Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0686235	02/22/2024
Name of Provider or Supplier	**Street Address, City, State**	
Mid-South Dermatology, Pc	6644 Summer Knoll Circle, Bartlett, TN	

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**
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, testing personnel competency assessments, lack of documentation and staff interview, the laboratory failed to have a competency assessment procedure that included all six criteria as required in subpart M, and failed to follow the established policy when competency assessment was not performed for Mohs surgeon number two in 2022, 2023 or 2023. The findings include: 1. Review of the laboratory's quality assessment policy for testing personnel competency assessment revealed the following statement: "If the laboratory has employees, the Laboratory Director will use personal observation to perform an ongoing evaluation of all employees of the laboratory to ensure competence in job performance." The policy did not include all six elements as required in Subpart M. The six required elements are: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem-solving skills. 2. Review of the 2022, 2023 and 2024 competency assessments performed for the tissue grosser revealed the competencies were performed without including all six required elements. 3. No documented competency was performed for Mohs surgeon #2 in 2022, 2023 or 2024. 4. During interview on 02/22/24 at 11:50 am, the office manager confirmed the survey findings.

D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's verification of accuracy documents and staff interview, the laboratory failed to document review of the twice-a-year verification of accuracy performed in 2022, 2023, and 2024. The findings include: 1. Review of the laboratory's twice-a-year verification of accuracy, performed by split case review with an outside laboratory, revealed no documented review of the findings. Dates of performance were 12/23/22, 6/20/23, and 12/20/23. 2. Interview on 02/22/24 at 11:50 am with the office manager confirmed there was no documented review of the verification of accuracy performed in 2022, 2023 and 2024.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, Mohs surgical case slides, and staff interview, the laboratory failed to follow the policy for labeling of slides for three of three cases (eight of eight slides) reviewed from 2022, 2023, and 2024. 1. Review of the laboratory policy for labeling patient histopathology slides revealed the labeling would include patient name, chart number, site location, the date done, and "label slides with numbers (1. 2, 3, etc.)." 2. Review of slides for Mohs cases revealed slides for three of three cases (eight of eight slides) were not labeled according to laboratory policy (patient chart #50923-performed on 10/10/22, patient chart number #76858-performed on 08/17/23, and patient chart #314801-performed on 01/29/24). The slides were missing the patient chart numbers. 3. During interview on 02/22/24 at 11:50 am, the office manager confirmed the survey 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:

	Based on observation of the laboratory areas, the laboratory's environmental records, and staff interview, the laboratory failed to define acceptable ranges for room temperature and humidity in the technical component laboratory and Mohs laboratory in 2022, 2023, and 2024. The findings include: 1. Observation of the laboratory areas on 02/22/24 at 8:30 am revealed the following equipment used for processing dermatology tissue in preparation for microscopic examination: a. In the technical component laboratory-ThermoScientific Shandon Linistain automated stainer, Thermo Scientific Excelsior tissue processor, Thermo Scientific Shandon Histocentre 3 tissue embedding station, Pemiere Lighted Tissue Bath, Thermo Scientific Microm HM355S. b. In the Mohs laboratory - QS 12 Advantik Croystat, Thermo Shandon Cryostat, and Thermo Shandon Linistat stainer. 2. The laboratory's environmental records for 2022, 2023, and 2024 for the technical component laboratory and the Mohs laboratory did not define acceptable ranges for either room temperature or room humidity. 3. During an interview on 02/22/24 at 11:50 am, the office manager confirmed the laboratory failed to define acceptable ranges for room temperature and humidity in the technical component laboratory and the Mohs laboratory in 2022, 2023, and 2024.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) 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. This STANDARD is not met as evidenced by: Based on observation of the laboratory and staff interview, the laboratory failed to ensure marking dyes and eosin stain used for inking and staining tissue had not expired on the date of the survey (02/22/24). The findings include: 1. Observation of the laboratory areas on 02/22/24 at 8:30 am revealed equipment, reagents, stains, and dyes used for performing grossing, inking, staining, and processing of tissue to prepare slides for diagnostic interpretation. In the technical component laboratory area expired marking dyes were observed: orange marking dye (Lot 1142550) expired on 01/31/23, and green marking dye (Lot 114352) expired on 12/31/22. In the Mohs laboratory area, the following expired reagents/stains were observed: the eosin stain expired on 01/15/23 (Lot 2101123), the green marking dye expired on 09/30/23 (Lot 131529), the orange marking dye expired on 08/31/23(Lot 128166). 2. The office manager confirmed the survey findings during interview on 02/22/24 at 11:50 am.
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 observation of the laboratory, lack of records, review of Mohs surgical cases, lack of documentation, and staff interview, the laboratory failed to retain

	records of reagent/stain lot numbers used and failed to document hematoxylin and eosin stain quality in 2022, 2023, and 2024. The findings include: 1. Observation of the Mohs laboratory area on 02/22/24 at 8:30 am revealed equipment and reagents used in preparing tissue removed during Mohs surgical procedure for microscopic analysis, including hematoxylin and eosin stains. 2. No records of the reagent and stain lot numbers used in 2022, 2023, and 2024, dates put into use, or stain quality assessment when reagent lots changed were available on the date of the survey. 3. Review of Mohs surgical cases revealed no documentation of the daily hematoxylin and eosin stain quality for three of three dates selected (patient chart #50923-performed on 10/10/22, patient chart number #76858-performed on 08/17/23, and patient chart #314801-performed on 01/29/24). 4. During an interview on 02/22/24 at 11:50 am, the office manager confirmed the laboratory failed to retain records of reagent lot numbers, expiration dates, and dates put into use, stain quality when lot numbers changed, and failed to document daily hematoxylin and eosin stain quality assessment in 2022, 2023, and 2024.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment plan, review of documented corrective action, review of manintenance and temperature records and staff interview, the laboratory failed to follow the policy for laboratory director review of corrective actions and failed to document review of laboratory maintenance and temperature records in 2022, 2023, and 2024. The findings include: 1. Review of the laboratory's quality assessment plan under the section for remedial actions revealed the following statement: "Any remedial action taken by the laboratory will be documented on the Corrective Action Request From (see Corrective Action Request From, Section IV-page 25) and reviewed by the Laboratory Director." 2. Review of corrective action documents spanning 11/17/22 to 01/04/24 revealed no documented review by the laboratory director. 3. Review of maintenance and temperature records for both the technical component lab and the Mohs lab revealed no documented review by the laboratory director. Months reviewed included October 2022, August 2023, and January 2024. 4. During interview on 02/22/24 at 11:50 am, the office manager confirmed the laboratory failed to follow its' own policy for laboratory director review of corrective actions in 2022, 2023, and 2024 and failed to perform review of analytic records.