

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  18D0320597	<b>(X3) Date Survey Completed</b>  10/28/2019
<b>Name of Provider or Supplier</b>  Bullitt County Family Practioners	<b>Street Address, City, State</b>  170 Dr Aria Way Suite 104, Louisville, KY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5413</b>	<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 October 28, 2019, the laboratory failed to monitor and document the humidity in the laboratory using the correct reference range where the testing was performed from January 11, 2018 through October 27, 2019. Findings include: 1. The Manufacturer's operations manual for the Act Diff analyzer lists an operating range for humidity for the analyzer between twenty percent (20%) to eighty percent (80 %). 2. Review of Maintenance log revealed the humidity was not monitored and document from January 11, 2018 through October 27, 2019. 3. Testing personnel acknowledged in an interview at 3:20 PM on October 28, 2019, the laboratory failed to have a system in place to ensure the humidity was monitored and documented daily, using the manufacturer's recommended range.</p>
<b>D6046</b>	<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 October 28, 2019, the Technical Consultant failed to perform and document annual competency using the 6 mandated competency assessment requirements for testing personal. Competency assessment was not performed using six (6) methods of assessment for two (2) out of two (2) employees from January 19, 2018 through October 27, 2019 This is a repeat deficiency from January 10, 2018. Findings include: 1. Record review on October 28, 2019 revealed there was no documented competency assessments between January 19, 2019 and October 27, 2019, for two (2) employee that included the following: 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 October 28, 2019 at 03:20 PM revealed the facility failed to have a system in place between January 19, 2018 and October 27, 2019 to ensure competency was performed using all six (6) mandated competency assessment requirements.