

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D1066135	<b>(X3) Date Survey Completed</b>  04/14/2022
<b>Name of Provider or Supplier</b>  Mansfield Dermatology	<b>Street Address, City, State</b>  130 Regency Parkway, Mansfield, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	<p>Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Southern Operations Branch-Dallas for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid Services (CMS)-116 form, laboratory records and confirmed by staff interview, the laboratory failed to verify the accuracy of non-regulated potassium hydroxide (KOH) procedures at least twice annually for 2 of 2 testing events in 2020 and 2 of 2 testing events in 2021. Findings: 1. Review of the CMS-116 form submitted at survey by the laboratory revealed the laboratory performed KOH procedures. 2. Review of the laboratory's proficiency testing records for 2020 and 2021 revealed the laboratory failed to verify the accuracy of KOH procedures at least twice annually for 2 of 2 testing events in 2020 and 2 of 2</p>

	<p>events in 2021. 3. During an interview on 04/14/2021 at 9:15 am, the Laboratory Director was asked for documentation of twice annual accuracy for KOH procedures for 2020 and 2021. The Laboratory Director stated that there were no twice annual accuracy assessments for KOH procedures because he was unaware that it was a requirement. This confirmed the above findings.</p>
<p><b>D5413</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, laboratory documents, and staff interview, the laboratory failed to ensure the proper storage conditions were maintained for potassium hydroxide (KOH) reagents and immersion oil for 5 of 5 months in 2020, 12 of 12 months in 2021, and 4 of 4 months in 2022. Findings: 1. During a tour of the second laboratory area ("PA room") on 04/14/2022 at 10:55 am, the following was observed stored on the counter next to the microscope: 1 bottle of EDM3 Potassium Hydroxide; Lot# 1271; expiration date 09/28/2023; store at room temperature 2. Review of the laboratory's annual test volume revealed the laboratory performed 5 KOH tests. 3. During an interview on 04/14/2022 at 10:55 am, the Histotechnician was asked if the temperature was monitored and documented in the second laboratory area and she stated "no", confirming the above findings. The laboratory failed to ensure the proper storage conditions were maintained for KOH reagents.</p>
<p><b>D5417</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observations, review of records, and interview with the Laboratory Director, the laboratory failed to ensure one of one tissue marking stains were not expired when used in processing histopathology specimens. Findings: 1. During a tour of the histopathology (MOHs) laboratory on 04/14/2022 at 10:40 am, the surveyor observed the following expired tissue marking stains located at the grossing station: Tissue Marking Dye - Red; lot # 099871 Expired 3/31/2022 2. Based on review of patient testing records, the laboratory performed 40 histopathology tests between 04/04/2022 - 04/13/2022. 3. During an interview 4/14/2022 at 10:40 am in the laboratory, the Histotechnician confirmed the tissue marking stains had exceeded their expiration date.</p>
<p><b>D5473</b></p>	<p><b>CONTROL PROCEDURES</b></p>

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 Log, patient test reports, laboratory records, 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 46 of 46 days in 2020 (08/2020-12/2020), 136 of 136 days in 2021 (01/2021-12/2021) and 38 of 38 days in 2022 (01/2022-04/2022). Findings: 1. Review of the laboratory's policy "MANUAL HEMATOXYLIN AND EOSIN STAIN" revealed: "Quality Assurance: The first case submitted to the mohs lab which consists of NORMAL tissue will be stained for H&E and documented on the control sheet as the QA. The slide will be kept in the file with the case. This slide will show, blue nuclei and pink cytoplasm." 2. Review of the laboratory's "QUALITY CONTROL STAINING" log stated the following at the bottom of the log: "The first case submitted to the mohs lab which consists of NORMAL tissue will be stained for H&E, documented on the control sheet as the QA. This slide will be kept in the file with the case. The Quality control for each stain will be documented. Each stain will have the results documented in the procedure." Further review of the laboratory's quality control log revealed the log 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 2020, 2021 and 2022: 2020: August: 18, 19, 20, 24, 25, 31 September: 1, 9, 10, 14, 15, 21, 22, 28, 29 October: 5, 6, 12, 13, 14, 19, 20, 21, 26, 27, 28 November: 2, 3, 4, 9, 10, 11, 16, 17, 30 December: 1, 7, 9, 14, 15, 21, 22, 28, 29, 30, 31 2021: January: 4, 5, 6, 11, 12, 13, 18, 19, 20, 25, 26 February: 1, 2, 8, 9, 10, 22, 23, 24 March: 1, 2, 3, 4, 8, 9, 10, 15, 16, 17, 29, 30 April: 5, 6, 7, 12, 13, 14, 19, 20, 21, 26, 27, 28 May: 3, 4, 10, 11, 12, 17, 18, 19, 25, 26, 27 June: 1, 2, 14, 15, 21, 22, 23, 28, 29, 30 July: 6, 7, 12, 13, 14, 19, 20, 21, 26, 27, 28 August: 2, 3, 4, 9, 10, 11, 16, 23, 24, 30, 31 September: 1, 7, 8, 13, 14, 15, 20, 21, 22, 27, 28, 29 October: 4, 5, 6, 11, 12, 13, 18, 19, 20, 25, 26, 27 November: 1, 2, 3, 8, 9, 10, 15, 16, 17, 29, 30 December: 1, 6, 7, 8, 13, 14, 15, 20, 21, 22, 27, 28, 29 2022: January: 3, 4, 5, 17, 18, 24, 25, 26 February: 1, 2, 7, 8, 9, 14, 15, 16, 21, 22, 23, 28 March: 1, 2, 7, 8, 9, 14, 15, 16, 21, 22, 23, 28, 29 April: 4, 5, 6, 11, 12, 13 The laboratory failed to document the intended reactivity to ensure predictable H&E characteristics for the above dates. 3. The following is a random sampling of patients that were tested and reported when quality control was not documented: 08/18/2020 Case #: S20-001, S20-002, S20-003, S20-004, S20-005, S20-006 08/19/2020 Case #: S20-007, S20-008 08/20/2020 Case #: S20-009, S20-010, S20-011, S20-012, S20-013, S20-014, S20-015, S20-016, S20-017 02/23/2021 Case #: S21-073, S21-074, S21-075, S21-076, S21-077, S21-078 02/24/2021 Case #: S21-079, S21-080, S21-081 03/01/2021 Case #: S21-082, S21-083, S21-084, S21-085, S21-086, S21-087 04/06/2022 Case #: S22-239, S22-240, S22-241, S22-242, S22-243, S22-244 04/11/2022 Case #: S22-245, S22-246, S22-247, S22-248, S22-249, S22-250, S22-251 04/12/2022 Case #: S22-252, S22-253, S22-254, S22-255, S22-256, S22-257, S22-258, S22-259 4. Review of laboratory records revealed the laboratory performed an annual volume of 725 histopathology (MOHs) tests. 5. During an interview on 04/14/2022 at 12:15 pm, the Laboratory Director confirmed the above findings.

**D5801**

**TEST REPORT**

CFR(s): 493.1291(a)

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 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 review of the laboratory's policy, potassium hydroxide (KOH) patient logs, patient charts and in interview with staff, the laboratory failed to ensure 2 of 4 patients KOH results were transcribed accurately to the final test report (03/2022-04/2022). Findings: 1. Review of the laboratory's policy "KOH examination" stated, "All KOH will be logged in the KOH log book with the patient name and the results will be logged after review. All results are then logged and or dictated in the patient chart." 2. Review of "KOH LOG - 2022" from 03/2022 through 04/2022 revealed the following patient KOH results documented: Patient #1 Date: 04/11/2022; Patient Name: [XX]; Location: (Bottom-Buttocks) Mansfield; POS/NEG: Neg; Surgeon Signature: [ordering Provider's signature] Patient #2 Date: 04/13/2022; Patient Name: [XX]; Location: Mansfield; POS/NEG: Neg; Surgeon Signature: [ordering Provider's signature] The laboratory's practice was documenting the patient's result in the log and then transcribing it manually or by dictation in the patient's chart ("Visit Note"). The laboratory was asked to provide the above-mentioned patients charts to review the KOH results for those dates. The charts were provided, and KOH results were transcribed in the patients charts as follows: Patient #1: MRN (medical record number): 56395; Visit Note date: 04/13/2022 "Plan: KOH Prep. A KOH prep was ordered and evaluated from the right buttock. A 15-blade scalpel was used to scrape the skin. The skin scrapings were placed on a glass slide, covered with a coverslip and a KOH solution was applied. Examination of the slide showed: branching hyphae." Patient #2: MRN: 44880; Visit Note date: 04/14/2022 "Plan: KOH Prep. A KOH prep was ordered and evaluated from the mid-occipital scalp. A 15-blade scalpel was used to scrape the skin. The skin scrapings were placed on a glass slide, covered with a coverslip and a KOH solution was applied. Examination of the slide showed: branching hyphae." The final report test results did not reflect results in the patient log. The laboratory failed to ensure test results were transcribed accurately when entered into the patient chart. 3. During an interview on 04/14/2022 at 12:15 pm, the Laboratory Director reviewed and confirmed the above findings.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of Centers for Medicare and Medicaid (CMS)-209 form, personnel

records, and confirmed in interview, the technical consultant failed to perform annual personnel competency assessment for 4 of 4 testing persons (TP-2, TP-3, TP-4, TP-5) who perform moderate complexity testing in 2020 and 2021. Findings: 1. Review of CMS 209 form revealed moderate complexity potassium hydroxide (KOH) procedures were performed by Testing Person-2 (TP-2), Testing Person-3 (TP-3), Testing Person-4 (TP-4), Testing Person-5 (TP-5). 2. Review of personnel records revealed annual competency assessments were NOT performed for TP-2, TP-3, TP-4 and TP-5 in 2020 and 2021. 3. The laboratory was asked to provide documentation of competency assessments for 2020 and 2021 and none were provided. 4. During an interview on 04/14/2021 at 9:15 am, the Laboratory Director, who was also the technical consultant, was asked for annual competency assessments for testing personnel who perform moderate complexity for 2020 and 2021. The Laboratory Director stated that there were no annual competency assessments for testing personnel performing KOH procedures because he was unaware that it was a requirement. This confirmed the above findings.