

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0991526	(X3) Date Survey Completed 03/16/2018
Name of Provider or Supplier Arizona Urology Specialists, Llc - Tpk	Street Address, City, State 17300 N Perimeter Dr, 2nd Floor, Scottsdale, AZ	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES 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 lack of proficiency testing (PT) attestation statements presented for review for 2016 and 2017 and interview with the facility personnel, the laboratory failed to provide evidence of the testing personnel and director's attestations that PT samples were tested in the same manner as patient specimens. Findings include: 1. The laboratory performs semen analysis and anti-sperm antibody(ASA) testing under the specialty of Hematology and the sub-specialty, General Immunology with an approximate annual test volume of 576. The laboratory participates in two annual PT events as a means to verify the accuracy of testing. 2. PT attestation statements for each event of 2016 and 2017 were not provided to the surveyor for review. 3. The facility personnel acknowledged that the attestation statements indicated above were not available for review at the time of the survey.</p>