

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2155756	(X3) Date Survey Completed 05/23/2023
Name of Provider or Supplier Epiphany Dermatology Of Arizona, Llc	Street Address, City, State 6648 E Carondelet Dr, 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
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> <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 Hematoxylin & Eosin (H&E) staining materials each day of use, for intended reactivity to ensure predictable staining characteristics. Findings include: 1. The laboratory began reading and diagnosing patient specimens during the Mohs procedure in the sub-specialty of Histopathology on August 14, 2020, with a reported annual test volume of 903. Each Mohs specimen is stained with the H&E stain prior to the microscopic interpretation. 2. During the survey conducted on May 23, 2023, no documentation of the H&E stain acceptability was presented for review for testing that occurred on April 8, 2022 and April 15, 2022. 3. A total of 8 Mohs cases were performed on the dates indicated above. 4. The facility personnel interviewed on May 23, 2023 at 11:05am confirmed the laboratory failed to document the H&E stain acceptability on the testing dates indicated above, for intended reactivity to ensure predictable staining characteristics.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The</p>

laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality assessment (QA) records, review of the Quality Control Staining log and interview with the facility personnel, the laboratory's QA processes failed to identify and correct errors found in the analytic systems specified in 493.1251 through 493.1283. Findings include: 1. The laboratory processes and interprets dermatopathology slides from patient specimens for Mohs testing. The laboratory's approximate annual test volume is 903. 2. The laboratory failed to document the acceptability of the H&E stain used on patient specimens on each day of use in April 2022. See D5473 for specific findings. 3. The laboratory utilizes a "Monthly Quality Assurance Checklist" which includes, but is not limited to, the following items that are monitored by the laboratory: "All quality control /calibrations were performed and were within acceptable limits before test results were reported", and "Quality control results were examined for possible problems." The laboratory completes the form on a monthly basis and marks a 'Y' (Yes), 'N' (No), or 'N/A' (Not Applicable) next to each item. 4. Review of the 'Monthly Quality Assurance Checklist' from April 2022 (documented by laboratory personnel on 5/06 /22) indicated a "Y" next to "All quality control/calibrations were performed and were within acceptable limits before test results were reported", and there was no documentation next to "Quality control results were examined for possible problems". 5. The laboratory's QA process failed to identify and correct errors found with the performance and documentation of the H&E stain acceptability during April 2022. 6. The facility personnel interviewed on May 23, 2023 at 11:20am confirmed that the laboratory's QA process failed to identify and correct errors found with documenting the H&E Stain acceptability on each day of use.