

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0384356	(X3) Date Survey Completed 05/16/2025
Name of Provider or Supplier Pocahontas Community Hospital	Street Address, City, State 606 Nw Seventh Street, Pocahontas, IA	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing records and confirmed by interview with general supervisor (GS) #1 at 8:40 am on 05/16/2025, the laboratory failed to verify the accuracy of post-vasectomy (qualitative semen analysis) examinations twice annually for four out of four time periods from 01/01/2023 - 12/31/2024. The findings include: 1. GS #1 stated the laboratory performs post-vasectomy (qualitative semen analysis) examinations. 2. At the time of the survey, GS #1 confirmed the laboratory did not enroll in proficiency testing or perform twice annual accuracy testing for post-vasectomy (qualitative semen analysis) examinations by another method from 01/01/2023 - 12/31/2024.</p>
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p>

This STANDARD is not met as evidenced by:

Based on review of the Laboratory Test List & Annual Volume form, chemistry quality control (QC) records, the Dimension operator's guide, and confirmed by interview with General Supervisor (GS) #1 at 12:25 pm on 05/16/2025, the laboratory failed to perform and document corrective action when the chemistry equipment failed to meet the laboratory's established operating parameters for two out of 28 days of patient testing reviewed from 02/01/2025- 02/28/2025. The findings include: 1. The laboratory performed chemistry testing on a Dimension EXL chemistry instrument. 2. Review of QC records revealed the system flagged results with the test report message "abnl assay" for the following analytes and dates: *02/13/2025- calcium (level 1) *02/19/2025- free thyroxine (level 3) 3. The Dimension operator's guide stated that results flagged with the "abnl assay" test report message are not reportable and must be addressed. 4. The laboratory reported a total of 14 calcium and 3 free thyroxine patient test results for the dates listed above. 5. At the time of the survey, GS #1 confirmed that the laboratory did not take and document additional corrective action for QC results flagged with abnl assay test report messages on the dates listed above.