

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0916444	(X3) Date Survey Completed 06/22/2023
Name of Provider or Supplier Minnesota Urology	Street Address, City, State 3366 Oakdale Ave N Suite 303, Robbinsdale, MN	
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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES 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 four of six PT events in 2022 and 2023 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 Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 06/22/23. 2. The laboratory performed PT 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 multiple times in three of three PT events reviewed from 2022 and one of two PT events reviewed from 2023 as indicated on testing labels affixed to the API attestation statements. See below. 2022 Chemistry 1st event Date of testing: 01/27/22 Samples Time of test IA-01 11:15, 12:11, 12:20 IA-02 9:05, 9:59, 10:26 2022 Chemistry 2nd event Date of testing: 06/03/22 Samples Time of test IA-06 6:16, 7:20, 8:00 IA-07 6:31, 7:05, 9:04 2022 Chemistry 3rd event Date of testing: 08/25/22 Samples Time of test IA-11 11:58, 12:41, 12:45 IA-12 12:12, 12:58, 13:55 2023 Chemistry 2nd event Date of testing: 06/06/23 Samples Time of test IA-06 12:23, 13:10, 15:28 IA-07 12:09, 12:46, 15:41 5. In an interview at 11:20 a.m. on 06/22/23, TP1 confirmed the above finding. .</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p>

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the laboratory director failed to approve each and every policy and procedure in use by the laboratory. Findings are as follows: 1. The laboratory performed Prostrate Specific Antigen (PSA) testing as confirmed by the Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 06/22/23. 2. The following manuals were observed as present and available for use on date of survey: -FastPack System Procedure Manual -FastPack System QA Manual -FastPack System QA Log - Procedure Manual Clinitek and Qualigen -Procedure and Safely Manual 3. Laboratory Director approval of the manuals and the policies and procedures contained therein was not found during review on date of survey. 4. In an interview at 12:00 p.m. on 06/22/23, TP1 confirmed the above finding. 5. The Laboratory Director assumed the role on 01/11/22 as indicated in Federal database records. .

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform quality control (QC) activities as established in an Individualized Quality Control Plan (IQCP) for 75 patient specimens tested in 2021. Findings are as follows: 1. The laboratory performed Prostrate Specific Antigen (PSA) testing as confirmed by the Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 06/22/23. 2. Three Qualigen FastPack Systems were observed as present and available for use during the tour. 3. QC performance using two levels of control material was required weekly as established in the Qualigen procedure found in the Clinitek and Qualigen Procedure Manual and in the laboratory's IQCP for the test. 4. The laboratory exceeded the weekly QC performance time interval for 75 patient specimens tested in the time frame reviewed, October through December of 2021, as indicated in laboratory records. See below. QC date QC due QC performed 10/18/21 10/25/21 10/28/21 4 patient specimens were tested on 10/26/21 8 patient specimens were tested on 10/27/21 QC date QC due QC performed 11/01/21 11/08/21 11/12/21 1 patient specimen was tested on 11/09/21 7 patient specimens were tested on 11/10/21 23 patient specimens were testing on 11/11/21 QC date QC due QC performed 11/29/21 12/06/21 12/09/21 12 patient specimens were tested on 12/07/21 7 patient specimens were tested on 12/08/21 QC date QC due QC performed 12/12/21 12/19/21 12/21/21 13 patient specimens were tested on 12/20/21 5. In an interview at 1:20 p.m. on 06/22/23, TP1 confirmed the above finding. .