

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D1023301	(X3) Date Survey Completed 10/17/2022
Name of Provider or Supplier Urology Associates Of Green Bay Sc	Street Address, City, State 720 S Van Buren St Ste 301, Green Bay, WI	
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
D6020	<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 quality control (QC) records and Individualized Quality Control Plan (IQCP) and interview with the general supervisor, the laboratory director did not document review of the IQCP plan to ensure the quality control plan was established for the BioRad CFX96 Pathogen Multiplex polymerase chain reaction (PCR) test. Findings include: 1. Review of QC records showed four assay controls were run with each patient and external QC was being performed weekly on the BioRad CFX96 Pathogen Multiplex PCR test. 2. Review of the BioRad CFX96 Pathogen Multiplex PCR test IQCP showed data had been compiled for external QC to be performed weekly. Further review showed no documentation of review and acceptance by the laboratory director to institute the use of the IQCP. 3. Interview with the general supervisor on October 17, 2022, at 11:35 AM confirmed the laboratory director did not document review of the IQCP plan to ensure the quality control plan was established for the BioRad CFX96 Pathogen Multiplex polymerase chain reaction (PCR) test.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of</p>

all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on surveyor review of the test menu and personnel records and interview with the general supervisor, the technical consultant (who is the laboratory director) did not provide training or competency assessment for two of two testing personnel to ensure staff were competent to perform microscopic urinalysis evaluations. Findings include:

1. Review of the test menu showed the facility began urine microscopy testing on September 20, 2021.
2. Review of personnel training and competency records showed no documentation of training or competency assessment for microscopic urinalysis evaluations for two of two testing personnel, staff A and staff B.
3. Interview with the general supervisor on October 17, 2022, at 11:30 AM confirmed the technical consultant (who is the laboratory director) did not provide training or competency assessment for two of two testing personnel to ensure staff were competent to perform microscopic urinalysis evaluations.