

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0991526	(X3) Date Survey Completed 01/09/2025
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
D5425	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3)</p> <p>The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control records for semen analysis testing and interview with the technical supervisor (TS), the laboratory failed to establish and define acceptable ranges for the control material, Accu-Beads+. Findings include: 1. The laboratory performs Semen Analysis testing (count and morphology) under the specialty of Hematology with a reported annual test volume of 800. The laboratory uses a Makler chamber to perform the sperm count. 2. The QC ranges listed on the laboratory's QC forms failed to align with the manufacturer's QC ranges for the Accu-Beads+ control material. 3. The laboratory's QC forms used from January 1, 2023 through the survey date on January 9, 2025 indicated two levels of Accu-Beads+ QC material are used each day of patient testing with the following acceptable ranges: - Accubead Count 1 - (30-40 M/ml) using a Leja chamber, (33-59 M/ml) using a Makler chamber - Accubead Count 2 - (15.5-20.5 M/ml) using a Leja chamber, (16-30 M/ml) using a Makler chamber 4. The manufacturer's package insert for the Accu-beads+ control material in use at the time of the survey (lot# 232908181, exp. 09 /2025) failed to list an acceptable range for QC results if using a Makler chamber. The package insert listed the following: - For Fixed Coverslip Chambers: vial 1 = 35 +/- 5 M/ml, vial 2 = 18 +/- 2.5 M/ml - For Hemacytometer: vial 1 = 46 +/- 7 M/ml, vial 2 = 23 +/- 4 M/ml 5. The laboratory failed to provide documentation of established control procedures for the control material, Accu-Beads+, using a Makler chamber, specifically establishment of the QC ranges that are listed on the laboratory's QC forms for the Makler chamber. 6. The TS interviewed on 1/09/25 at 10:45 AM acknowledged that the laboratory could not produce documentation to show the QC</p>

ranges listed on the laboratory's QC forms for the Makler chamber were established by the laboratory.