

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D2097023	<b>(X3) Date Survey Completed</b>  01/22/2025
<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>D6020</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Individualized Quality Control Plan (IQCP) provided by the laboratory as evidence of correction and other laboratory records and interview with the clinic manager (staff A) by email, the laboratory had not retained one of one IQCP for this laboratory for the Prostate Specific Antigen (PSA) test performed with the Qualigen Diagnostics FastPack analyzer and the director did not ensure the quality control program was maintained. Findings include: 1. Review of the 'IQCP for Quality Control on the Qualigen FastPack PSA' document provided by the clinic manager via email on January 16, 2025, showed the laboratory director had not signed the IQCP. Further review showed the document was not specific for the PSA test system as performed at this laboratory. a. The IQCP referenced use of College of American Pathologists (CAP) Proficiency Testing (PT). Record review during the on-site survey on December 19, 2024, showed the laboratory did not use CAP PT products. b. The IQCP identified roles for a Medical Technologist and Technical Supervisor. Review of personnel records during the on-site survey showed no evidence the laboratory had hired a Medical Technologist or Technical Supervisor. c. The IQCP addressed nucleic acid contamination and mitigation procedures that are not a risk factor for the Qualigen FastPack PSA test system. d. The IQCP stated the director or designee review all verified results prior to release. Review of test records during the on-site survey showed no evidence the director or designee reviewed all</p>

results prior to release. e. The IQCP stated, "Appropriate utilities are employed in the laboratory to service the Verigene Instrumentation" and "All reagents used in the Xpert MRSA are used within expiration dates." Review of the laboratory's test menu showed no testing for the Xpert MRSA or testing with Verigene instrumentation. 2. Email interview with Staff A on January 22, 2025, at 1:20 PM revealed, "We couldn't locate an IQCP for Marinette for PSA. We are thinking it was thrown out with the older lab paperwork" showing the director had not ensured the quality control program was maintained.