Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2053266	10/28/2020
Name of Provider or Supplier	**Street Address, City, State**	
Mid-Florida Pathology Llc	2882 S Osceola Ave 5c, 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 October 28, 2020. Mid-Florida Pathology LLC clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
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 stain specific negative control slide for immunohistochemical (IHC) stains from 10/28/18 to 10/28/20. Findings: Review of the Clinical Laboratory Improvement (CLIA) Application for Certification signed and dated by the Laboratory Director on 10/28/20 noted the laboratory reported the results of the following IHC stains: 34BE12 (Carcinoma IHC stain), AFP (Alpha-1-Fetoprotein IHC stain), ALK-1 (anaplastic lymphoma kinase IHC stain), AMACR (alpha methyacyl CoA racemase IHC stain), Amyloid IHC stain, BCL-2 (B cell lymphocytic IHC stain), BCL-6 (Lymphocytic IHC stain), BerEp4 aka Ep-CAM (Epithelial Antigen IHC stain), Calponin B (actin filament associated regulatory protein IHC stain), Calret (Calretinin calcium binding protein IHC stain), CD3 (Cluster of Differentiation 3, T cell lymphocytic IHC stain), 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), CD15 (Cluster of Differentiation 15, lymphocytic IHC stain), CD20 (Cluster of Differentiation 20, B cell lymphocytic IHC stain), CD21 (Cluster of Differentiation 21, B cell lymphocytic IHC stain), CD23 (Cluster of Differentiation 23, B cell lymphocytic IHC stain), CD30 (Cluster of Differentiation 30, lymphocytic IHC stain), CD31 (Cluster of Differentiation 31, platelet endothelial cell adhesion molecule-1 IHC stain), CD43 (Cluster of Differentiation 43, T cell lymphocytic IHC stain), CD44 (Cluster of Differentiation 43, phagocytic glycoprotein 1 IHC stain), CD45 LCA (Cluster of Differentiation 45, leukocyte IHC stain), CD56 (Cluster of Differentiation 56, leukocyte IHC stain), CD61 (Cluster of Differentiation 61, megakaryocytes IHC stain), CD68 (Cluster of Differentiation 68, macrophages IHC stain), CD79a ((Cluster of Differentiation 23, B cell lymphocytic IHC stain), CD117 (Cluster of Differentiation 117, stem cell IHC stain), CD138 (Cluster of Differentiation 138, plasma cells IHC stain), CDX2 (Intestinal Epithelium IHC stain), CEA (Carcinoembryonic Antigen IHC stain), Chromogranin (Neuroendocrine cell IHC Marker), CK 5/6 (Cytokeratin 5/6 IHC stain), CK7 (Cytokeratin 7 Protein IHC stain), CK20 (Cytokeratin 20 IHC stain), CMV (cytomegalovirus IHC stain), Cyclin D1(Lymphocytic B cell IHC stain), Desmin (Smooth Muscle Tumor IHC stain), ECAD (E-Cadherin, epithelial cells IHC stain), EMA (Epithelial Membrane Antigen IHC stain), EP-CAM (epithelial cell adhesion molecule IHC stain), ER (Estrogen Receptor IHC stain), Factor XIIIa (Factor XIIIa protein IHC stain), GATA-3 (epithelial and nonepithelial tumors IHC stain), GCDFP-15 (Gross cystic disease fluid protein 15 IHC stain), GLUT1 (Glucose transporter isoform 1 IHC stain), HCG (human chorionic gonadotropin IHC stain), Her2 (Cell surface receptor IHC stain), H. pylori (Helicobacter pylori IHC stain), HMB45 (Anti-Human Melanosome IHC stain), HSV1 (Herpes Simplex Virus Type IHC stain), HSV2 (Herpes Simplex Virus Type 1 &2 IHC stain), Kappa (Immunoglobulin Kappa-light chain IHC stain), Ki-67 (Nuclear Non-histone Protein IHC stain), Lambda (Immunoglobulin Lambda-light chain IHC stain), MCK (Epithelial IHC stain), MCT (Mast Cell Tryptase IHC stain), Melan-A (Melanocytic Marker IHC stain), MITF (Microphthalamia Transcription Factor IHC stain), MLH1 (MutL Homolog 1 Colorectal Cancer IHC stain), MPO (Myeloperoxidase IHC stain), MSH2 (Melanocyte Stimulation Hormone 2 Tumor Suppressor Gene IHC stain), MSH6 (Melanocyte Stimulation Hormone 6 Colorectal Cancer and Endometrial Cancer IHC stain), MUC2 (Epithelial IHC stain), MUM 1 (Lymphocytic cell IHC stain), Napsin A (Novel Aspartic Proteinase IHC stain), NSE (Neuron Specific Enolase IHC Stain), P16 (Tumor suppressor protein IHC stain), P40 (Carcinoma marker IHC stain), P53 (Tumor suppressor gene IHC stain), P63 (Myoepithelial marker IHC stain), Pax-5 (B cell-lineage specific activator protein IHC stain), PGP9.5 (Protein gene product 9.5 neuroendocrine IHC stain), PLAP (Placental-like alkaline phosphatase, Germ Cell Tumor IHC stain), PMS2 (Postmeiotic Segregation Increase 2 IHC stain), PR (Progesterone Receptor IHC stain), PSA (Prostate specific antigen IHC stain), PSAP (Prostatic specific acid phosphatase IHC stain), PSMA (Prostate specific membrane antigen IHC stain), S100 (Neural Tissue /Lesion and Melanoma IHC stain), SMA (Smooth Muscle Actin IHC stain), SMM (smooth muscle myosin IHC stain), SOX-10 (Melanoma IHC stain), SOX-11 Lymphocytic cell IHC stain), Synapto (Neuroendocrine IHC stain), TdT (Terminal deoxynucleotidyl transferase IHC stain), TTF1 (Thyroid transcription factor 1 IHC stain), Vimentin (Mesenchymal cells IHC stain), and WT1 (Tumor suppressor gene IHC stain). Review of the final pathology report showed that 7 (#1, #5, #7, #8, #11, #14, #15) out of 15 (#1-#15) patients had IHC stain results. Review of patients #1's and #8's pathology report showed results for CD3 and H. pylori IHC stains. Observation of patient #1's and 8's slides showed there was not a stain specific negative control slide for CD3 or H. pylori IHC stains. Review of patients #5's and #7's pathology report showed results for a H. pylori IHC stain. Observation of patient

	#5's and #7's slides showed there was not a stain specific negative control slide for the H. pylori IHC stain. Review of patients #11's pathology report showed results for a CK20 and Ki-67 IHC stains. Observation of patient #11's slides showed there was not a stain specific negative control slide for the CK20 or Ki-67 IHC stains. Review of patients #14's pathology report showed results for an AMACR, 34BE12, and p63 IHC stains. Observation of patient #14's slides showed there was not a stain specific negative control slide for the AMACR, 34BE12, or p63 IHC stains. Review of patients #15's pathology report showed results for a CD3, CD20, CD138, MCK and Pax-5 IHC stains. Observation of patient #15's slides showed there was not a stain specific negative control slide for the AMACR, 34BE12, or p63 IHC stains. On 10/28 /20 at 1:00 PM, the Laboratory Quality Assessment Coordinator stated they did not have stain specific IHC negative control slides.