

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D0516925	(X3) Date Survey Completed 04/17/2023
Name of Provider or Supplier Keefe Memorial Health Services District	Street Address, City, State 602 N 6th St W, Cheyenne Wells, 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 desk review of the CMS-155 report for Proficiency Testing (PT), test reports from the American Proficiency Institute (API), and communication with the laboratory chief of operations, the laboratory failed to successfully participate in PT during 2022 and 2023 . (Refer to D2096, D2107, D2108, and D2130).</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two</p>

	<p>consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a routine desk review of the CMS-155 report for Proficiency Testing (PT), American Proficiency Institute (API) reports, and communications with the laboratory chief of operations, the laboratory failed to achieve a satisfactory score for Lactate Dehydrogenase (LDH, Total) for event 3 in 2022 and event 1 in 2023. Findings: 1. A review of the CMS-155 Individual Laboratory Profile on 4/17/2023, at 11:52 AM, revealed the API PT results for LDH, Total testing scores for event 3 in 2022 was 0% and 0% for event 1 in 2023. 2. A phone call with the laboratory's Chief Operations Officer on 04/13/2023, at 11:32 AM, with the laboratory chief of operations confirmed the laboratory failed to achieve satisfactory test performance for LDH.</p>
<p>D2107</p>	<p>ENDOCRINOLOGY CFR(s): 493.843(f)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing scores from the American Proficiency Institute (API) and an interview with the laboratory chief of operations, the laboratory failed to achieve a satisfactory proficiency testing score for Free Thyroxine (TY) in event 3 in 2022 and event 1 in 2023. Findings include: 1. A review of the proficiency testing scores from API and the CMS-155 Individual Laboratory Profile on 04/17/2023, revealed the TY testing scores for event 3 in 2022 was 60% and event 1 in 2023 was 60%. 2. A phone call with the laboratory's Chief Operations Officer on 04/13/2023, at 11:32 AM, confirmed unsuccessful proficiency scores for TY testing.</p>
<p>D2108</p>	<p>ENDOCRINOLOGY CFR(s): 493.843(g)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing scores from the American Proficiency Institute (API) and communication with the laboratory, the laboratory failed to achieve an overall satisfactory testing score for the subspecialty of Endocrinology for events 1 and 3 in 2022. Findings include: 1. A review of the proficiency testing scores from API and the CMS-155 Individual Laboratory Profile on 04/17/2023, revealed the overall testing scores for Endocrinology for events 1 and 3 in 2022 was 70% 2. A phone call with the laboratory's Chief Operations Officer on 04/13/2023, at 11:32 AM, confirmed the unsuccessful proficiency scores for the overall testing events for Endocrinology.</p>
<p>D2130</p>	<p>HEMATOLOGY</p>

CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a routine desk review of the CMS-155 report for Proficiency Testing (PT) performance and email communications with the laboratory director of operations, the laboratory failed to achieve a score of 80% for the American Proficiency Institute (API) PT for Cell I.D. or WBC Differential for Events 2 and 3 in 2022. Findings Include: 1. A review of the CMS-155 Individual Laboratory Profile on 04/17/2023, revealed the API PT for Cell I.D. or WBC Diff testing scores for 2022 event 2 was 0% and for event 3 was 20%. 2. A phone call with the laboratory's Chief Operations Officer on 04/13/2023, at 11:32 AM, confirmed two consecutive unsuccessful PT scores for Cell I.D. or WBC Diff.