

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  43D2264700	<b>(X3) Date Survey Completed</b>  07/29/2025
<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>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 CONDITION is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the laboratory manager, the laboratory failed to achieve successful participation for the carbon dioxide (CO2) test method. Unsatisfactory results had been received in two of three PT testing events (American Proficiency Institute [API] 2025 Chemistry-Core first and second events) resulting in unsuccessful PT participation. Refer to D2096.</p>
<b>D2096</b>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(f)</p>

(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 the laboratory manager, the laboratory failed to achieve a satisfactory score of 80% or above for the carbon dioxide (CO<sub>2</sub>) test method for two of three testing events (API 2025 Chemistry-Core first and second testing events). Findings include: 1. Review of the 7/14/25 CASPER Unsuccessful PT report 153D revealed the laboratory had received unsatisfactory scores (less than 80%) for the CO<sub>2</sub> test method in each of the two testing events listed above. Review of the 7/14/25 CASPER Individual Laboratory Profile PT report 155D and API PT 2025 Chemistry-Core first and second event evaluation reports revealed the laboratory had received unsatisfactory scores of 60% in the first event and 20 % in the second event for the CO<sub>2</sub> test method. Review of the individual event CO<sub>2</sub> test method scores for the two API PT events revealed: \*2025 Chemistry-Core first event CO<sub>2</sub> results were: a. CH-01 13 The range of acceptability was 20-31 millimoles/liter (mmol/L) . b. CH-05 16 The range of acceptability was 17-27 mmol/L. \*2025 Chemistry-Core second event CO<sub>2</sub> results were: a. CH-07 22 The range of acceptability was 23-36 mmol/L. b. CH-08 17 The range of acceptability was 18-28 mmol/L. c. CH-09 20 The range of acceptability was 21-32 mmol/L. d. CH-10 22 The range of acceptability was 26-41 mmol/L. Interview on 7/28/25 via email with the laboratory manager revealed:\*The laboratory had been aware of the PT failures. \*Her investigation into the first unsuccessful testing event determined that there had been an issue with the analyzer. Service had been notified and the issue was corrected. \*Her investigation into the second unsuccessful testing event determined that there had been an issue with the analyzer. PT samples had been repeated after the analyzer issue was corrected. It had been determined that the PT specimens had been retested after the open expiration date had expired which had resulted in potential deterioration of the PT samples.