

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0450938	(X3) Date Survey Completed 04/04/2023
Name of Provider or Supplier Caldwell Regional Medical Center	Street Address, City, State 761 West 175th Street South, Caldwell, 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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on the review of proficiency testing (PT) records from American Proficiency Institute (API), the laboratory failed to successfully participate in PT under the specialty Routine chemistry for the regulated analytes: total bilirubin, pH blood gas, pO2 blood gas, pCO2 blood gas, total cholesterol and total iron. (Refer to D2096)
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two

consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a desk review of proficiency testing (PT) from the provider API for Chemistry, and phone interview, the laboratory failed to achieve an acceptable score of 80% or higher for two of three consecutive testing events for the regulated analytes: total bilirubin, pH blood gas, pO₂ blood gas, pCO₂ blood gas, total cholesterol and total iron. Findings: 1. Review of API PT scores for 2022 Event 3 revealed a 0% performance scores for total bilirubin, pH blood gas, pO₂ blood gas, pCO₂ blood gas, total cholesterol and total iron 2. Review of the API PT scores for 2023 Event 1 revealed the following scores: a. Total bilirubin 60% b. pH blood gas 60% c. pO₂ blood gas 40% d. pCO₂ blood gas 40% e. Total cholesterol 40% f. Total iron 20% 2. Phone interview with the lab manager on 4/4/23at 8:10 a.m. confirmed, the laboratory failed to achieve an acceptable score of 80% or higher for two of three consecutive testing events for the regulated analytes: total bilirubin, pH blood gas, pO₂ blood gas, pCO₂ blood gas, total cholesterol and total iron.