

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0991526	(X3) Date Survey Completed 02/01/2023
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 for review from 2021 and 2022 and interview with the testing personnel, the laboratory failed to provide evidence of the testing personnel and director's attestations to the routine integration of PT samples into the workload using the laboratory's routine methods. Findings include: 1. The laboratory participates in two PT events annually for Semen Analysis testing. 2. The PT attestation statements from each testing event of 2021 and 2022 were not provided to the surveyor for review during the survey conducted on February 1, 2023. 3. The testing personnel interviewed on 2/01/23 at 10:30am acknowledged that the attestation statements indicated above were not available for review at the time of the survey.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an</p>

ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on review of Proficiency Testing (PT) records from 2021 and interview with the testing personnel, the laboratory failed to document corrective action for unsatisfactory PT scores for testing performed under the specialty of Hematology. Findings include: 1. The laboratory participates in PT for Semen Analysis including, but not limited to, the following test: Antisperm Antibody. The lab performs two Proficiency Testing events annually for Antisperm Antibody, with two separate samples tested with each event. 2. The laboratory received a score of 0% on one out of two samples tested for the analyte, Antisperm Antibody IgA, during the second testing of 2021. 3. No documentation of corrective action was presented for review during the survey to indicate the laboratory investigated and corrected issues found with the unsatisfactory PT score indicated above. 4. The testing personnel interviewed on 2/01/23 at 10:45am confirmed that the laboratory failed to document corrective action for the unsatisfactory PT score referenced above.

D5473

CONTROL PROCEDURES

CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on lack of Quality Control (QC) documentation and interview with the testing personnel, the laboratory failed to document the intended reactivity of staining materials used for testing performed in the specialty of Hematology. Findings include: 1. The laboratory performs semen analysis testing in the specialty of Hematology, with an approximate annual test volume of 800. 2. It is the practice of the laboratory to perform a Leucoscreen stain if the specimen meets certain criteria established in the laboratory's procedure manual. 3. No documentation of stain acceptability was presented for review during the survey to indicate the laboratory tested the Leucoscreen stain (lot# LS071122 , exp. 2/02/24) for its intended reactivity on January 6, 2023. 4. One patient sample was tested with the Leucoscreen stain on January 6, 2023 (patient ID# 26732140). 5. The testing personnel interviewed on 2/01/23 at 11:40am confirmed that the laboratory failed to document the intended reactivity of the Leucoscreen stain prior to testing patient specimens on January 6, 2023.