

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2089195	(X3) Date Survey Completed 06/17/2024
Name of Provider or Supplier Premier Dermatology	Street Address, City, State 1525 Hickory St, Abilene, TX	
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 laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, patient test records, and confirmed in interview, the laboratory failed to ensure patient histopathology (Mohs) slides were labeled with at least 2 unique patient identifiers for 34 of 34 slides in 2022 (December), 35 of 35 slides in 2023 (December) and 29 of 29 slides in 2024 (June). Findings included: 1. Review of the laboratory policy titled "SLIDE LABELING" revealed: " 2. Slides are to be labeled with mohs log accession number, patient last name, number of stages will be marked with Roman numeral; stage I, II, III, etc. Quadrant or number of tissue /chucks [sic] per stage will be marked numeral; # "1 ", "2", "3", etc. and, number of slides per case will be marked, level 'A', for first cuts, level 'B' for second and so on." The laboratory policy did NOT include labeling instructions to reliably identify patients using at least two unique patient identifiers to distinguish between specimens. 2. A random review of patient slides from 2022 (December), 2023 (December) and 2024 (June) revealed: 12/13/2022: 19 slides labeled with a patient last name, Mohs accession number, number of stages, quadrant number and slide number; 15 slides were labeled with patient last name and first initial, Mohs accession number, number of stages, quadrant number and slide number The Mohs accession numbers were as</p>

follows: 22M-077, 22M-078, 22M-079, 22M-080, 22M-081, 22M-082, 22M-083 12 /05/2023: 35 slides were labeled with patient last name and first initial, Mohs accession number, number of stages, quadrant number and slide number The Mohs accession numbers were as follows: 23M-052, 23M-053, 23M-054, 23M-055, 23M-056, 23M-057, 23M-058 06/11/2024: 29 slides were labeled with patient last name and first initial, Mohs accession number, number of stages, quadrant number and slide number The Mohs accession numbers were as follows: 24M-022, 24M-023, 24M-024, 24M-025, 24M-026, 24M-027 The laboratory failed to ensure patient histopathology (Mohs) slides were labeled with at least two unique patient identifiers. 3. During an interview on 06/17/2024 at 2:52 pm, the Receptionist after a review of the records, confirmed the above findings.

D5413

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)**

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

I. Based on review of laboratory policies, environmental records, and confirmed in staff interview, the laboratory failed to monitor the room temperature and humidity requirements for 20 of 20 days in 2022 (August through December), 53 of 53 days in 2023 (January through December) and 27 of 27 days in 2024 (January through June). Findings included: 1. Review of laboratory policy titled: "LABORATORY DAILY MAINTENANCE" stated: "7. Temperature charts and logs are checked daily or whenever in use [sic]" 2. Review of the laboratory "ROOM TEMP/HUMIDITY" records for 2022, 2023 and 2024 revealed: "1. 68 degrees F to 80 degrees F for temp & lwss [sic] than 60% for humidity [sic] 2. The room temperature will be checked at the beginning of each workday. Any corrective action will be documented for out of range and addressed immediately. 3. The humidity will be documented at the beginning of each workday. Any corrective action will be documented for out of range and addressed immediately." The log further revealed that each day of documentation the laboratory only documented the initials of the personnel completing the log and failed to document the numerical value of the temperature and humidity. The following dates were documented with initials only: 2022 August: 8, 9, 10, 26 September: 16, 26, 27, 28 October: 10, 11, 12, 27 November: 10, 14, 15, 16 December: 12, 13, 14, 20 2023 January: 13, 16, 17, 18 February: 3, 13, 14, 15 March: 3, 17, 27, 28, 29 April: 14, 24, 25, 26 May: 5, 22, 23, 24 June: 9, 12, 13, 14, 23 July: 7, 14, 24, 25, 26 August: 11, 21, 22, 23 September: 8, 11, 12, 13, 28 October: 6, 9, 10, 11, 20 November: 6, 7, 8, 17 December: 4, 5, 6, 15 2024 January: 5, 8, 9, 10, 26 February: 2, 5, 6, 7, 23 March: 4, 5, 6, 22 April: 5, 8, 9, 10 May: 3, 6, 7, 8, 20 June: 3, 10, 11, 12 The laboratory was asked to provide documentation, and none was provided. 3. During an interview on 06/17/2024 at 2:52 pm, the Receptionist after a review of the records, confirmed the above findings. Word Key: F- Fahrenheit II. Based on review of laboratory policies, environmental records, and confirmed in staff interview, the laboratory failed to monitor the cryostat temperature requirements for 20 of 20 days in 2022 (August through December), 53 of 53 days in 2023 (January

through December) and 27 of 27 days in 2024 (January through June). Findings included: 1. Review of laboratory policy titled: "CRYOSTAT MAINTENANCE" stated: "1. Console temperature is recorded daily. The cryostats should be maintained at -21 *C to no colder than -26*C for best sectioning. Any variance out of range will be recorded and reported to the supervisor, immediately. If the range variance cannot be repaired, the console will not be used until serviced." 2. Review of the laboratory "CRYOSTAT MAINTENANCE" records for 2022, 2023 and 2024 revealed: "1. Console temperature is recorded daily. 2. The cryostat should be maintained at -20 degrees C to -30 degrees C for best Mohs sectioning. Any variance out of range will be recorded and reported to the supervisor, immediately. If the range variance cannot be repaired, the console will not be used until serviced." The log further revealed that each day of documentation the laboratory only documented the initials of the personnel completing the log and failed to document the numerical value of the cryostat temperature. The following dates were documented with initials only: 2022 August: 8, 9, 10, 26 September: 16, 26, 27, 28 October: 10, 11, 12, 27 November: 10, 14, 15, 16 December: 12, 13, 14, 20 2023 January: 13, 16, 17, 18 February: 3, 13, 14, 15 March: 3, 17, 27, 28, 29 April: 14, 24, 25, 26 May: 5, 22, 23, 24 June: 9, 12, 13, 14, 23 July: 7, 14, 24, 25, 26 August: 11, 21, 22, 23 September: 8, 11, 12, 13, 28 October: 5, 9, 10, 11, 20 November: 6, 7, 8, 16 December: 4, 5, 6, 15 2024 January: 5, 8, 9, 10, 27 February: 2, 5, 6, 7, 23 March: 4, 5, 6, 22 April: 5, 8, 9, 10 May: 3, 6, 7, 8, 20 June: 3, 10, 11, 12 The laboratory was asked to provide documentation, and none was provided. 3. During an interview on 06/17/2024 at 2:52 pm, the Receptionist after a review of the records, confirmed the above findings. Word Key: F- Fahrenheit

D5473

CONTROL PROCEDURES
CFR(s): 493.1256(e)(2)(g)

(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.

This STANDARD is not met as evidenced by:
Based on review of laboratory's policy, Quality Control Staining log, patient MOHS logs, and confirmed in interview, the laboratory failed to test and document the intended reactivity of Hematoxylin & Eosin (H&E) stain for Mohs histopathology slides each day of use for five of five days in 2022, 14 of 14 days in 2023 and seven of seven days in 2024. Findings included: 1. Review of the laboratory's policy "HEMATOXYLIN AND EOSIN STAIN" revealed: "Quality Assurance The first case submitted to the mohs [sic] lab which consists of NORMAL tissue will be stained for H&E and documented on the control sheet as the QA." 2. Review of the laboratory's "QUALITY CONTROL STAINING" log stated: "The first case submitted to the mohs [sic] lab which consists of NORMAL tissue will be stained for H&E and documented on the control sheet as the QA." Further review of the laboratory's "QUALITY CONTROL STATING" did not include for each day of use, documentation of the intended reactivity for the H&E stain on the following days patients were tested and reported in 2022, 2023 and 2024: 2022 08/09/2022; 5 patients were tested and reported 09/27/2022; 6 patients were tested and reported 10/11/2022; 6 patients were tested and reported 11/15/2022; 7 patients were tested and reported 12 /13/2022; 7 patients were tested and reported 2023 01/17/2023; 7 patients were tested and reported 02/14/2023; 6 patients were tested and reported 03/28/2023; 2 patients

were tested and reported 04/25/2023; 5 patients were tested and reported 05/23/2023; 4 patients were tested and reported 06/13/2023; 3 patients were tested and reported 07/25/2023; 3 patients were tested and reported 08/22/2023; 5 patients were tested and reported 09/12/2023; 4 patients were tested and reported 09/13/2023; 1 patient was tested and reported 10/09/2023; 1 patient was tested and reported 10/10/2023; 6 patients were tested and reported 11/07/2023; 4 patients were tested and reported 12/05/2023; 7 patients were tested and reported 2024 01/09/2024; 5 patients were tested and reported 02/06/2024; 3 patients were tested and reported 03/05/2024; 2 patients were tested and reported 04/09/2024; 5 patients were tested and reported 05/07/2024; 5 patients were tested and reported 06/10/2024; 1 patient was tested and reported 06/11/2024; 6 patients were tested and reported

The following is a random sampling of patients from the above listed dates that were tested and reported when the laboratory failed to for each day of use, document the intended reactivity for the H&E stain: 08/09/2022 Patient MOHS accession numbers: 22M-053, 22M-054, 22M-055, 22M-056, 22M-057 09/27/2022 Patient MOHS accession numbers: 22M-058, 22M-058, 22M-059, 22M-060, 22M-061, 22M-062, 22M-063 03/28/2023 Patient MOHS accession numbers: 23M-014, 23M-015 04/25/2023 Patient MOHS accession numbers: 23M-016, 23M-0017, 23M-018, 23M-019, 23M-020, 23M-021, 23M-022, 23M-023, 23M-024 06/10/2024 Patient MOHS accession number: 24M-021 06/11/2024 Patient MOHS accession numbers: 24M-022, 24M-023, 24M-024, 24M-025, 24M-026, 24M-027

3. During an interview on 06/17/2024 at 2:52 pm, the Receptionist after a review of the records, confirmed the laboratory failed to for each day of use, document the intended reactivity for the H&E stain.