recorded from June 9, 2016 through June 5, 2018. Findings include: The Manufacturer's operations manual for the Sysmex CBC analyzer lists an operating range for humidity for the analyzer between thirty percent (30%) and eighty-five percent (85%). Review of Maintenance log revealed no documented evidence the humidity had been monitored from June 9, 2016 through June 5, 2018. Testing personnel acknowledged in an interview at 10:30 am on 06/06/2018 the laboratory failed to have a system in place to ensure the humidity was monitored and documented daily.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p>

This STANDARD is not met as evidenced by:

Based on staff interview and record review on 06/06/2018, the Technical Consultant failed to perform and document annual competency using the 6 mandated competency assessment requirements for testing personnel. Competency assessment was performed using zero (0) of six (6) methods of assessment for two (2) out of seven (7) employees from January 1, 2017 to December 31, 2017. Findings include: Record review revealed competency assessments failed to include direct observation of routine patient test performance, direct observation of performance of instrument maintenance function checks and calibration, monitoring the recording and reporting of test results, review of worksheets, review of quality control records, review of proficiency test results, review of maintenance records, assessment of testing external proficiency testing samples and problem solving skills. An interview with the staff on 06/06/2018 at 9:10 AM, revealed the facility failed to have a system in place to ensure competency was performed using all six mandated competency assessment requirements.