Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2024003	09/24/2020
Name of Provider or Supplier	**Street Address, City, State**	
Mid Florida Dermatology Associates Pa	7350 Futures Dr Ste 12a, Orlando, 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 September 24, 2020. Mid Florida Dermatology Associates PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory procedure manual failed to include a procedure on Immunohistochemical (IHC) Quality Control (QC). Findings: Review of the procedure manual QC/QA (Quality Assurance) manual, signed and dated by the Laboratory Director on 10/5/19, did not reveal a procedure on IHC QC.

	During an interview on 9/24/20 at 1:06 PM, the General Supervisor stated there was no procedure on IHC QC. During an interview on 9/24/20 at 3:10 PM, the General Supervisor stated the laboratory had 90 patients from 1/1/20 to 9/24/20, 165 patients in 2019, and 37 patients from 9/24/18 to 12/31/18 that had IHC stains performed on them.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review, observation, and interview, the laboratory failed to have a separate negative control slide for immunohistochemical (IHC) stains from 9/24/18 to 9/24/20. Findings: Review of the Clinical Laboratory Improvement (CLIA) Application for Certification signed and dated by the Laboratory Director on 9/23/20 noted the laboratory performed the following IHC stains: AE1/AE3 (Epithelial IHC stain), Androgen Receptor, BerEp4 (Epithelial Antigen IHC stain), CD1A (Cluster of Differentiation 1A gastrointestinal epithelium and cytoplasmic hepatocytes IHC stain), CD3 (Cluster of Differentiation 3 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), CD117 (Cluster of Differentiation 117, stem cell IHC stain), CD123 (Cluster of Differentiation 123 hematopoietic progenitor cell IHC stain), CD163 (Cluster of Differentiation 163 monocyte and macrophage IHC stain), Chromogranin IHC stain, CK3 (Cytokeratin 3 Epithelial IHC stain), CK20 (Cytokeratin 20 Protein IHC stain), Desmin (Smooth Muscle Tumor IHC stain), EMA (Epithelial Membrane Antigen IHC stain), Factor XIIIa (Factor XIIIa protein IHC stain), HHV-8 (Herpes Virus Type 8 IHC stain), HSV (Herpes Simplex Virus Type 1 &2 IHC stain), Melan-A (Melanocytic Marker IHC stain), MITF (Microphthalamia Transcription Factor IHC stain), MLH1 (MutL Homolog 1 Colorectal Cancer IHC stain), MSH2 (Melanocyte Stimulation Hormone 2 Tumor Suppressor Gene IHC stain), MSH6 (Melanocyte Stimulation Hormone 6 Colorectal Cancer and Endometrial Cancer IHC stain), NSE (Neuron Specific Enolase IHC Stain), P63 (P63 gene IHC stain), PMS2 (Postmeiotic Segregation Increase 2 IHC stain), S100 (Neural Tissue/Lesion and Melanoma IHC stain), SMA (Smooth Muscle Actin IHC stain), SOX-10 (Melanoma IHC stain), Spirochetes (Treponema Palladium IHC stain), and Tryptase (Mast Cell IHC stain). Review of the Dermatopathology Report showed that 2 (#6, #7) out of 7 (#1 - #7) patients had IHC stain results. Review of patients #6's Dermatopathology Report showed results for Melan-A and Sox-10 IHC stains, and the stains were performed by Mid Florida Pathology. Observation of patient #6's slides showed there was not any negative control slide for the Melan-A IHC stain and there was not any negative control slide for the Sox-10 IHC stain. Review of patient #7's Dermatopathology Report showed results for CD1a and S100 IHC stains. The

	stains were performed by CBL Path. Observation of patient #7's slides showed there was no negative control slide. During an interview on 9/24/20 at 2:27 PM, the Laboratory Director stated that Mid Florida Pathology did not send stain specific IHC negative control slides. During an interview on 9/24/20 at 3:02 PM, the General Supervisor stated that CBL Path did not send IHC negative control slides. During an interview on 9/24/20 at 3:10 PM, the General Supervisor stated the laboratory had 90 patients from 1/1/20 to 9/24/20, 165 patients in 2019, and 37 patients from 9/24/18 to 12/31/18 that had IHC stains performed on them.