

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D0385251	<b>(X3) Date Survey Completed</b>  08/06/2025
<b>Name of Provider or Supplier</b>  Family Health Care Of Siouxland-Indian Hills	<b>Street Address, City, State</b>  2600 Outer Drive North, Sioux City, IA	
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>	A proficiency testing desk review survey was completed on August 6, 2025. The laboratory was found to be out of compliance with the following CONDITION LEVEL DEFICIENCIES: D2016 - 42 C.F.R 493.803 Condition: Successful Participation D6000 - 42 C.F.R 493.1403 Condition: Laboratory Director, moderate complexity
<b>D2016</b>	<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 review of the Certification and Survey Provider Enhanced Reporting (CASPER) 155 report and graded results from the American Proficiency Institute, the laboratory failed to successfully participate in two consecutive testing events for the</p>

	<p>analytes, free thyroxine and thyroid-stimulating hormone and the subspecialty of endocrinology. The laboratory had unsatisfactory scores for 2025 event 1 and 2025 event 2. Refer to D2107 and D2108.</p>
<p><b>D2107</b></p>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.843(f)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) 155 report and graded results from the American Proficiency Institute (API), the laboratory failed to successfully participate in two consecutive testing events for the analytes, free thyroxine (free T4) and thyroid stimulating hormone (TSH). The findings include: 1. For 2025 event 1, the laboratory received unsatisfactory performance scores of 20% for the analytes, free T4 and TSH. 2. For 2025 event 2, the laboratory received unsatisfactory performance scores of 20% for the analyte free T4 and zero for the analyte TSH. 3. The CASPER 155 report and graded results from API confirm the findings listed above.</p>
<p><b>D2108</b></p>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.843(g)</p> <p>(g) 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 review of the Certification and Survey Provider Enhanced Reporting (CASPER) 155 report and graded results from the American Proficiency Institute (API), the laboratory failed to successfully participate in two consecutive testing events for the subspecialty, endocrinology. The findings include: 1. For 2025 event 1, the laboratory received an unsatisfactory performance score of 20% for the subspecialty, endocrinology. 2. For 2025 event 2, the laboratory receive an unsatisfactory performance score of 10% for the subspecialty, endocrinology. 3. The CASPER 155 report and graded results from API confirm the findings listed above.</p>
<p><b>D6000</b></p>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting</p>

(CASPER) 155 report and graded results from the American Proficiency Institute (2025 event 1 and 2025 event 2), the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:  
Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) 155 report and graded results from the American Proficiency Institute (API), the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2107 and D2108.