

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0047295	(X3) Date Survey Completed 04/04/2018
Name of Provider or Supplier Rawlins County Health Center	Street Address, City, State 707 Grant Street, Atwood, 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
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: A review of proficiency testing records from American Proficiency Institute (API) (a year consists of three testing events) and interview with laboratory Supervisor revealed the laboratory failed to verify the accuracy of analytes for which the proficiency testing program does not obtain the agreement required for scoring. Findings were as follows: a. Proficiency testing records form API for the third event of 2016, revealed that the proficiency testing program failed to obtain the agreement required for scoring the Free Thyroxin CHG--13 , Thyroid Stimulating Hormone CH--13. b. Proficiency Testing records from API for the first event of 2017 revealed that the proficiency testing program failed to obtain the agreement required for scoring the Triglycerides CH--01 and Free Thyroxine CH--01 At the time of survey (04/04/2018), there was no evidence of verification activities of accuracy by self grade (comparison to the published expected results) for any of these analytes available for review. An interview with the General Supervisor from the CMS form 209 on 04/04/2018, at 09: 20 hrs confirmed that no verification of accuracy.</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</p>

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.

This STANDARD is not met as evidenced by:
A review of Temperature and humidity logs and interview with staff revealed the laboratory failed the humidity for the laboratory as the XS-1000i hematology analyzer requires and temperature for the drawing room and store room failed to document. Findings were as follows: a. Based upon review of manufacture's operators guide the laboratory failed the humidity 30% to 85% . The laboratory failed to define the acceptable humidity range according to the manufacture's range for 76 of 90 days.. b. Based upon a tour of the laboratory the surveyor observed the drawing room and store room in which BD vacutainer tubes are stored at a temperature of 4 to 25 degrees C no documentation was provided. c. At the time of the survey 04/04/2018 the laboratory failed to produce corrective action documentation of humidity and temperature., This was confirmed by the General Supervisor. from the CMS 209 form on 04/04/2018 at 1000 hours.

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(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 General Supervisor from the CMS 209 04 /04//2018 at 9:30 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 QC failure. Therefore, the accuracy or reliability of the QC plan cannot be verified. This was confirmed in interview with General Supervisor on 04/04/2018 at 11;30 hrs.