

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D0516925	(X3) Date Survey Completed 12/08/2023
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), and telephone interview with the laboratory manager, the laboratory failed to achieve satisfactory performance in proficiency testing for Cell I.D. or WBC Differential for four consecutive events in 2022-2023 (Events 2 and 3 in 2022 and Events 1 and 2 in 2023), resulting in subsequent unsuccessful PT performance. (Refer to D2130).</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p>

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 telephone interview with the laboratory manager, the laboratory failed to achieve a score of at least 80% for Cell I.D. or WBC Differential for four consecutive PT events in 2022-2023 (Events 2 and 3 in 2022 and Events 1 and 2 in 2023) resulting in subsequent unsuccessful performance. Findings Include: 1. A review of the CMS-155 Individual Laboratory Profile report on 12/07/2023, revealed the American Proficiency Institute (API) PT scores for Cell I.D. or WBC Differential testing were: 2022 Event 2 0% 2022 Event 3 20% 2023 Event 1 28% 2023 Event 2 52% 2. A telephone interview with the laboratory manager on 12/08/2023, at 10:20 AM, confirmed the four consecutive unsuccessful PT scores for Cell I.D. or WBC Diff.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on a routine desk review of the CMS-155 report for Proficiency Testing (PT) performance and telephone interview with the laboratory manager, the laboratory director failed to fulfill the responsibility for overall operation of the laboratory by failing to review and evaluate the unsatisfactory proficiency testing for events 2 and 3 in 2022 and events 1 and 2 in 2023, resulting in subsequent unsuccessful PT participation for Cell I.D. or WBC Differential . (See D6091).

D6091

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

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 telephone interview with the laboratory manager, the laboratory director failed to ensure that PT reports were reviewed and evaluated for the unsatisfactory proficiency testing performance for Cell I.D. or WBC Differential in four consecutive events (events 2 and 3 in 2022, and events 1 and 2 in 2023), resulting in subsequent unsuccessful proficiency testing performance. Findings include: 1. A review of the CMS-155 Individual Laboratory Profile report on 12/07/2023, revealed the American Proficiency Institute (API) PT scores for Cell I.D. or WBC Differential testing were: 2022 Event 2 0% 2022 Event 3 20% 2023 Event 1 28% 2023 Event 2 52% 2. A telephone interview with the laboratory manager on 12/08/2023, at 10:20 AM, confirmed four consecutive unsuccessful PT scores for Cell I.D. or WBC Diff.