

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0324266	(X3) Date Survey Completed 09/21/2018
Name of Provider or Supplier Family Care Associates Psc	Street Address, City, State 1210 Ky Hwy 36e, Suite 2c, Cynthiana, 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 09/21/2018, the laboratory failed to monitor and document the humidity of the laboratory where the testing was performed. Humidity was not recorded from September 14, 2016 through September 20, 2018 Findings include: The Manufacturer's operations manual for the Medonic CBC analyzer lists an operating range for humidity for the analyzer between zero percent (0%) and less than eighty percent (80%). Review of Maintenance log revealed no documented evidence the humidity had been monitored from September 14, 2016 through September 20, 2018. Testing personnel acknowledged in an interview at 09:49 AM on 09/21/2018, 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, 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 nine (9) out of nine (9) employees from September 14, 2016 through September 20, 2018. Findings include: Record review on 09/21/2018 revealed there was no documented competency assessments between September 14, 2016 and September 20, 2018, for nine (9) 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 09/21/2018 at 10:55AM revealed the facility failed to have a system in place between September 14, 2016 and September 20, 2018 to ensure competency was performed using all six (6) mandated competency assessment requirements from September 14, 2016 and September 20, 2018.