Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2307728	03/24/2025
Name of Provider or Supplier	**Street Address, City, State**	
Lockhart Matter Dermatology Plano	5805 Coit Road Ste 203, Plano, 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.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor observation, review of manufacturer's instructions, laboratory policy, Daily Maintenance Logs in 2024 and 2025, and confirmed in interview, the laboratory failed to follow manufacturer's instructions for weekly maintenance on the Leica Cryostat for 17 weeks in 2024 and 11 weeks in 2025. Findings included: 1. During a tour of the facility on 03/24/2025 at 3:10 PM, the surveyor observed a Leica CM1850 tissue processors in the laboratory available for patient specimen processing. (Serial Number: 0690) 2. Review of manufacturer's instructions for the Leica CM1850 Cryostat (V2.2) revealed the following: " ...9.3.1 General Maintenance ... Once a week: Apply a drop of oil to the plastic coupling. Lubricate the specimen cylinder." 3. Review of the laboratory's, "Daily Maintenance Log" in 2024 and 2025, revealed the laboratory failed to document weekly maintenance on the cryostat. The laboratory was asked to provide documentation of performing weekly maintenance on the Leica Cryostat in 2024 and 2025. No documentation was provided. 4. In an interview on 03/24/25 at 02:32 PM in the facility break room, Testing Person 1 (TP1), confirmed the above findings.
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 surveyor observation, review of manufacturer's instructions, Daily Maintenance Logs in 2024 and 2025, and confirmed in interview, the laboratory failed to follow manufacturer's instructions for acceptable humidity range prior to patient testing for 38 of 38 patient test days in 2024 and 2025. Findings included: 1. During a tour of the facility on 03/24/2025 at 3:10 PM, the surveyor observed one Leica CM1850 tissue processor in the laboratory available for patient specimen processing. (Serial Number: 0690) 2. Review of manufacturer's instructions for the Leica CM1850 Cryostat (V2.2) revealed the following: " ...Operating Specifications: ... Humidity: Less than 60% Relative Humidity" 3. Review of the laboratory's, "Daily Maintenance Log" in 2024 and 2025, revealed the laboratory failed to document humidity in the laboratory. The laboratory was asked to provide documentation of humidity in the laboratory prior to patient testing in 2024 and 2025. No documentation was provided. Further review revealed the following patient test days in 2024 and 2025 when the laboratory failed to document humidity prior to testing: Dates in 2024 09/09/24 09/16/24 09/23/24 09/30/24 10/07/24 10/14/24 10/21/24 10/28 /24 11/04/24 11/11/24 11/18/24 11/26/24 12/2/24 12/03/24 12/09/24 12/10/24 12/16 /24 12/23/24 12/24/24 12/30/24 Dates in 2025 01/06/25 01/13/25 01/14/25 01/20//25 01/28/25 02/03/25 02/04/25 02/05/25 02/10/25 02/11/25 02/17//25 02/18/25 02/24/25 02/25/25 03/03/25 03/04/25 03/10/25 03/11/25 03/17/25 03/24/25 4. In an interview on 03/24/25 at 02:15 PM in the facility break room, the facility manager confirmed the above findings.
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 policy, manufacturer's instructions, Daily Maintenance Logs in 2024 and 2025, and confirmed in interview, the laboratory failed to document predicted staining characteristics for Hematoxylin and Eosin (H&E) frozen tissues daily control slides for 38 of 38 patient testing days in 2024 and 2025. Findings included: 1. Review of laboratory policy, "Lockhart Matter Dermatology-Plano MOHS Lab Policy and Procedure" (Reviewed by the laboratory director on 03/04 /2025) revealed the following: "Control Slide The Mohs surgeon will examine a control slide ...to determine if stain quality is acceptable. If staining quality does not meet the surgeon's standards, the stains are replaced or changed as needed, and a Request of Corrective Action is completed." Further review of the policy revealed no

	documentation of control slide predicted staining characteristics. 2. Review of H&E stain manufacturer's instructions revealed the following: "StatLab Hematoxylin and Eosin Frozen Section Results Nuclear Chromatin: Purple Cytoplasm: Orange to Pink" 3. Review of facility Daily Maintenance Logs in 2024 and 2025, revealed no predicted staining characteristics documented for daily H&E control slides performed prior to patient testing. The facility was asked to provide documentation of the above and none was provided. 4. In an interview on 03/24/25 at 02:08 PM in the facility break room, the facility representative confirmed the above findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of laboratory's Daily Maintenance Log in 2024 and 2025, and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions when the laboratory temperature was documented outside the laboratory's acceptable range for 9 of 21 testing days in 2024, and 9 of 17 testing days in 2025. Findings included: 1. A review of the laboratory's Daily Maintenance Log in 2024 and 2025, from September 2024 to March 2025, revealed the following acceptable temperature range: " ...2. Log temperature (Acceptable temperature range Lab Room 70F - 75F.)" Further review of the Daily Maintenance Log in 2024 and 2025, revealed the following days when the documented laboratory temperatures were outside the laboratory's acceptable range: Date 2024 Recorded Temperature 09/16/24 77F 09/23/24 77F 09/30/24 76F 10/07/24 78F 10/14/24 77F 10/28/24 78F 11/18/24 76F 12/02/24 68F 12/30/24 68F 2025 01/06/25 63F 01/13/25 66F 01/14/25 67F 01/20/25 63F 02/10/25 69F 02/17/25 68F 03/04/25 76F 03/10/25 69F 03/11/25 76F The laboratory was asked to provide documentation of performing corrective actions when the laboratory temperature was outside of the acceptable range. No documentation was provided. 2. In an interview on 03/24/25 at 02:15 PM in the facility break room, the facility manager confirmed the above findings. Word Key F- Fahrenheit