Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2176721	01/26/2022
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	A recertification survey was conducted on January 26, 2022. Michael J Freeman MD PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify accuracy of the reading and interpretation of the Hematoxylin and Eosin (H&E) stain, Special Stains, and Immunohistochemistry (IHC) stains, and failed to perform a blind peer review for one (A) of two (A, B) testing personnel at least twice annually in 2021. The laboratory also failed to verify the accuracy of the reading and interpretation of the H&E stain for one (B) of two (A, B) testing personnel at least twice annually in 2021. Findings: 1. Documentation showed that peer review for biopsy case diagnosed by Laboratory Director (Testing Personnel A) was performed on 8/24/21. The laboratory's form titled Quality Assurance Proficiency Testing Peer Review noted, "This is documentation of a blind peer review . . . ." Review of the form showed that reviewing Dermatopathologist reported the diagnosis of "Agree" for 12 of 12 cases sent for peer review on 8/24/21. The laboratory directory evaluated H&E stains and the following special stains: AFB (Acid Fast Bacilli, Mycobacterium stain), Collodial Fe (iron stain), Fite (Acid Fast Bacilli, Mycobacterium leprae stain), Giemsa (histological stain), Gram Stain (Bacteria stain), PAS (Periodic Acid Schiff, polysaccharides stain), and VVG (Verhoeff-Van Gieson, elastic fibers stain). The Laboratory Directory evaluated the following IHC stains: AE1/AE3 (Epithelial IHC stain), BerEp4 (Epithelial Antigen IHC stain), Chromogranin (Neuroendocrine cell IHC Marker), CD4 (Cluster of Differentiation 4 T cell Lymphocytic IHC stain), CD5

	(Cluster of Differentiation 5 T cell Lymphocytic IHC stain), CD7 (Cluster of Differentiation 7 T cell Lymphocytic IHC stain), CD8 (Cluster of Differentiation 8 T cell Lymphocytic IHC stain), CD10 (Cluster of Differentiation 10 Cell Surface Enzyme IHC stain), CD20 (Cluster of Differentiation 20 B cell Lymphocytic IHC stain), CD30 (Cluster of Differentiation 30 Transmembrane Cytokine Receptor IHC stain), CD31 (Cluster of Differentiation 31 platelet endothelial cell adhesion molecule-1 IHC stain), CD34 (Cluster of Differentiation 34 progenitor cells IHC stain), CD45 (Cluster of Differentiation 45 leukocyte IHC stain), CD68 (Cluster of Differentiation 68 transmembrane glycoprotein), CK7 (Cytokeratin 7 Protein IHC stain), CK20 (Cytokeratin 20 IHC stain), D2-40 (Podoplanin, lymphatic endothelial IHC stain), EMA (Epithelial Membrane Antigen IHC stain), Factor XIIIa (Factor XIIIa protein IHC stain), HMB-45 (Melanoma-associated marker IHC stain), Melan-A/MART-1 (Melanocytic Marker IHC stain), pHH3 (Phosphohistone H3 Protein IHC stain), S100 (Neural Tissue/Lesion and Melanoma IHC stain), SOX-10 (Melanoma IHC stain), and Synaptophysin (Neuroendocrine IHC stain). On 01/26/2022 at 1:40 PM, the General Supervisor stated the laboratory sent the final report to the reviewing Dermatopathologist per their request and the peer review cases for July to December 2021 were performed in January 2022. 2. Review of Mohs Micrographic Surgery (MMS) Consultation/Peer Review Record showed peer review for Mohs surgical case diagnosed by Testing Personnel B for the case from January to June were reviewed by a Dermatopathologist from an outside facility. The peer review report for the Mohs surgical cases for July to December was performed by the Laboratory Director on 01 /07/22. On 01/26/2022 at 1:40 PM, the General Supervisor stated peer review cases for July to December 2021 were performed in January 2022.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 observation and interview, the laboratory failed to store four immunohistochemical (IHC) reagents at the required temperature as per manufacturer's instructions. Findings: On 01/26/2022 at 9:40 AM, four Immunohistochemistry reagents were stored in the refrigerator. The label for Tris Buffered Saline noted the storage temperature should be 15 to 30 degrees Celsius (C). The label for Cell Marque Peroxide Block received on 09/24/2021, showed the storage requirement of 20 to 26 degrees C. The label for 10X Tris-ETDA Retrieval Buffer, pH 9.0 received on 11/10/2021 read the storage requirement was 15 to 25 degrees C. The label for Trilogy Pretreatment Solution 3 Step in 1 received on 12 /2020 indicated storage requirement of 20 to 26 degrees C. On 01/26/2022 at 9:47 AM, the General Supervisor acknowledged the reagents were stored in the refrigerator but should have been stored at room temperature.