

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0648397	(X3) Date Survey Completed 11/14/2018
Name of Provider or Supplier Goodland Regional Medical Center	Street Address, City, State 220 West 2nd St, Goodland, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based upon direct observation during a tour of the laboratory, review of manufacturer's package insert and staff interview, the laboratory failed to ensure that gram stain reagents in use were not being used beyond their open expiration date. Findings were: 1. During a tour of the lab the surveyor observed BD Gram Stain Kits and Reagents with lot # 7340813 that expired 5/31/2019 in use on November 14, 2018. There was no open date or expiration date noted on this gram stain kit. 2. Review of the gram stain quality control (QC) log had lot # 7340813 expired 5/31/2019 had QC performed and documented for the first time on July 3, 2018. 3. Review of the BD Gram Stain Kits and Reagents stated "The expiration date is for product in unopened bottles stored as direct. Do not open until ready to use. Use the traditional Gram Iodine within 3 months of preparation, not exceeding the Expiration date." 4. Interview with general supervisor (GS) #1 (refer to laboratory personnel report (CMS-209)) at 2:22 PM on November 14, 2018 they only ordered one grams stain kit at a time when the current kit in use was almost completely gone and that the above kit had been in use since July 3, 2018 as stated on the gram stain log.</p>
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <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</p>

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 11 /14//2018 at 09::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: a. Based upon the Quality Assessment Action plan the laboratory failed to establish a action plan for any manual calculation (INR) for 2017 any analyte that is reported . Therefore, the accuracy or reliability of the analytes cannot be verified. This was confirmed in interview with Technical Consultant on 11/14/2018 at 14:30 hrs. .b. Shifts and Trends for. Chemistry and Hematology were failed to be addressed. This was confirmed by the Technical Consultant #1 on 11/14/2018 at 14:30