

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0398942	<b>(X3) Date Survey Completed</b>  12/18/2020
<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>D5211</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE 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 Hematology and Microbiology testing as confirmed by the Technical Consultant 2 (TC2) during a tour of the laboratory on 12/18/20, at 10:05 a.m. 2. The laboratory performed proficiency testing (PT) using the College of American Pathologists (CAP) and American Proficiency Institute (API) as PT providers. 3. The laboratory received unacceptable PT results for the following API PT events: Event = 2019 - Heme / Coag - 3rd Event Sample = BCI-13 Test = Blood Cell ID Event = 2019 - Microbiology - 3rd Event Sample = GS-14 Test = Gram Stain Morphology Event = 2020 - Heme / Coag - 1st Event Sample = COU-05 Test = Monocytes 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 12/18/20, at 10:20 a.m., TC2 confirmed the above finding. .</p>
<b>D5215</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>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).</p>

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 Hematology, Parasitology, Urinalysis, and Microbiology testing as confirmed by the Technical Consultant 2 (TC2) during a tour of the laboratory on 12/18/20, at 10:05 a.m. 2. The laboratory performed proficiency testing (PT) using the College of American Pathologists (CAP) and American Proficiency Institute (API) as PT providers. 3. An evaluation for accuracy of non-graded results for the following API PT events was not found during review of the following laboratory documents: Event: 2019 - Heme / Coag - 1st Event Sample: COU-02 Test: Nucleated RBC's\* Sample: US-02 Test: PPM / Urine Sediment Sample: VKP-01 Test: Vaginal Wet Prep (KOH)\* Sample: UA-01 Test: Urobilinogen Event: 2019 - Microbiology - 3rd Event Sample: UR-11 Test: Urine Culture MIC\* Event: 2020 - Heme / Coag - 1st Event Sample: US-06 Test: PPM / Urine Sediment Event: 2020 - Microbiology - 1st Event Sample: UR-01 Test: Urine Culture MIC\* 4. The laboratory was unable to provide an evaluation of non-graded results upon request. 5. In an interview on 12/18/20, at 10:20 a.m., TC2 confirmed the above finding. \* RBC = Red Blood Cells \* KOH = Potassium hydroxide \* MIC = Minimum Inhibitory Concentration .

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1407(e)(4)(iii)

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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:  
 . Based on document review and interview with laboratory staff, the laboratory director failed to ensure corrective actions were taken when the laboratory received an unacceptable result on a proficiency testing sample. Findings include: 1. The laboratory director failed to ensure corrective actions were taken for 3 of 36 proficiency testing events reviewed. Refer to D-5211. .