Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2305985	**(X3) Date Survey Completed** 09/05/2025
Name of Provider or Supplier Monarch Dermatology, Pllc	**Street Address, City, State** 4312 Heritage Trace Pkwy Suite 708, Fort Worth, 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.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid Services (CMS)-116 form, laboratory policies, laboratory records and confirmed by staff interview, the laboratory failed to verify the accuracy of non-regulated potassium hydroxide (KOH) procedures in the subspecialties of parasitology and mycology at least twice annually for two of two testing events in 2024. Findings included: 1. Review of the CMS-116 form submitted at survey by the laboratory revealed the laboratory performed KOH procedures in the subspecialties of parasitology and mycology. 2. Review of the laboratory's policy titled "BI-ANNUAL PROFICIENCY TESTING" failed to include KOH procedures in the subspecialties of parasitology and mycology. 3. Review of the laboratory's proficiency testing records for 2024 revealed the laboratory failed to verify the accuracy of KOH procedures in the subspecialties of parasitology and mycology at least twice annually for two of two testing events in 2024. 4. During an interview on 09/05/2021 at 10:20 a.m., the histotechnician was asked for documentation of twice annual accuracy for KOH procedures for 2024. The histotechnician stated that there were no twice annual accuracy assessments for 2024. This confirmed the laboratory failed to verify the accuracy of KOH procedures in the subspecialties of parasitology and mycology at least twice annually for two of two testing events in 2024.

D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. 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 patient name or unique patient identifier for 32 of 32 slides reviewed in 2025 (random review August through September). Findings included: 1. Review of the laboratory policy titled "Mohs Procedure" stated: "Post-Microscopic Examination Steps in Mohs Micrographic Surgery 7. Staining and Cover-Slipping: Once the tissue sections have been checked microscopically, they are ready for staining. The stain of choice is hematoxylin and eosin (H&E). After staining, the slides are cover-slipped using permanent glue. These slides are kept indefinitely for reference." The laboratory policy did NOT include labeling instructions to reliably identify patients using at least the patient's name or unique patient identifier to distinguish between specimens. 2. A random review of patient slides from 2025 (August through September) revealed: 08 /26/2025: 17 slides were labeled with patient last name, chronological number (as listed on the Mohs case log), block and section, slide number, and stage. The patient's Mohs accession numbers were as follows: M25-037, M25-038. 09/02/2025: 15 slides were labeled with patient last name, chronological number (as listed on the Mohs case log), block and section, slide number, and stage. The patient's Mohs accession number was as follows: M25-039, M25-040, M25-041. The laboratory failed to ensure patient histopathology (Mohs) slides were labeled with patient name or unique patient identifiers. 3. During an interview on 09/05/2025 at 11:00 a.m., the histotechnician after a review of the records, the laboratory failed to ensure patient histopathology (Mohs) slides were labeled with patient name or unique patient identifiers.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of laboratory policies and confirmed in staff interview, the laboratory failed to ensure 13 of 13 laboratory policies were approved, signed, or dated by the laboratory director before use in July 2024. Findings included: 1. Review of the laboratory's policy manual revealed the following policies were not approved, signed, or dated by the laboratory director before it was placed into use in July 2024: "KOH examination" "BI-ANNUAL PROFICIENCY TESTING" "PROFICIENCY TESTING" "FORMAL POLICY STATEMENT" "Microscope Maintenance" "MANUAL HEMATOXYLIN AND EOSIN STAIN" "Auto Stainer Hematoxylin And Eosin Stain" "H&E Stainin2 Line Maintenance" "DAILY ROUTINE" "Mohs Procedure" "QUALITY ASSURANCE" "STORAGE OF DIAGNOSED SLIDES"

	"SPECIMEN ACCEPTANCE OR REJECTION" 2. During an interview on 09/05 /2025 at 10:35 a.m., the histotechnician confirmed the laboratory failed to ensure 13 of 13 laboratory policies were approved, signed, or dated by the laboratory director before use in July 2024.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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: Based on direct observation, manufacturer's instructions, laboratory policy, the lack of environmental logs, and confirmed in staff interview the laboratory failed to ensure the proper storage conditions of the Olympus BX41 System Microscope were maintained according to manufacturer's instructions for seven of seven months in 2024 (July-December) and nine of nine months in 2025 (January-September). Findings included: 1. During a tour of the laboratory director's office on 09/05/2025 at 11:27 a.m., the surveyor observed a Olympus BX41 System Microscope (Serial # 8G17664) on a desk. 2. Review of the Olympus BX41 System Microscope user's manual stated: "5 SPECIFICATIONS ... Item 8. Operating environment Specification ... Ambient temperature: 5 degrees to 40 degrees C (41 degrees to 104 degrees F) Maximum relative humidity: 80% for temperatures up to 31 degrees C (88 degrees F), decreasing linearly through 70% at 34 degrees C (93 degrees F), to 50% relative humidity at 40 degrees C (104 degrees F)." 3. Review of the laboratory's policy titled "Microscope Maintenance" stated: "1. The microscope should be covered at the close of every day 2. Use xylene substitute or alternative to clean stage of microscope 3. Wipe eye pieces and lenses with lens cloth 4. Change bulbs as needed and have regular service contracts performed 5. Document daily, monthly care, Annual PM is needed" The policy failed to state to monitor and document the operating environment for room temperature and humidity. 4. On 09/05/2025 at 11:27 a.m. the laboratory was asked to provide documentation of environmental logs for room temperature and humidity from July 2024 through the date of the survey. No environmental logs were provided. 5. During an interview 09/05/2025 at 11:27 a.m., the histotechnician stated that room temperature and humidity logs were not kept, confirming the above findings. The laboratory failed to ensure the proper storage conditions of the Olympus BX41 System Microscope were maintained according to manufacturer's instructions. Word Key: C- Celsius F- Fahrenheit
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (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.

	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 two of two days in 2024 (September-October), 12 of 12 days in 2025 (January-September). Findings included: 1. Review of the laboratory's policy "MANUAL 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 [sic]. The slide will be kept in the file with the case. This slide will show blue nuclei and pink cytoplasm." Review of the laboratory's policy "Auto Stainer 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 QC. The slide will be kept in the file with the case and log. This slide will show blue nuclei and pink cytoplasm." 2. Review of the laboratory's "QUALTIY CONTROL STAINING" log stated the following at the bottom of the log: "The first section from the first case of the day will be submitted to the Mohs surgeon. Tissue will be stained for H&E, documented on the control sheet as the QA [sic]. This slide will be kept in the file with the case." 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 2024, 2025: 09/05/2024 10/15/2024 01/29/2025 02/13/2025 04/10/2025 04/21/2025 05/06/2025 05/29/2025 06/04/2025 06/26/2025 07/08/2025 07/22/2025 08/26/2025 09/02/2025 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: 09/05/2024 Case #s: M24-001, M24-002 10/15/2024 Case #s: M24-003, M24-004 M24-005 07/22/2025 Case #s: M25-032, M25-033, M25-034, M25-035 08/26/2025 Case #s: M25-036, M25-037, M25-038 09/02/2025 Case #s: M25-039, M25-040, M25-041, M25-042 4. Review of laboratory records revealed the laboratory performed an annual volume of 47 histopathology (MOHs) tests. 5. During an interview on 09/05/2025 at 11:00 a.m., the histotechnician after a review of records, confirmed the laboratory failed to document the intended reactivity to ensure predictable H&E characteristics.
D5801	TEST REPORT CFR(s): 493.1291(a) (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: ensure two of nine patient KOH preparation results were transcribed accurately to the final test report in 2024 (random review September 2024 through October 2024). Findings included: 1. Review of the laboratory's policy titled "KOH examination"

	stated: "5. Documentation: Log all KOH preparations in the KOH log book [sic], including patient names. After review, record the results in the patient chart." 2. Review of the laboratory's "KOH Log" and corresponding patient final reports revealed the following: 09/04/2024 Patient chart#: MM000000376 KOH Log: "(pos)" Final report: "Examination of the slide showed: spores" 10/16/2024 Patient chart#: MM000000053 KOH Log: "(pos)" Final report: "Examination of the slide showed: scabies" The laboratory failed to accurately transcribe results of KOH preparations to the final reports. 2. During an interview on 09/09/2025 at 10:10 a.m., the histotechnician confirmed the laboratory failed to ensure two of nine patient KOH preparation results were transcribed accurately to the final test report in 2024. Word Key: pos - positive