

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 52D2097023	<b>(X3) Date Survey Completed</b> 04/08/2021
<b>Name of Provider or Supplier</b> Urology Associates Of Green Bay, Sc	<b>Street Address, City, State</b> 2720 Cahill Rd, Marinette, WI	
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>D6072</b>	<p><b>TESTING PERSONNEL RESPONSIBILITIES</b> CFR(s): 493.1425(b)(3)</p> <p>Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and quality control records and interview with testing personnel, testing personnel did not test quality control materials with each new lot number of PSA (Prostate Specific Antigen) reagents prior to testing patient samples as specified by the manufacturer and established by the laboratory in their Individualized Quality Control Plan (IQCP). In 2020, testing personnel did not test control material before testing patient samples for two of six lot numbers used. Testing personnel tested nine patient samples before testing control materials with two new lots of PSA reagents. Findings include: 1. Review of the laboratory's PSA procedures and IQCP showed the quality control procedures require testing two levels of control material prior to testing patient samples with a new lot of reagents. 2. Review of quality control records from January through December 2020 showed testing personnel performed testing using six different lot numbers of PSA reagent throughout the year. Records showed testing personnel first tested control material with lot number 1910026-5P on March 12, 2020. Testing personnel used lot 1910026-5P for PSA testing of five patient samples on March 10, 2020 before controls were tested. Records also showed testing personnel first tested control materials with lot number 2001041-8p on July 8, 2020. Testing personnel used lot 2001041-8p for PSA testing of four patient samples on June 30 and July 1, 2020 before controls were tested. 3. Interview with testing personnel (staff A) on April 8, 2021 at 10:43 and 11:07 AM confirmed testing personnel performed patient PSA tests using reagents that had not first been tested with control materials and that testing personnel did not adhere to the laboratory's quality control procedures.</p>