Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2130431	(X3) Date Survey Completed 08/26/2025
Name of Provider or Supplier Cleaver Medical Group Dermatology, Inc	**Street Address, City, State** 105 Professional Park Drive, Cumming, GA	
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	An announced CLIA validation survey was conducted at Cleaver Medical Group Dermatology on August 26, 2025, by a federal surveyor from the CMS DCLIQ Survey Branch. The laboratory was surveyed under 42 CFR part 493 CLIA regulations and was found to be compliance with condition-level CLIA requirements. The following standard-level deficiencies were found during the CLIA validation survey.
D3013	FACILITIES CFR(s): 493.1101(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation. This STANDARD is not met as evidenced by: Based on observation of the laboratory area and interview with the laboratory manager, the laboratory failed to monitor temperature conditions for storage of Mohs slides to ensure proper preservation for two of two years (August 26, 2023 to August 27, 2025). Findings Include: 1. Observation of the Mohs micrographic surgery area first floor on August 26, 2025 at 10:45 am revealed Mohs slides were stored in a Microscope Slide Storage Cabinet which was in a closest on the first floor. 2. The laboratory could not provide documentation for temperature being monitored in the closest where Mohs micrographic surgery slides have kept since 2017. 3. Per the Clinical laboratory improvement Amendment (CLIA) Application for Certification signed by the laboratory director on August 25, 2025, the laboratory performed an estimated 800 MOHS examinations annually. 4. By interview, the laboratory manager confirmed that the storage conditions where the Mohs micrographic surgery slides were stored where not being monitored on August 26, 2025 at 11:00 am. Key: Mohs = Micrographic Surgery.
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: I. Based on the lack of records and interview with the laboratory manager, the laboratory failed to verify at least twice annually the accuracy of KOH preparations performed for two of two years (2023 and 2024). Findings Included: 1. On August 26, 2025 at 10:45 am, the laboratory could not provide documentation for the performance of accuracy of KOH testing on a semi-annual basis in 2023 and 2024. 2. Per the Clinical laboratory improvement Amendment (CLIA) Application for Certification signed by the laboratory director on August 25, 2025, the laboratory performed an estimate of 120 KOH preparations annually. 3. By Interview, the laboratory manager on August 26, 2025 at 11:00 am confirmed the above findings. Key: KOH - Potassium Hydroxide. II. Based on review of laboratory records and interview with the laboratory manager, the laboratory failed to verify at least twice annually the accuracy (peer review) of MOHS examinations performed for two of two years (2023 and 2024). Findings Included: 1. Review of laboratory records on August 26, 2025 at 10:45 am revealed the MOHS peer review performed by laboratory director was not assessed by another physician on a semi-annual basis in 2023 and 2024. 2. Per the Clinical laboratory improvement Amendment (CLIA) Application for Certification signed by the laboratory director on August 25, 2025, the laboratory performed an estimated 800 MOHS examinations annually. 3. By Interview, the laboratory manager on August 26, 2025 at 11:00 am confirmed the above findings. Key: Mohs = Micrographic Surgery.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the KOH policy, lack of reference collection material and

	interview with the laboratory manager, the laboratory failed to establish a KOH examination policy that included included references to photomicrographs to meet control requirements for KOH examinations performed for two of two year (August 26, 2023 to August 26, 2025). Findings included: 1. Review of laboratory KOH policy on August 26, 2025 at 11:00 am revealed, the KOH policy did not include references to photomicrographs to meet control requirements. 2. The laboratory could not provide reference collection material for the reported diagnostic specimens types: a. Scabies. b. Head Lice. c. Crab louse Red blood Cells. d. Hyphae. e. Tinea versicolor. f. Bed bugs. 3. Review of the below three sampling of patient specimens revealed, no photomicrographs were reviewed for: a. Test Date: 05/13/2025 - MRN#MM0000071889. b. Test Date: 01/08/2024 - MRN#MM0000040666. c. Test Date: 07/10/2024 - MRN#MM0000057261. 4. Per the Clinical laboratory improvement Amendment (CLIA) Application for Certification signed by the laboratory director on August 25, 2025, the laboratory performed an estimated 120 KOH preparations annually. 5. By interview, the laboratory manager confirmed references to photomicrographs to meet control requirements were not included in the KOH examinations policy nor were photomicrographs reviewed and documented when patient examinations were performed on August 26, 2025 at 1:30 pm. Key: KOH = Potassium Hydroxide. MRN = Medical Record Number.
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 the review of manufacturers' documents, lack of monitored temperature records, observation of the microscope slide reading area, and an interview with the laboratory manager, the laboratory failed to monitor and document room temperature and humidity conditions where one of one Olympus BX43 microscope was kept. Findings Included: 1. The Olympus BX43 microscope instrument manual, 8. Specifications, 8. Operating environment table stated: - "Ambient temperature: 5 to 40C (41 to 104F)". - "Maximum relative humidity: 80% for temperatures up to 31C (88F), decreasing linearly through 70% at 34C (93F), 60% at 37C (99F), to 50% relative humidity at 40C (104F)". 2. On August 26, 2025, at 11:00 a.m., while on a tour of the Mohs laboratory, a room next to the laboratory housed one Olympus BX43 microscope used for the microscopic examination Mohs and KOH slides. 3. The laboratory was unable to provide documentation for monitored room temperature where one Olympus BX43 microscope was kept. 4. By interview, the laboratory manager on August 26, 2025 at 11:15 am, confirmed the finding above. Key: Mohs = Micrographic Surgery. KOH = Potassium Hydroxide.
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. This STANDARD is not met as evidenced by: Based on review of the quality assurance (QA) Potassium Hydroxide (KOH) preparation procedure, lack of QA records and interview with the laboratory manager, the laboratory failed to establish a QA KOH preparation procedure that included procedures for a ongoing mechanisms to monitor analytic systems for KOH preparation performed for two of two years (August 26, 2023 to August 26, 2025). Findings Included: 1. On August 26, 2025 at 12:00 pm, review of the QA KOH preparation procedure revealed the procedure did not include ongoing QA program to monitor analytic systems for KOH preparation performed for two years (August 26, 2023 to August 26, 2025). 2. The laboratory was unable to provide documentation for a QA program to monitor analytic systems for KOH preparation performed for two years (August 26, 2023 to August 26, 2025). 3. Per the Clinical laboratory improvement Amendment (CLIA) Application for Certification signed by the laboratory director on August 25, 2025, the laboratory performed an estimate of 120 KOH preparations annually. 4. By Interview, the laboratory manager on August 26, 2025 at 1:00 pm confirmed the above findings. Key: KOH = Potassium Hydroxide.