

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D0920429	<b>(X3) Date Survey Completed</b>  09/02/2025
<b>Name of Provider or Supplier</b>  Horn Physicians Clinic - Odebolt	<b>Street Address, City, State</b>  300 South Maple, Odebolt, 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 September 2, 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><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 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 out of three consecutive testing</p>

	<p>events for the specialty, hematology, and the analytes, red blood cell count, hematocrit, and hemoglobin. The laboratory had unsatisfactory scores for 2024 event 3 and 2025 event 2. Refer to D2131 and D2130.</p>
<p><b>D2130</b></p>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(f)</p> <p>(f) Failure to achieve satisfactory performance for the same analyte in two consecutive 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 out of three consecutive testing events for the analytes, red blood cell count, hematocrit, and hemoglobin. The findings include: 1. For 2024 event 3, the laboratory received unsatisfactory performance scores of 60% for the analytes, red blood cell count, hematocrit, and hemoglobin. 2. For 2025 event 2, the laboratory received unsatisfactory performance scores of 60% for the analytes, red blood cell count, hematocrit, and hemoglobin. 3. The CASPER 155 report and graded results from API confirm the findings listed above.</p>
<p><b>D2131</b></p>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(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 achieve satisfactory performance (100% or greater) for two out of three consecutive testing events in the specialty, hematology. The findings include: 1. The laboratory received unsatisfactory performance scores of 76% for 2024 testing event 3 and 61% for 2025 testing event 2 for the specialty, hematology. 2. 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 (2024 event 3 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 D2131 and D2130.