Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2176721	06/18/2026
Name of Provider or Supplier	**Street Address, City, State**	
Michael J Freeman Md Pa	13690 Us 441 North Suite 300, The Villages, 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 CLIA recertification survey was conducted at Michael J Freeman MD Pa on 6/18/26. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on document review, and interview, it was determined the laboratory failed to document the following written procedure for Histology staining for two (3/2026 and 5 /2025) of three months (8/2024, 3/2026 and 5/2025) reviewed. Findings included: 1. Review of the Linear Stain Logs for 8/2024, 3/2026 and 5/2025 indicated "C" was to indicate changed and a check mark was for checked. The monthly Linear Stain Logs for 3/2026 and 5/2025 documented only check marks for each week of use. 2. The laboratory manual approved by the Laboratory Director on 7/2025 included a Quality Assurance Analytic Plan for Staining Lines for reagents to be changed weekly. 3. The Chief Executive Officer (CEO) confirmed on 6/18/2026 at 1:30 PM, there was no documentation the laboratory had followed the written procedure for Histology staining for two (3/2026 and 5/2025) of three months (8/2024, 3/2026 and 5/2025) reviewed.
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 record review, and interview, the laboratory failed to have an established ongoing mechanism that identified problems in the Histology staining analytic systems for two (3/2026 and 5/2025) of three months (8/2024, 3/2026 and 5/2025) reviewed. Findings included: 1. The laboratory manual approved by the Laboratory Director on 7/2025 included a memo the Quality Assurance (QA) Plan was changed to monthly review. 2. Two (3/2026 and 5/2025) of three months (8/2024, 3/2026 and 5 /2025) Monthly QA reports reviewed, failed to identify the laboratory failed to document following written procedure for Histology staining for two (3/2026 and 5 /2025) of three months (8/2024, 3/2026 and 5/2025) reviewed, (See D5401). 3. The Chief Executive Officer (CEO) confirmed on 6/18/2026 at 1:30 PM, there was no documentation the laboratory QA had identified the problem with not following the written procedure for Histology staining for two (3/2026 and 5/2025) of three months (8/2024, 3/2026 and 5/2025) reviewed.
D5805	TEST REPORT CFR(s): 493.1291(c) (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 final reports, and interview, the laboratory failed to document the name of the laboratory on one of two patient reports reviewed. Findings included: 1. Patient reports for 5/27/2025 and 3/17/2026 were reviewed. The patient final report for 3/17/2026 failed to include the name of the laboratory and instead listed another laboratory name. 2. The Chief Executive Officer (CEO) confirmed on 6 /18/2026 at 1:30 PM, the patient report for 3/17/2026 failed to include the name of the laboratory and instead listed another laboratory name.