Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2012290	05/27/2025
Name of Provider or Supplier	**Street Address, City, State**	
Mclaughlin Dermatology	16 Hospital Circle Ste B, Batesville, AR	

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
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 upon a review of the laboratory's policy and procedure "Daily Routine", the policy and procedure for Mohs Surgery, review of Mohs surgery log, review of cryostat temperature records, and interview with laboratory staff the laboratory failed to document proper cryostat operating temperatures for 3 of 55 days when Mohs surgery procedures were performed in 2024 affecting 11 cases of Mohs surgery. Findings follow: A) Review of the laboratory policy and procedure "Daily Routine" revealed a daily task of "check and log temperature of Cryostat" B) Review of the policy and procedure for Mohs surgery revealed "to begin a Mohs procedure the cryostat temerature needs to be turned to minus 20 degrees Centigrade (C) to minus 30 degrees C". C) Review of the Mohs surgery log for 2024 revealed that Mohs surgery procedures were performed on two patients (specimen numbers 24M-204, 24M-205) on 9/12/24; four cases (specimen numbers 24M-247, 24M-248, 24M-249, 24M-250) on 11/5/24, and 5 cases (specimens numbers 24M-277, 24M-278, 24M-270, 24M-280, 24M-281) on 12/10/24. D) Review of the cryostat temperature revealed that no operating temperature was recorded on 9/12/24, 11/5/24, and 12/10

	/24 . E) In an interview on 5/27/25 at 3:15 p.m. the laboratory staff member (#1 on the CMS 209 form) confirmed that the cryostat remperatures were not documented on the days identified above and Mohs surgery was performed on those days.
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 upon a review of the Mohs surgery log, the stain quality assurance log, and interviews with laboratory staff, the laboratory failed to document the quality of the Hematoxylin and Eosin (H and E) stain each day of use in 3 of 55 days in which Mohs surgery was performed affecting 11 Mohs surgery cases. Findings follow. A) Review of the Mohs surgery log for 2024 revealed that Mohs surgery procedures were performed on two patients (specimen numbers 24M-204, 24M-205) on 9/12/24; four cases (specimen numbers 24M-247, 24M-248, 24M-249, 24M-250) on 11/5/24, and 5 cases (specimens numbers 24M-277, 24M-278, 24M-270, 24M-280, 24M-281) on 12 /10/24. B) Review of the H and E stain quality log revealed that H an E stain quality was not documented on 9/12/24, 11/5/24, and 12/10/24. C) In an interview on 5/27/25 at 3:15 p.m. the laboratory staff member (#1 on the CMS 209 form) confirmed that the quality of the H and E stains were not documented on the days identified above and Mohs surgery was performed on those days.