

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  18D0689147	<b>(X3) Date Survey Completed</b>  09/19/2018
<b>Name of Provider or Supplier</b>  Family Care Associates, Psc	<b>Street Address, City, State</b>  1102 W Shelby St, Falmouth, 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 09/19/2018, the laboratory failed to monitor and document the humidity of the laboratory where the testing was performed. Humidity was not recorded from October 5, 2016 through September 18, 2018. Findings include: The Manufacturer's operations manual for the ACT Diff CBC analyzer lists an operating range for humidity for the analyzer between twenty percent (20%) and eighty-five percent (85%). Review of Maintenance log revealed no documented evidence the humidity had been monitored from October 5, 2016 through September 18, 2018. Testing personnel acknowledged in an interview at 11:47 AM on 09/19/2018, the laboratory failed to have a system in place to ensure the humidity was monitored and documented daily.</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, 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 one (1) of six (6) methods of assessment for six (6) out of six (6) employees from October 5, 2016 through September 18, 2018. Findings include: Record review on 09/19/2018 revealed there was no documented competency assessments between October 5, 2016 and September 18, 2018, for six (6) employees 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 09/19/2018 at 11:47 AM revealed the facility failed to have a system in place between October 5, 2016 and September 18, 2018 to ensure competency was performed using all six (6) mandated competency assessment requirements from October 5, 2016 and September 18, 2018.