

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D0865477	<b>(X3) Date Survey Completed</b>  11/07/2018
<b>Name of Provider or Supplier</b>  Urology Of Indiana, Llc	<b>Street Address, City, State</b>  8240 Naab Road, Suite 200, Indianapolis, IN	
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>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to maintain a copy of instrument printouts and attestation statements for two of two assays reviewed (Urinalysis and Semen testing) for three of three events in 2017 and two of two events in 2018. Annual test volume amounts for Urinalysis and Semen testing=1,678. Findings Include: 1) Review of the laboratory's policy titled, "PROFICIENCY TESTING," policy number "ORG-5 V.2," approved by the laboratory director on 10/18/18 reads on page 2, "The PT attestation statement is signed by the Laboratory Director and the individual (s) performing the testing...All paperwork involving PT samples is saved for at least two years. This includes instrument printouts..." 2) Review of proficiency testing records for Urinalysis and Semen testing indicated the following events had no instrument printouts for the test results reported to the proficiency testing provider, API (American Proficiency Institute): a) Event 1/2017: Urinalysis testing and Semen testing b) Event 2/2017: Semen testing c) Event 1/2018: Semen testing 3) Review of proficiency testing records for Urinalysis and Semen testing indicated the following attestation statements were not available for review: a)</p>

Events 1&3/2017: Urinalysis testing b) Events 1&2/2017: Semen testing 4) Medical record review indicated the following patients had Urinalysis and Semen testing performed in 2017 and 2018: Semen testing (671 annually): a) PT#1 on 10/16/18 at 9:56 am b) PT#2 on 9/18/18 at 11:44 am c) PT#3 on 8/27/18 at 11:24 am d) PT#4 on 2/13/18 at 12:42 am e) PT#5 on 7/3/18 at 9:00 am f) PT#13 on 4/17/17 at 2:31 pm g) PT#14 on 5/8/17 at 3:40 pm Urinalysis (1,007 annually): a) PT#6 on 1/26/18 at 10:40 am b) PT#7 on 11/20/17 at 12:18 pm c) PT#8 on 2/9/18 at 1:05 pm d) PT#9 on 3/23/18 at 10:17 am e) PT#10 on 4/27/18 at 3:46 pm f) PT#11 on 7/20/18 at 12:43 pm g) PT#12 on 8/25/17 at 12:35 pm 5) In interview on 11/7/18 at 2:00 pm, SP-2 confirmed attestation statements and instrument printouts were not maintained and available for review for the above listed proficiency testing events.

**D6091**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure 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 record review and interview the laboratory director failed to ensure proficiency testing reports were reviewed by the laboratory director or designee for one of five events reviewed (Event 1/2017) for two of two analytes (Urinalysis and Semen Analysis). Annual test volume amounts for Urinalysis and Semen testing=1,678. Findings Include: 1) Review of the laboratory's policy titled, "PROFICIENCY TESTING," policy number "ORG-5 V.2," approved by the laboratory director on 10/18/18 reads on page 2, "...All PT results are reviewed by the Laboratory Director or designee upon receipt. Failures, unacceptable scores, and lack of participation issues are addressed within 30 days of result receipt." 2) Review of proficiency testing scores for Event 1/2017 for Urinalysis (UA) and Semen testing indicated the following failing scores reported by API (American Proficiency Institute): Urinalysis=0% (bilirubin, glucose, ketones, leukocytes, nitrite, pH, protein, urobilinogen) Semen=50% (sperm count and sperm motility) 3) Medical record review indicated the following patients had urine and semen testing performed with results reported in 2017: Urinalysis (1,007 annually): a) PT#7 on 11/20/17 at 12:18 pm b) PT#12 on 8/25/17 at 12:35 pm Semen testing (671 annually): a) PT#13 on 4/17/17 at 2:31 pm b) PT314 on 5/8/17 at 3:40 pm 4) Upon request for the laboratory director and/or designee review documentation for the above failed event, SP-2 confirmed on 11/07/18 at 1:26 pm, none was available.

**D6092**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(4)(iv)

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:  
Based on document review and interview, the laboratory director failed to ensure the corrective action plan ("Proficiency Testing") was followed when proficiency testing results were unsatisfactory for one of five events reviewed (Event 1/2017) for two of two analytes (Urinalysis and Semen Analysis). Annual test volume amounts for

Urinalysis and Semen testing=1,678. Findings Include: 1) Review of the laboratory's policy titled, "PROFICIENCY TESTING," policy number "ORG-5 V.2," approved by the laboratory director on 10/18/18 reads on page 2, "...Corrective action is taken and documented for each unacceptable result/report..." The policy further states on page 3, "...If the laboratory fails a PT event, remedial action is taken...Details of the investigation are maintained with the proficiency testing data." 2) Review of proficiency testing scores for Event 1/2017 for Urinalysis (UA) and Semen testing indicated the following failing scores reported by API (American Proficiency Institute): Urinalysis= 0% (bilirubin, glucose, ketones, leukocytes, nitrite, pH, protein, urobilinogen) Semen=50% (sperm count and sperm motility) 3) Medical record review indicated the following patients had urine and semen testing performed with results reported in 2017: Urinalysis (1,007 annually): a) PT#7 on 11/20/17 at 12:18 pm b) PT#12 on 8/25/17 at 12:35 pm Semen testing (671 annually): a) PT#13 on 4/17 /17 at 2:31 pm b) PT314 on 5/8/17 at 3:40 pm 4) Upon request for corrective action documentation for the above failed event, SP-2 confirmed on 11/07/18 at 1:26 pm, none was available.