Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0953131	(X3) Date Survey Completed 02/01/2019
Name of Provider or Supplier Campus Health Services Of Louisville	**Street Address, City, State** 401 East Chestnut Street, Suite 110, 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 1, 2019, the laboratory failed to monitor and document the Humidity in the laboratory where testing was performed. There was no documented evidence Humidity was recorded from January 5, 2017 through January 31, 2019. Findings include: 1. Review of the Manufacturer's Operations Manual for the Sysmex analyzer, revealed the operating range for Humidity for the analyzer should be between thirty percent (30%) and eighty-five percent (85%). 2. Review of the Maintenance Log, revealed no documented evidence the Humidity had been monitored and recorded from January 5, 2017 through January 31,2019. 3. Testing personnel acknowledged in an interview on February 1, 2019 at 10:36 AM, the Laboratory Director failed to have a system in place to ensure the laboratory Humidity was monitored and documented daily.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (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.

	This STANDARD is not met as evidenced by: Based on staff interview and record review on February 1, 2019, the Technical Consultant failed to perform and document annual competency using the six (6) mandated competency assessment requirements for testing personal. Competency assessment was performed using one (1) of six (6) methods of assessment for three (3) out of three (3) employees from January 5, 2017 through January 31, 2019. Findings include: 1. Record review on February 5, 2019, revealed there was no documented competency assessments between January 5, 2017 and January 31, 2019, for three (3) employees that included the following: 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. 2. Interview with staff on February 1, 2019 at 10: 36 AM, revealed the facility failed to have a system in place between January 5, 2017 and January 31, 2019 to ensure competency was performed using all six (6) mandated competency assessment requirements.