

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D1097308	<b>(X3) Date Survey Completed</b>  09/20/2022
<b>Name of Provider or Supplier</b>  Arizona Skin & Laser Therapy Institute	<b>Street Address, City, State</b>  2224 W Northern Ave, Ste D-302, Phoenix, AZ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on lack of accuracy verification documentation for review and interview with the facility personnel, the laboratory failed to verify the accuracy of testing performed under the sub-specialty of Histopathology at least twice annually during 2020 and 2021. Findings include: 1. No documentation was presented for review during the survey conducted on September 20, 2022 to indicate the laboratory verified the accuracy of the microscopic interpretation (reading/diagnosis) of histopathology specimens at least twice annually during 2020 and 2021. 2. The facility personnel interviewed on 9/20/22 at approximately 10:05am confirmed that the laboratory failed to verify the accuracy of histopathology testing at least twice annually during 2020 and 2021. 3. The laboratory's approximate annual test volume under the sub-specialty of Histopathology is 27,079.</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation of histopathology stain reagents and interview with the facility personnel, the laboratory used the stain reagent, Hematoxylin, past the</p>

expiration date. Findings include: 1. The laboratory performs the PAS (Periodic acid-Schiff) stain on patient slides in conjunction with dermatopathology biopsy interpretations, with an approximate annual test volume of 27,079. 2. During the survey conducted on September 20, 2022, direct inspection of the Hematoxylin reagent used with the PAS stain, lot #109495, indicated an expiration date of August 2022. 3. The laboratory used the stain reagent for 7 days past the reagent expiration date. A total of 16 patients were tested using the expired reagent. 4. At approximately 10:25am on 9/20/22, the facility personnel interviewed stated that the expired reagent indicated above was in use at the time of the survey.

**D5787**

**TEST RECORDS**  
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:  
Based on review of pathology test records and interview with the facility personnel, the laboratory failed to maintain a record system that includes the identity of the individual who performs the gross description on histopathology specimens. Findings include: 1. The laboratory performs the gross description on skin biopsies under the sub-specialty of Histopathology, with an approximate annual test volume of 27,079. 2. No documentation was presented for review during the survey performed on September 20, 2022 to indicate the laboratory maintained a record system to include the identity of the personnel who performs the gross description on histopathology specimens. 3. The facility personnel confirmed the laboratory failed to maintain a record system that includes the identity of the testing personnel who performs the gross description on patient specimens.

**D6102**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:  
Based on lack of training documentation for two out of two testing personnel who perform testing in the sub-specialty of Histopathology and interview with the facility personnel, the laboratory director failed to ensure that all testing personnel receive the appropriate training and demonstrate that they can perform all testing operations reliably and accurately prior to testing patients' specimens. Findings include: 1. No initial training documentation was presented for review for two out of two testing personnel hired in February 2022 and August 2022, who perform the gross evaluation on patient specimens in the sub-specialty of Histopathology. 2. The facility personnel

confirmed that the laboratory failed to have documentation of initial training for the testing personnel indicated above.

**D6127**

**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 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 facility personnel, 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 individuals tested patient specimens. Findings include: 1. No semi-annual competency evaluation documentation was presented for review for one testing personnel who began grossing patient specimens in February 2022. 2. The facility personnel confirmed that the technical supervisor failed to document a semi-annual competency evaluation for the testing personnel indicated above.