

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  43D0407239	<b>(X3) Date Survey Completed</b>  06/29/2023
<b>Name of Provider or Supplier</b>  Urology Specialists	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 6/29/23. Urology Specialists laboratory was found not in compliance with the following requirements: D2015 and D6028.
<b>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain a copy of required documentation related to the processing of nine of nine proficiency testing (PT) events reviewed (2022 Chemistry Core 1st, 2nd and 3rd events; 2022 Hematology/Coagulation 1st, 2nd and 3rd events; 2023 Chemistry Core 1st and 2nd events; 2023 Hematology/Coagulation 1st event). That documentation would ensure the results submitted for evaluation had been the results obtained by the laboratory processing the PT samples. Findings include: 1. Review on 6/29/23 of the laboratory's 2022 and 2023 American Proficiency Institute (API) PT event records revealed: *The laboratory subscribed to PT events through API. *PT specimens were processed and submitted electronically via the API website upon completion of testing. *The laboratory had the ability to print a copy of the final PT results that were submitted for</p>

evaluation. \*The laboratory failed to retain copies of the final electronically submitted results for the following events: -2022 API Chemistry Core 1st testing event -2022 API Chemistry Core 2nd testing event -2022 API Chemistry Core 3rd testing event -2022 API Hematology/Coagulation 1st testing event -2022 API Hematology /Coagulation 2nd testing event -2022 API Hematology/Coagulation 3rd testing event -2023 API Chemistry Core 1st testing event -2023 API Chemistry Core 2nd testing event -2023 API Hematology/Coagulation 1st testing event Review of the laboratory PT policy revealed, "before mailing or submitting online the completed questionnaire, be sure to photocopy or print the results." Interview on 6/29/23 at 10:00 a.m. with laboratory staff (A) revealed: \*PT results were electronically reported after PT samples were processed. \*The laboratory could print a copy of all final PT results that were submitted for evaluation. \*The laboratory had not printed copies of all final submitted PT results.

**D6028**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(10)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory director failed to ensure competency evaluations for three of three sampled laboratory staff (A, B, and C) were completed by qualified personnel (their credentials had not been reviewed to determine if they were qualified to serve as technical consultant) for the nonwaived test methods they had been performing under the laboratory's certificate. Findings include: 1. Review of the laboratory's personnel files revealed: \*Laboratory staff A's competency assessment was performed on 5/22/23 by laboratory staff B. Laboratory staff B's competency assessment was performed on 5/19/23 by laboratory staff A. Laboratory staff C's competency assessment was performed on 5/8/23 by laboratory staff A. \*There was no documentation the laboratory director was involved in the competency assessment process. Review of the Center for Medicare and Medicaid Services 209 Laboratory Personnel Report form signed by the laboratory director on 6/27/23 revealed employee D was listed as a technical consultant. Laboratory staff A, B, and C were listed only as testing personnel. Review of the education records for laboratory staff A and B revealed they had an associate degree. There was no documentation that a higher degree had been obtained. Interview with laboratory staff A on 6/29/23 at 9:45 a.m. revealed: \*She confirmed employee D was not involved in the competency assessment process. \*She confirmed laboratory staff A and B had an associate degree for their highest level of education. \*She was unaware that competency assessments needed to have been completed by personnel who were qualified to serve as a technical consultant. The laboratory director was unavailable for interview at the time of the survey.