

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2057816	(X3) Date Survey Completed 02/13/2023
Name of Provider or Supplier Yuma Dermatology	Street Address, City, State 1079 W 23rd Street, Yuma, 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 staining materials each day of use for intended reactivity to ensure predictable staining characteristics. Findings include: 1. The laboratory performs the microscopic interpretation of Mohs specimens under the sub-specialty of Histopathology, with an approximate annual test volume of 530. The laboratory performs the Hematoxylin and Eosin (H & E) stain on each specimen prior to the microscopic interpretation. 2. The laboratory failed to perform and document the H & E stain acceptability each day of use for intended reactivity to ensure predictable staining characteristics for testing that occurred on the following dates: 1/25/2023, 1/24/2023, 1/11/2023, 1/10/2023, 10/05/2022, 9/22/2022, 9/21/2022, 8/25/2022, 4/20/2021, 4/19/2021, 4/05/2021, 3/30/2021, 3/29/2021, 3/16/2021, 3/15/2021, 3/01/2021, and 1/18/2021. 3. The number of patient specimens tested using the H & E Stain on the testing dates indicated above could not be determined at the time of the survey. 4. The facility personnel interviewed on February 13, 2023 at 1:45pm confirmed the laboratory failed to document the H&E stain acceptability for intended reactivity to ensure predictable staining characteristics on the testing dates indicated above.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</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.

This STANDARD is not met as evidenced by:

Based on review of established quality assessment (QA) policies and procedures for review and interview with the facility personnel, the laboratory failed to follow established QA policies and procedures to monitor, assess and correct errors found in the analytic systems specified in 493.1251 through 493.1283. Findings include: 1. The laboratory performs the microscopic interpretation of Mohs specimens under the sub-specialty of Histopathology, with an approximate annual test volume of 530. The laboratory performs the Hematoxylin and Eosin (H & E) stain on each specimen prior to interpretation. 2. The laboratory's established QA policy titled, "Yuma-Laboratory Quality Assurance Policy" states, "The clinic laboratory shall randomly pick at a minimum two (2) patient samples, including slides, Mohs map, procedure note, and pathology report, at least twice a year to be audited for accuracy." 3. The laboratory's audit (QA) documentation presented for review from 2021 and 2022 failed to identify and correct errors found with the lack of performance of the Hematoxylin and Eosin (H & E) stain acceptability each day of patient testing. See D5473 for findings. 4. During the survey conducted on February 13, 2023, the laboratory presented corrective action documentation for review for errors associated with quality control performance during 2021 through 1/25/2023, specifically the failure to perform and document Hematoxylin & Eosin (H&E) stain acceptability each day of patient testing, however the corrective action was not completed until 2/08/2023. 5. The laboratory failed to identify and correct errors with quality control performance as they occurred during 2021 through 1/25/2023, as evidenced by the corrective action documentation that was not completed until 2/08/2023. 6. The facility personnel interviewed on February 13, 2023 at 1:55pm confirmed that the laboratory failed to identify QC errors during the QA audit and failed to identify and correct QC errors as they occurred during 2021 through 1/25/2023.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on lack of H & E Stain Acceptability records for review for testing that occurred during 2021 through January 25, 2023, the laboratory director failed to ensure that quality control programs are maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5473 and D5791 for findings.