

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0472771	(X3) Date Survey Completed 06/16/2023
Name of Provider or Supplier Harper County Community Hospital	Street Address, City, State 1003 Hwy 64 North, Buffalo, OK	
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
D0000	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database and from the proficiency testing provider. The laboratory was found out of compliance with the following CLIA Conditions: 493.803; D2016: Successful Participation 493.1441; D6076: Laboratory Director, High Complexity
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 desk review of proficiency testing records, the laboratory failed to successfully participate in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under</p>

	<p>CLIA The laboratory failed to achieve satisfactory performance in three of four consecutive proficiency testing events for Compatibility Testing. (Refer to D2181).</p>
D2181	<p>COMPATIBILITY TESTING CFR(s): 493.863(e)</p> <p>Failure to achieve an overall testing event score of satisfactory 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 desk review of proficiency testing scores, the laboratory failed to achieve satisfactory performance for Compatibility Testing in three of four consecutive testing events. Findings include: (1) The laboratory received the following scores: (a) 60% on the first 2022 event (b) 80% on the second 2022 event (c) 0% on the first 2023 event (2) A proficiency testing desk review from API 2022 and 2023 proficiency testing records confirmed the above findings.</p>
D6076	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on a desk review of proficiency testing scores obtained from the Casper 0155D report and the American Proficiency Institute, the laboratory demonstrated non-initial unsuccessful participation for Compatibility Testing in three of four consecutive testing events. The laboratory failed to achieve a passing score of 100% for the first 2022 event, second 2022 event, and first 2023 event. Refer to D6089.</p>
D6089	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i)</p> <p>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a desk review of proficiency testing scores obtained from the Casper 0155D report and the American Proficiency Institute, the laboratory demonstrated non-initial unsuccessful participation for Compatibility Testing in three of four consecutive testing events. The laboratory failed to achieve a passing score of 100% for the first 2022 event, second 2022 event, and first 2023 event. Refer to D2181.</p>