| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 19D2197164 | 05/12/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Mcdaniel Dermatology And Skin Surgery Institute | 222 Hwy 21, Madisonville, LA | |

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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| **D0000** | A Recertification survey was performed at McDaniel Dermatology and Skin Surgery Institute, CLIA ID 19D2197164, on May 12, 2025. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited. |
| **D5391** | PREANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1249(a)<br><br>(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 preanalytic systems specified at 493.1241 through 493.1242.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policies, patient records, and interview with personnel, the laboratory failed to establish complete quality assessment procedures to identify issues within the pre-analytic system. Findings: 1. Review of the laboratory's policies and patient records revealed the laboratory utilized a "Monthly Patient Quality Assurance Checklist" that included a review of one (1) randomly selected patient case each month. The following items were monitored: a) "Pre-Analytical: Specimens were logged in correctly: Lab requisitions and maps contain correct information, specimens were handled and collected according to protocol and specimens were labeled legible prior to receipt in the laboratory." b) "Analytical: Specimen was logged and accession number given, dye markings were handled properly, Proper embedding was followed correctly, cryostat sectioning was done properly, any necessary remedial action was performed and documented, and quality control stain results were examined for possible problems." c) "Post Analytical: Slides were reviewed by surgeon and map/slides were properly reported by surgeon." 2. Review of randomly selected patient records revealed two (2) of eight (8) patients had the following incorrect information documented on the "Moh's map:" a) April 24, 2024: Patient MD24-220: Incorrect address of the facility submitting the specimen b) |

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| | February 4, 2025: Patient MD24-37: Incorrect Moh's accession number assigned. Surveyor's review of the Moh's case log book, patient slides, and electronic patient notes (final report) revealed the Moh's accession number was documented as MD25-37, which differed from the "Moh's Map." 3. In interview on May 12, 2025 at 2:18 pm, Assistant 1 stated the laboratory moved and operated from its current location on April 1, 2024. Assistant 1 stated the address on the "Moh's map" for Patient MD24-220 was the facility's old address and should have been updated to their current address. 4. In interview on May 12, 2025 at 2:29 pm, Assistant 1 and 2 stated the Moh's accession number for Patient MD24-37 was listed incorrectly on the "Moh's Map." Assistant 1 and 2 stated for the identified patient, the Moh's accession number should have been MD25-37, not MD24-37. 5. In further interview on May 12, 2025 at 2:29 pm, Assistant 1 stated the laboratory reviews one (1) randomly selected patient each month. Assistant 1 stated the selected patient's case information documented in the log book, "Moh's Map" form, slides and patient notes (final report) are compared and reviewed each month for accuracy. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with personnel, the Laboratory Director failed to ensure the quality assessment programs were established to assure the quality of laboratory testing. Refer to D5391. |