Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0272706	(X3) Date Survey Completed 06/06/2024
Name of Provider or Supplier Michael J Freeman Md Pa	**Street Address, City, State** 2723 Se Maricamp Rd, Ocala, FL	
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 recertification survey was conducted on 6/6/24 at Michael J Freeman, a clinical laboratory in Ocala, Florida. Michael J Freeman was found not in compliance with Code of Federal Regulations (CFR), Part 493, requirements for clinical laboratories.
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 record review and staff interview, the facility failed to maintain daily quality control (QC) slide documentation for Mohs testing for 2 out of 7 testing days reviewed in 2023. Findings include: Record review of the document titled "Mohs Micrographic Surgery Specimen Log (MO23)" showed 9 cases of Mohs were tested on 5/16/23 and 3 cases of Mohs were tested on 8/16/23. Review of the document titled "Daily Cryotomy Slide/Stain Quality Control" showed QC documentation was blank on 5/16/23 and 8/16/23. The facility policy titled "Testing Procedures B. Moh's Micrographic Surgery 4. Staining" effective 3/1/2022 states "Stain is checked daily for acceptable results by the reading physician. The reading physician will complete the stain quality control sheet each day of staining." During the interview with the Practice Manager on 6/6/24 at 1:00 pm, it was confirmed the QC documentation was missing.
D5805	TEST REPORT CFR(s): 493.1291(c)

	The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports and staff interview, the laboratory failed to have the correct laboratory address where the histopathology reading (testing) was performed in 2023 and 2024. Findings Included: Review of the document titled "Mohs Flowsheet/Operative Report" showed the patient reports had the incorrect laboratory address. On 6/6/24 at 12:45 pm., the Practice Manager confirmed the patient test reports did not have the correct laboratory address for the reading/testing location.