

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D0535227	(X3) Date Survey Completed 11/17/2020
Name of Provider or Supplier New Mexico Dermatology Associates	Street Address, City, State 7520 Montgomery Blvd Ne, D5, Albuquerque, NM	
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
D0000	The following deficiencies were cited as the result of a recertification survey on 11/17/2020 for 42 CFR part 493 Laboratory Requirements.
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 interview with the Office Manager, the laboratory failed to establish a written microscope maintenance protocol, resulting in a failure to perform and document routine and preventative maintenance for either of the two microscopes used for the analysis of patient slides/cases. The laboratory read 275 Hematoxylin and Eosin (a commonly used staining method used in staining tissues) patient slides in 2019. Findings are: During interview on 11/17/2020 at 10:15 am, in response to a request for microscope maintenance records, the Office Manager stated that she thought the last microscope service was done on one of the microscopes in 2015. The Office Manager also stated that she didn't have any maintenance records.</p>
D5801	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from</p>

the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on the review of patient medical records, 2019 & 2020 pathology log, and interview with the Office Manager, the laboratory failed to have an adequate manual or electronic system to ensure the accuracy and the timely reporting of test results for 3 patients (Pt#2, Pt#3, Pt#8) of 10 patients (Pt#1 - Pt#10). Findings are: A. Review of the 2019 & 2020 pathology log and patient medical records revealed collection date discrepancies between the pathology log and the patient's final test report. 1. Final report for Pt#2 had an incorrect "Date Specimens Obtained" of 4/18/2018 instead of 4/18/2019, as noted on the pathology log and patient office visit notes. 2. Final reports confirmed the date of collection of biopsy sample or specimen for Pt#3 as being on 7/23/2019 and not on 7/22/2019, as indicated by the pathology log. B. Review of the medical records for Pt#8 revealed that the final test report was not in the medical record. 1. Review of the pathology log indicated that the biopsy for Pt#8 was collected on 10/08/2020. 2. As of the date of the survey (11/17/2020), 40 days after collection, there was no final report in the patient medical record. 3. During interview on 11/17/2020 at 12:00 pm, the Office Manager stated the transcriptionist (person responsible for typing the physician's verbal dictation) did not print the report because the patient's date of birth was missing. C. Review of the 2019 & 2020 pathology log and patient medical records revealed that the accession number on the final test report for 10 (Pt#1 - Pt#10) of 10 (Pt#1-Pt#10) did not match the accession number on the pathology log. 1. The laboratory recorded the accession number on the pathology log as "TKH (year)-(###)" but the final report used the following format "KH (year)-(###)."