

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0382665	(X3) Date Survey Completed 01/31/2018
Name of Provider or Supplier Mercyone Carlisle Family Medicine Clinic	Street Address, City, State 2755 South Gateway Drive, Carlisle, IA	
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 review of the Clinical Laboratory Improvement Amendments (CLIA) application (Form CMS-116), room temperature and humidity records, and confirmed by laboratory personnel identifier #4 at approximately 10:30 am on 01/31/2018, the laboratory failed to document the laboratory room temperature and humidity for seven out of 23 days of patient testing in August 2017. The findings include: 1. The CLIA application (Form CMS-116) states the hours of laboratory testing are 7:00 am- 5:00 pm, Monday through Friday. 2. The Installation Procedures and Special Requirements section of the Abbott Cell Dyn Emerald hematology instrument Operator's Manual states that the following are environmental requirements: *Temperature range: 64- 90 degrees Fahrenheit (18-32 degrees Celsius) *Maximum relative humidity 80% for temperatures up to 80 degrees Fahrenheit (31 degrees Celsius) 3. Review of the laboratory's temperature log revealed that the laboratory failed to document the room temperature and humidity on the following dates: 08/07/2018, 08/14/2018, 08/15 /2018, 08/16/2018, 08/17/2018, 08/18/2018, and 08/21/2018.</p>