

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D1012009	(X3) Date Survey Completed 04/12/2019
Name of Provider or Supplier Lewis Family Care	Street Address, City, State 6628 Us 60, Ashland, 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 April 12, 2019, the laboratory failed to monitor and document the humidity in the laboratory where the testing was performed. Humidity was not recorded from April 5, 2017 through April 11, 2019. Findings include: The Manufacturer's Operations Manual for the Medonic Analyzer lists an operating range for humidity for the analyzer between zero percent (0%) and eighty percent (80%). The Manufacturer's Operations Manual for the Access 2 analyzer and the Alpha Wasserman lists an operating range for humidity for the analyzer between twenty percent (20%) and eighty percent (80%). Review of the Laboratory Temperature Log, revealed no documented evidence the humidity had been monitored and recorded from April 5, 2017 through April 11, 2019. Testing Personnel acknowledged in an interview on 04/12/19 at 9:10 AM, the Laboratory Director 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</p>

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 April 12, 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 not performed using six (6) methods of assessment for one (1) out of one (1) employee reviewed from May 1, 2018 through April 11, 2019. Findings include: Record review on April 12, 2019 revealed there was no documented Competency Assessments between May 1, 2018 and April 11, 2019, for one (1) employee 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. Interview with staff on 04/12/19 at 8:55 AM, revealed the facility failed to have a system in place between May 1, 2018 and April 11, 2019 to ensure competency was performed using all six (6) mandated competency assessment requirements.