

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0398942	<b>(X3) Date Survey Completed</b>  10/23/2018
<b>Name of Provider or Supplier</b>  Minnesota Urology, Pa	<b>Street Address, City, State</b>  6025 Lake Road, Suite 200, Woodbury, MN	
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>D3037</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to retain proficiency testing records for at least 2 years. Findings are as follows: 1. The laboratory performed Chemistry and Microbiology testing as confirmed by General Supervisor 3 (GS3) during a tour of the laboratory on 10/22/18 at 8:05 a.m. 2. The laboratory performed proficiency testing (PT) using the College of American Pathologists (CAP) and Wisconsin State Lab of Hygiene (WSLH) as PT providers. 3. The following PT evaluation reports and documentation of review by the Laboratory Director (LD) were not present in laboratory records: PT provider Event WSLH 2017 - BactiReg 2 WSLH 2017 - BactiReg 3 WSLH 2018 - Chem / Endo / Tx 2 4. The laboratory was unable to provide the documentation of review by the Laboratory Director (LD) for these PT events upon request. 5. In an interview on 10/22/18 at 12:15 p.m., GS3 confirmed the above finding. .</p>
<b>D5211</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to evaluate unacceptable proficiency testing (PT) results. Findings are as follows: 1. The laboratory performed Chemistry, Hematology and Microbiology</p>

testing as confirmed by General Supervisor 3 (GS3) during a tour of the laboratory on 10/22/18 at 8:05 a.m. 2. The laboratory performed proficiency testing (PT) using the College of American Pathologists (CAP) and Wisconsin State Lab of Hygiene (WSLH) as PT providers. 3. The laboratory received unacceptable PT results for the following WSLH PT events: Event = 2017 - HemeReg3 Sample = AFA-14 Test = Eosinophils Event = 2017 - BactiReg2 Sample = UC-10 Test = Sensitivity (Levofloxacin) + (Quinupristin / Dalfopristin) Event = 2017 - BactiReg3 Sample = UC-13 Test = Organism ID Event = 2018 - Chem/Endo/Tx 2 Sample = CET-8 Test = Sodium Sample = CET-10 Test = Carbon Dioxide 4. An evaluation of the unacceptable PT results was not found during review of laboratory records. The laboratory was unable to provide evaluations upon request. 5. In an interview on 10/22/18 at 12:15 p.m., GS3 confirmed the above finding. .

**D5215**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
 CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:  
 . Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of proficiency testing (PT) results that were not scored by the PT provider. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by General Supervisor 3 (GS3) during a tour of the laboratory on 10/22/18 at 8:05 a.m. 2. The laboratory performed proficiency testing (PT) using the College of American Pathologists (CAP) and Wisconsin State Lab of Hygiene (WSLH) as PT providers. 3. An evaluation for accuracy of non-graded results for the following WSLH PT events was not found during review of the following laboratory documents: Event Sample Test 2017 - BactiReg2 UC-6 Gram Stain UC-7 Gram Stain UC-8 Organism ID Gram Stain UC-9 Gram Stain 2017 - BactiReg3 UC-11 Gram Stain UC-13 Gram Stain UC-14 Gram Stain UC-15 Trimethoprim 2018 - BactiReg3 UC-11 Gram Stain UC-12 Gram Stain UC-13 Gram Stain UC-14 Gram Stain UC-15 Rifampin 4. The laboratory was unable to provide an evaluation of non-graded results upon request. 5. In an interview on 10/22/18 at 12:15 p.m., GS3 confirmed the above finding. .

**D5807**

**TEST REPORT**  
 CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:  
 . Based on observation, document review and interview with laboratory personnel, the laboratory failed to ensure reference intervals were consistent between a Chemistry procedure and a patient final test report. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by General Supervisor 3 (GS3) during a

tour of the laboratory on 10/22/18 at 8:05 a.m.. 2. A Beckman Coulter DxI 600 immunoassay chemistry analyzer was observed as present and available for use during the tour. 3. The TSH reference interval listed in the TSH (3rd IS) procedure, located in the on-line procedure manual, was not consistent with those included on a patient test report (Male - 28 years, Date performed = 8/29/18) reviewed on date of survey. See below. Procedure Report 0.45 - 5.33 0.340 - 5.600 4. In an interview on 10/23/18 at 10:15 a.m., GS3 confirmed the above finding.