

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D1102253	(X3) Date Survey Completed 05/26/2026
Name of Provider or Supplier Arizona Urology, Llc	Street Address, City, State 13555 W McDowell Rd, Suite 302, Goodyear, 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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, direct observation of patient specimens, and interview with the laboratory director (LD) on 5/26/26 at 2:56 PM, (A) the laboratory failed to include the date and time of specimen collection on the specimen label from November 2025 through May 2026; and (B) the laboratory failed to establish policies and procedures for specimen preservation and specimen acceptability and rejection. Findings include: 1. The laboratory began patient testing on 11/07/25 on the Sciteck AUA-450 analyzer in the subspecialty of Urinalysis, and reports an annual test volume of 14,400. A2. The laboratory's established policy titled, "Specimen Labeling Requirements" states, "Required Label Elements - Each specimen must include the following: Date of Collection, Time of Collection." A3. Direct observation of patient specimens maintained in the laboratory on 5/26/26 revealed the specimen labels failed to include the date and time of collection. A4. The LD interviewed on 5/26/26 at 2:56 PM confirmed the laboratory failed to include the date and time of collection on the specimen labels, as required in laboratory policy, from 11/07/25 through 5/26/26. B1. The policy and procedure manual reviewed on 5/26/26 failed to include evidence of established policies and procedures for specimen acceptability, specimen rejection and specimen preservation (stability). B2. The LD</p>

interviewed on 5/26/26 at 3:31 PM confirmed the laboratory failed to present evidence of established policies and procedures for specimen acceptability, specimen rejection and specimen preservation (stability).

D5807

TEST REPORT

CFR(s): 493.1291(d)

(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on review of the approved reference ranges in the laboratory procedure manual, review of patient test reports generated from the laboratory information system (LIS) and interview with the laboratory director (LD) on 5/26/26 at 2:14 PM, the laboratory failed to ensure the test report included pertinent reference ranges as determined by the laboratory, during the timeframe of 11/07/25 through 5/26/26. One of the twelve urine parameters (Urine Bilirubin) listed on the LIS test report differed from those in the approved procedure manual. Findings include: 1. Review of patient reports from the LIS system revealed one of the twelve parameters for urinalysis testing failed to correctly match those reference ranges determined by the laboratory and listed in the procedure manual. Urine Bilirubin LIS reference range: 0.0-1.4 mg/dL Urine Bilirubin reference range listed in procedure manual: 0.0-0.9 mg/dL 2. Interview with the LD on 5/26/26 at 2:14 PM confirmed the laboratory failed to ensure correct reference ranges for Urine Bilirubin were included on the LIS patient reports for the timeframe of 11/07/25 through 5/26/26. 3. The laboratory began patient testing on the Sciteck AUA-450 urinalysis analyzer on 11/07/25 and reports approximately 14,400 tests annually.