

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 24D0927575	<b>(X3) Date Survey Completed</b> 07/29/2022
<b>Name of Provider or Supplier</b> Minnesota Urology Plymouth	<b>Street Address, City, State</b> 2855 Campus Dr #650, Plymouth, 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>D2010</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by:                      . Based on document review and interview with laboratory personnel, the laboratory failed to ensure proficiency testing (PT) samples from one of two 2021 PT events were tested consistent with the number of times the laboratory routinely tested patient specimens. Findings are as follows: 1. The laboratory performed Prostrate Specific Antigen (PSA) testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:00 a.m. on 07/29/22. 2. The laboratory performed PT in 2021 using the American Proficiency Institute (API) proficiency testing provider. 3. The Proficiency Testing Procedure found in the laboratory's Procedure Manual indicated PT samples would be tested in the same manner as patient specimens. 4. The PSA PT samples were tested by multiple testing personnel (TP) in one of two PT events reviewed from 2021 as indicated on the API attestation statement. See below. 2021 Chemistry 2nd event Samples: IA-06, IA-07 Tested by: TP4, TP5, former TP's RG and EP 5. In an interview at 11:10 a.m. on 07/29/22, the TC confirmed the above finding and indicated patient specimens would not be tested in this manner. .</p>
<b>D6051</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)(v)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.</p>

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the Technical Consultant (TC) failed to ensure four of seven testing personnel were assessed at least annually in 2021 through testing previously analyzed specimens, blind samples, or proficiency testing samples. Findings are as follows: 1. The laboratory performed Prostrate Specific Antigen (PSA) testing as confirmed by the TC during a tour of the laboratory at 10:00 a.m. on 07/29/22. 2. The Employee Training and Competency procedure found in the Education, Training, and Competency manual indicated competency assessments were documented on the laboratory Training and Competency Review form. This form included the assessment of blind samples or proficiency testing samples. 3. PSA proficiency testing or blind sample competency assessments were not found in 2021 laboratory records for the following four of seven TP in 2021: TP1, TP2, TP3, TP7 4. The laboratory was unable to provide the missing blind sample evaluation documents upon request. 5. In an interview at 11:40 a.m. on 07/29/22, the TC confirmed the above finding.