

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2056360	(X3) Date Survey Completed 11/05/2024
Name of Provider or Supplier Epiphany Dermatology Of Arizona, Llc	Street Address, City, State 2525 E Carefree Hwy, Ste 144, Bldg 6, Phoenix, 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
D5217	<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 Biopsy Interpretations, review of laboratory policies and interview with the facility personnel, the laboratory failed to verify the accuracy of testing performed under the subspecialty of Histopathology at least twice annually during 2022, 2023 and 2024. Findings include: 1. No documentation was presented for review to indicate the laboratory verified the accuracy of Biopsy Interpretations at least twice annually during 2022, 2023 and 2024 (through the date of the survey conducted on 11/05/24). 2. The laboratory's established policy titled, "Laboratory: Quality Assessment, Proficiency Testing" states, "Proficiency shall be assessed at least semiannually." 3. The facility personnel interviewed on 11/05/24 at 2:50 PM confirmed the laboratory failed to verify the accuracy of histopathology testing at least twice annually during 2022, 2023 and 2024. 4. The laboratory's reported annual test volume in the subspecialty of histopathology is 12,100.</p>
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:

Based on lack of Quality Control (QC) documentation and interview with the facility personnel, the laboratory failed to document the acceptability of the Hematoxylin & Eosin (H&E) staining materials on 2 out of 4 testing days reviewed during the survey, for intended reactivity and to ensure predictable staining characteristics. Findings include: 1. The laboratory performs Biopsy Interpretations under the subspecialty of Histopathology with a reported annual test volume of 12,100. 2. Testing records reviewed during the survey indicated the laboratory failed to document the acceptability of the H&E stain on 2 out of 4 testing days, 12/01/22 and 6/08/24. 4. The number of patient specimens read and diagnosed on 12/01/22 and 6/08/24 could not be determined at the time of the survey. 5. The facility personnel interviewed on 11/05/24 at 2:40 PM confirmed the laboratory failed to document the H&E stain acceptability each day of use for intended reactivity and to ensure predictable staining characteristics on the testing dates indicated above.