

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0992550	(X3) Date Survey Completed 08/21/2018
Name of Provider or Supplier Mercy Clinic Family Medicine - Lowell	Street Address, City, State 325 South 6th Place, Lowell, AR	
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: Through a review of the Sysmex XP-300 manufacturer's instructions, a review of the laboratory's temperature and humidity log, a review of a manufacturer's letter to the laboratory, and interviews with laboratory staff, it was determined the laboratory's criteria for acceptable humidity in the laboratory failed to be consistent with the manufacturer's instructions. Survey findings follow: A. The manufacturer's instructions for the Sysmex XP-300 hematology analyzer includes operating conditions. The acceptable humidity listed within the operating conditions is 30% to 85%. B. The laboratory temperature and humidity log used to document daily laboratory conditions lists the acceptable humidity range as 20% to 80%. C. In an interview, at 1:37 p.m. on 8/21/2018, the technical consultant (listed as #7 on the form CMS-209) confirmed the discrepancy in acceptable humidity. At that time a letter from the manufacturer was presented to the surveyor. The letter included information about studies of high and low humidity and it's affect on the analyzer but the letter also stated that the final decision to operate the analyzer outside of established ranges stated in the Operator's manual would have to be made by the end user which confirms that any operation of the instrument outside of the 30% to 85% range is outside of the established range..</p>

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Through a review of personnel records, and interviews with the technical consultant, it was determined that one of four testing personnel failed to have competency evaluated semiannually during the first year of patient testing. Survey findings follow: A. A review of personnel records for employee #5 (as listed on the form CMS-209) revealed that she was trained in January 2017 and only had one documented competency since her date of hire. B. In an interview at 12:50 on 8/21/2018, the technical consultant (listed as employee #7 on the form CMS-209) confirmed the failure to perform competency evaluations semiannually during the first year that employee #5 performed patient testing.