

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D0516921	(X3) Date Survey Completed 10/14/2022
Name of Provider or Supplier Kit Carson County Memorial Hospital	Street Address, City, State 286 16th St, Burlington, CO	
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	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on a routine proficiency test desk review of the CMS-155 report for proficiency testing performance and an interview with the laboratory director, the laboratory failed to achieve satisfactory performance scores for Human Chorionic Gonadotropin (HCG) for two out of three events (Event 3 in 2021 and Event 2 in 2022). See D2107.</p>
D2107	<p>ENDOCRINOLOGY CFR(s): 493.843(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two</p>

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 review of proficiency testing scores from the American Proficiency Institute (API) and email communication with the laboratory director, the laboratory failed to achieve a satisfactory score of at least an 80% for Human Chorionic Gonadotropin (HCG) testing performed for Event 3 in 2021 and Event 1 in 2022. Findings include: 1. A review of the proficiency testing scores from API and the CMS-155 Individual Laboratory Profile on 10/07/2022, at 3:00 PM, revealed the HCG testing scores for Event 3 in 2021 was 60% and Event 2 in 2022 was 60%. 2. An email communication with the laboratory director on 10/12/2022, at 3:54 PM, confirmed two out of three unsuccessful proficiency scores for HCG testing due to laboratory errors.