

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0991404	(X3) Date Survey Completed 02/27/2025
Name of Provider or Supplier Arizona Andrology Lab & Cryobank	Street Address, City, State 850 N Kolb Rd Ste B, Tucson, 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's test procedure for Semen Analysis testing and interview with the Technical Supervisor (TS), the Semen Analysis test procedure failed to include requirements for storage and preservation of the specimen. Findings include: 1. The laboratory performs Semen Analysis testing in the specialty of Hematology, with a reported annual test volume of 1,100. 2. The "Post Vasectomy Semen Analysis" test procedure reviewed during the survey conducted on February 27, 2025 failed to include storage and stability requirements for the specimen. 3. The</p>

TS interviewed on 2/27/2025 at 11:50 AM confirmed the test procedure presented for review during the survey failed to include storage and stability requirements for semen specimens.

D5801

TEST REPORT
CFR(s): 493.1291(a)

(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:
Based on review of patient-specific data maintained in the electronic medical record (EMR), review of laboratory worksheets used to record patient-specific data and test result information and interview with the Technical Supervisor (TS), the laboratory failed to accurately report the time of collection for one out of three patient records reviewed for Semen Analysis testing. Findings include: 1. The laboratory performs Semen Analysis testing in the specialty of Hematology, with an approximate annual test volume of 1,100. 2. The laboratory utilizes a worksheet to record patient-specific data and test result information for Semen Analysis testing. The final test result, patient-specific data and specimen-specific data are manually transcribed by laboratory personnel into the laboratory's EMR system, Fertility Pro. 3. The laboratory failed to accurately transcribe the time of collection into the EMR for 1 out of 3 patient records reviewed during the survey (accession# 250020 from 1/15/25). The worksheet indicated the time of collection as 0821 and the EMR showed the time of collection as 20:21. 4. The TS interviewed on 2/27/25 at 11:45 AM confirmed that the laboratory failed to accurately transcribe the time of collection into the EMR for the patient indicated above.

D6175

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1495(b)(1)

(b) Each individual performing high complexity testing must-- (b)(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;

This STANDARD is not met as evidenced by:
Based on review of the laboratory's test procedure for Semen Analysis testing, review of patient test requisitions and test reports for Semen Analysis testing and interview with the Technical Supervisor (TS), the testing personnel failed to follow the laboratory's procedures for testing the sample within the established timeframe for one out of three patient records reviewed. Findings include: 1. The laboratory performs semen analysis testing in the specialty of Hematology, with a reported annual test volume of 1,100. 2. The laboratory's test procedure for Post Vasectomy Semen Analysis states, "Record time examined. All specimens should be examined within 1 hour to ensure highest possible accuracy." 3. One out of three patient records

reviewed (accession# 250020 from 1/15/25) indicated the sample was collected at 8:21 AM and examined at 9:30 AM. 4. The testing personnel failed to test the sample indicated above within the 1 hour timeframe as instructed in the Post Vasectomy Semen Analysis test procedure. 5. The TS interviewed on 2/27/25 at 11:40 AM confirmed that the specimen referenced above was not tested within the laboratory's established timeframe listed in the test procedure for Post Vasectomy Semen Analysis.