

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0445722	(X3) Date Survey Completed 07/03/2018
Name of Provider or Supplier Mercy	Street Address, City, State 3125 Dr Russell Smith Way, Carthage, MO	
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:</p>
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on review of blood bank procedures, blood bank alarm checks and interview with technical supervisor #2 the laboratory failed to follow procedure and perform blood bank alarm checks quarterly in 2017. Findings: 1. Review of blood bank</p>

procedure states "The proper function of the alarm system should be validated quarterly", 2 Review of "quarterly blood bank refrigerator/freezer alarm" worksheet shows an alarm check was not completed in two of four quarters in 2017. 3. Interview with the technical supervisor on July 3, 2018 at 11:30 confirmed the laboratory failed to follow procedure and perform blood bank alarm checks quarterly in 2017.