

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  43D2264700	<b>(X3) Date Survey Completed</b>  11/24/2025
<b>Name of Provider or Supplier</b>  Hometown Family Health Pllc	<b>Street Address, City, State</b>  104 West Commerce St, Plankinton, SD	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database and verified with the proficiency testing provider. The facility was found to be out of compliance with the conditions of the CLIA program. The following <b>CONDITION LEVEL DEFICIENCIES</b> were found to be out of compliance: D2016 - 42 C.F.R 493.803 Condition: Successful participation (proficiency testing)
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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 <b>CONDITION</b> is not met as evidenced by: Based on review of the Federal proficiency testing (PT) reports 153D and 155D and the laboratory's American Proficiency Institute (API) PT report, the laboratory failed</p>

to achieve successful participation for the glucose test method. Unsatisfactory results for glucose in two of three PT testing events (API 2025 Chemistry-Core first and third events) resulting in unsuccessful PT participation. Refer to D2096.

**D2096**

**ROUTINE CHEMISTRY**

CFR(s): 493.841(f)

(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 review of the Federal proficiency testing (PT) reports 153D and 155D, the laboratory's American Proficiency Institute's (API) PT reports and interview with laboratory manager A, the laboratory failed to achieve a satisfactory score of 80% or above for the glucose test method for two of three testing events (API 2025 Chemistry-Core first and third events). Findings include: 1. Review on 10/30/25 of the CASPER Individual Laboratory Profile PT report 155D report revealed the laboratory had received unsatisfactory scores of 60% in the API 2025 Chemistry core first event and 20% in the third event for the glucose test method. Review on 10/1/25 of the individual event glucose test method scores for the two API PT events revealed: a. 2025 Chemistry-Core first event glucose results were: (i) CH-01 result was 198. The range of acceptable results was 167-197 milligrams/deciliter (mg/dl). (ii) CH-03 result was 359. The range of acceptable results was 363-427 mg/dl. b. 2025 Chemistry-Core third event glucose results were: (i) CH-11 result was 229. The range of acceptable results was 141-166 mg/dl. (ii) CH-12 result was 186. The range of acceptable results was 329-387 mg/dl. (iii) CH-14 result was 342. The range of acceptable results was 179-211 mg/dl. (iv) CH-15 result was 146. The range of acceptable results was 219-258 mg/dl. Interview on 10/9/25 via email with laboratory manager A revealed the laboratory's investigation revealed: a. There was an issue with the analyzer at the time the first event samples were processed. b. There was a potential issue with the API third event PT samples. i.. Four of the five PT samples were green in color. The PT samples are normally yellow in color. ii.. The laboratory repeated the original PT samples. The results were similar to the laboratory's reported results. iii. Laboratory manager A contacted API concerning the condition of the PT samples. API shipped a replacement set of PT samples for retesting. iv. The laboratory tested the replacement API samples. Results of the repeat testing were within the acceptable ranges.