

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0930456	(X3) Date Survey Completed 08/22/2022
Name of Provider or Supplier Epiphany Dermatology	Street Address, City, State 1916 Paseo San Luis, Sierra Vista, 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
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 laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's established quality assessment (QA) policies and procedures, review of the Quality Control Staining log and interview with the facility personnel, the laboratory's QA processes failed to monitor, identify and correct errors found in the analytic portion of histopathology testing which is performed by the laboratory. Findings include: 1. The laboratory processes and interprets dermatopathology slides from patient specimens for Mohs testing. The laboratory's approximate annual test volume is 464. 2. The laboratory utilizes a Quality Control Staining log to record the results of the Hematoxylin & Eosin (H&E) stain acceptability each day of patient testing. The log contains the date, case#, stain acceptability, and a corrections column which lists the initials of the individual documenting the form. 3. Review of the Quality Control Staining log for April 2022 indicated the form was completed on the following testing dates, in this order: 4/13/22, 4/14/22, 4/18/22, 3/19/22, 3/20/22, 3/21/22, 4/26/22, and 4/27/22. 4. No QA documentation was presented for review during the survey to indicate the laboratory monitored, identified and corrected issues found with the date discrepancies recorded on the Quality Control Staining log for April 2022. 5. The facility personnel interviewed during the survey on August 22, 2022 at approximately 1:20pm confirmed that the laboratory failed to monitor, identify and correct errors found with documenting the correct date on the Quality Control Staining log indicated above.</p>