

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0929179	(X3) Date Survey Completed 09/27/2018
Name of Provider or Supplier Mountain After Hours Clinic	Street Address, City, State 1908 North Main St Ste 120, Hazard, 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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and record review, the Technical Consultant failed to perform Quality Assurance from September 17, 2016 through September 26, 2018. Findings include: Record Review on 09/27/18, revealed no documented evidence Quality Assurance was performed from September 17, 2016 through September 26, 2018. The staff acknowledged in an interview on 09/27/18 at 3:42 PM, they did not have a system in place to document Quality Assurance on a quarterly basis.</p>
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, the laboratory failed to monitor and</p>

document the humidity of the laboratory where the testing was performed. Humidity was not recorded from September 17, 2016 through September 26, 2018. Findings include: The Manufacturer's Operations Manual for the Cell-Dyn Analyzer lists an operating range for humidity for the Analyzer between zero percent (0%) and eighty percent (80%). Review of the Maintenance Log, on 09/27/18, revealed no documented evidence the humidity had been monitored from September 17, 2016 through September 26, 2018. Testing personnel acknowledged in an interview on 09/27/18 at 2:30 PM, the laboratory failed to have a system in place to ensure the 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, 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 two (2) out of two (2) employees from September 17, 2016 through September 26, 2018. Findings include: Record review on 09/27/18, revealed there was no documented evidence of competency assessments between September 17, 2016 and September 26, 2018, for two (2) 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. An interview with the staff on 09/27/18 at 2:42 PM, revealed the facility failed to have a system in place between September 17, 2016 and September 26, 2018 to ensure competency was performed using all six (6) mandated competency assessment requirements.