Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2014982	04/22/2025
Name of Provider or Supplier	**Street Address, City, State**	
Metroderm, Pc- Hiram	4374 Atlanta Highway, Suite 103, Hiram, 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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on April 22, 2025. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) (b) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all preanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: A review of 2023 - 2025 CORRECTIVE ACTIONS RECORDS, confirmed that the laboratory failed to assess and implement effective corrective actions for the ongoing specimen processing failures by the laboratory staff during the preanalytical specimen processing phase. THE FINDINGS INCLUDE: 1. A review of laboratory records (2023 - 2025) confirmed that specimen processing staff repeatedly failed to record the MOHS Case# in the patients' records, at the time of processing, to ensure patient specimen integrity. 2. A review of the 2023 - 2025 Corrective Action Records confirmed that eleven (11) of the fifty (50) corrective actions showed continued failures of the same incident for dates of up to two years after the original incident occurrence. 3. Review of the records confirmed that the corrective actions taken to correct the recurring error was ineffective. There was no documentation to demonstrate the steps taken to eliminate the reoccurring error - i.e. retraining of personnel, changes to the current SOP, etc. 4. An exit interview, on April 22, 2025, at 12:30pm, in the office room, with the HistoTech (HT) and the Practice Manager (PM) confirmed that the laboratory failed to assess and implement effective corrective

	actions for the ongoing processing failure at the preanalytical specimen processing phase.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: A review of 2023 - 2025 CORRECTIVE ACTIONS RECORDS, confirmed that the Laboratory Director (LD) failed to ensure the quality of services for all aspects of test performance. THE FINDINGS INCLUDE: 1. A review of laboratory records (2023 - 2025) confirmed that specimen processing staff repeatedly failed to record the MOHS Case# in the patients' records at the time of processing to ensure patient specimen integrity. 2. A review of the 2023 - 2025 Corrective Action Records confirmed that eleven (11) of the fifty (50) corrective actions showed continued failures of the same incident for dates of up to two years after the original incident occurrence. 3. Review of the records confirmed that the Laboratory Director failed to implement effective corrective actions to correct the recurring error. There was no documentation to demonstrate the steps taken to eliminate the reoccurring error - i.e. retraining of personnel, changes to the current SOP, etc. 4. An exit interview, on April 22, 2025, at 12:30pm, in the office room, with the HistoTech (HT) and the Practice Manager (PM) confirmed that the Labortaory Director failed to assess and implement effective corrective actions for the ongoing processing failure at the preanalytical specimen processing phase.