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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 03D1098554 | (X3) Date Survey Completed 10/03/2023 |
| Name of Provider or Supplier Integrated Dermatology Of Yuma | Street Address, City, State 2500 S 8th Ave Ste 101, 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 |
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| D5433 | <p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's microscope maintenance policy and interview with the facility personnel, the laboratory failed to perform and document the annual and bi-monthly maintenance of the microscope used for patient testing during 2021, 2022 and 2023. Findings include: 1. The laboratory's established maintenance protocol for the microscope used to read patient slides indicates the stage and oculars are cleaned bi-monthly (every 2 months) and a grounding and cleaning is performed yearly. 2. The laboratory failed to provide evidence of annual maintenance activities for the microscope from 2021 and 2022. 3. The laboratory failed to provide evidence of bi-monthly maintenance performance for the microscope from February 3, 2021 though the date of the survey performed on 10/03/2023. 4. The facility personnel interviewed on October 03, 2023 at 12:55 PM confirmed the laboratory failed to provide documentation of annual and bi-monthly maintenance for the microscope used by the laboratory to read patient slides during the timeframes indicated above. 5. The laboratory's reported annual test volume in the subspecialty of Histopathology is 500.</p> |
| D5607 | <p>HISTOPATHOLOGY CFR(s): 493.1273(d)(f)</p> |

(d) Tissue pathology reports must be signed by an individual qualified as specified in paragraph (b) or, as appropriate, paragraph (c) of this section. If a computer report is generated with an electronic signature, it must be authorized by the individual who performed the examination and made the diagnosis. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of tissue pathology reports and interview with the facility personnel, the qualified individual who performed the examination and made the diagnosis failed to sign the Mohs test report for one out of three patient test reports reviewed during the survey. Findings include: 1. The laboratory performs patient testing in the subspecialty of Histopathology, with an approximate annual test volume of 500. 2. One out of three Mohs test reports (22-316) reviewed in the Electronic Health Record (EHR) failed to include the electronic signature of the individual who performed the examination and made the diagnosis. 3. The facility personnel interviewed on October 03, 2023 at 12:55 PM confirmed the tissue pathology report indicated above was not signed by the individual who performed the examination and made the diagnosis.