

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0991404	(X3) Date Survey Completed 02/08/2023
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 personnel form, the laboratory's lack of delegation of responsibility Policy or procedure and interview with the laboratory technical supervisor listed on the CMS-209 (TS-TP1) on August 08, 2022, the laboratory failed to establish written policies and procedures to assess employee and supervisor competency. Findings include: 1. The laboratory's CMS-209 personnel form lists one individual who is listed as the technical supervisor (TS-1), general supervisor (GS-1) and testing personnel (TP-1). The form also lists one individual who is listed as a testing personnel (TP-2). 2. The laboratory lacked documentation of competency assessments for the two (2) testing personnel listed on the CMS-209 form. See D6127 and D6128 for specific findings. 3. The laboratory lacked a policy or procedure for documenting annual competency assessments for persons performing preanalytical, analytic and post-analytic patient testing. 4. The laboratory lacked a policy or procedure for evaluation and documentation of the general supervisor and technical supervisor competency. 5. The laboratory TS-TP1 confirmed by interview on February 8, 2023 at 11:20 am, the lack of policy or procedures for performing and documenting competency for testing personnel, and supervisor competency. 6. The laboratory performs Semen Analysis testing in the specialty of Hematology, with an approximate annual test volume of 1,000.</p>
D6127	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p>

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on lack of documentation of a semi-annual competency evaluation for one testing personnel and interview with the technical supervisor, the technical supervisor failed to evaluate and document the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. Findings include: 1. No evidence of a semi-annual competency evaluation was presented for review for one testing personnel who began Semen Analysis testing in the specialty of Hematology on April 1, 2021. 2. The technical supervisor interviewed on 2/08/23 at 10:55am confirmed that the technical supervisor failed to document a semi-annual competency evaluation for the testing personnel indicated above.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on lack of testing personnel competency evaluation documentation and interview with the technical supervisor, it was determined that the technical supervisor failed to evaluate and document the performance of two out of two testing personnel at least annually. Findings include: 1. During the survey conducted on February 8, 2023, no documentation of an annual competency assessment from 2020, 2021 and 2022 was presented for review for one testing personnel who performs Semen Analysis testing on patient specimens in the specialty of Hematology. 2. During the survey conducted on February 8, 2023, no documentation of an annual competency assessment from 2022 was presented for review for one testing personnel who began Semen Analysis testing on patient specimens in April 2021. 3. The technical supervisor interviewed on 2/08/23 at 10:56am confirmed that no annual competency evaluation was performed during 2020, 2021 and 2022 as indicated for the testing personnel referenced above.