

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0449946	(X3) Date Survey Completed 08/20/2018
Name of Provider or Supplier Community Memorial Healthcare	Street Address, City, State 708 N 18th Street, Marysville, KS	
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: A review of temperature and humidity logs and interview with staff revealed the laboratory failed to establish a range for the humidity room temperature for the laboratory as the Ruby the hematology analyzer requires and Dimension the Chemistry analyzer failed . The laboratory failed to monitor the freezer temperature range according to manufacture guidelines for the Biorad controls. Findings were as follows: a. Based upon review of manufacture's guide for the Ruby (Hematology analyzers) the laboratory failed to establish the humidity less than 80% and room temperature of 15-30 degrees Celsius. The laboratory failed to define the acceptable humidity range according to the manufacture's range . b. Based upon review of manufacture's guide for the Dimension (chemistry analyzer) for the humidity range 20-80% room temperature 15-30 degrees Celsius the laboratory failed to define the acceptable ranges. c. Based upon review of freezer temperature Biorad manufacture guidelines require that the Biorad controls are stored >-20 degrees Celsius. The laboratory failed to store the Biorad controls within manufacture guidelines. d. This was confirmed by the Technical Consultant on 02/28/018 at 10::00 hrs</p>
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p>

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

A review of the Quality Control (QC) procedure and interview with staff revealed the laboratory failed to produce a policy concerning a failed QC concerning patient results Finding were as follows a. Interview with Technical Consultant from the CMS 209 08 /20/2018 at 10::30 hrs. confirmed the laboratory failed to have the policy, (All patients test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected).

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) 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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

A review of Quality Assessment and Interview with staff revealed the laboratory failed to have a plan that covered all aspects of the laboratory. Finding were as follows: 1. Based upon the Quality Assessment Action plan the laboratory failed to establish a action plan for any manual calculation for any analyte that is reported . Therefore, the accuracy or reliability of the analyte cannot be verified. This was confirmed in interview with Technical Consultant on 08/20/2018 at 10;30 hrs.