

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0407239	(X3) Date Survey Completed 04/09/2025
Name of Provider or Supplier Urology Specialists	Street Address, City, State 201 W 69th Street, Sioux Falls, SD	
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
D0000	A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 4/9/25. Urology Specialists laboratory was found not in compliance with this requirement: D5209
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to establish written policies and procedures for staff competency assessments that included the six areas required for assessing competency in 2024 and through the date of the survey. Competency assessments ensured laboratory personnel were competent to perform preanalytical, analytical and postanalytical tasks. Findings include: 1. Review on 4/9/25 of the laboratory's Laboratory Personnel Report (CLIA) (Clinical Laboratory Improvement Amendment) (Centers for Medicare and Medicaid Services form 209) revealed laboratory personnel A, B and C were listed as testing personnel. Review on 4/9/25 of the laboratory staff's competency assessment records revealed: *Testing personnel A's annual competency evaluation had been completed on 6/4/24. *Testing personnel B's annual competency evaluation had been completed on 6/4/24. *Testing personnel C had competency evaluations completed on 3/11/24 and 6/4/24. *The above competency assessments failed to document assessment of the required areas of quality control review and problem-solving skills. Review of the laboratory's competency evaluation policy last reviewed by the laboratory director on 4/7/24 revealed: *Competency assessments would be completed on initial hire, 6 months after hire and annually there-after. *The required elements of the competency assessments were not included in the laboratory's competency assessment policy.</p>

Interview on 4/9/25 at 11:15 a.m. with testing personnel A revealed, she confirmed:
*Quality control review and assessment of problem-solving skills were not part of the laboratory's annual competency assessment. *She was unaware those topics had been required as a part of the competency assessment. *She agreed it was important to review quality control and problem-solving as part of the competency assessment. The laboratory director was unavailable for interview during the survey.