

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2142655	(X3) Date Survey Completed 03/11/2024
Name of Provider or Supplier Nosky Pa	Street Address, City, State 518 Cypress Parkway, Kissimmee, 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	Recertification survey was conducted on March 11, 2024. Nosky PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of peer review records and interview, the laboratory failed to verify the accuracy of the reading and interpretation of the Hematoxylin and Eosin (H&E) stain, Special Stains, and Immunohistochemistry (IHC) stains in 2022. Findings: The laboratory used peer review (proficiency) to verify the accuracy of the reading and interpretation of the Hematoxylin and Eosin (H&E) stain, Special Stains, and Immunohistochemistry (IHC) stains. Review of the laboratory's policy titled "Proficiency Program" noted that "Random cases are sent out for a blind review twice annually to assess the performance of the pathologist (at least 20 cases) per year." The Laboratory Directory evaluates 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 evaluates the following IHC stains: BerEp4 (Epithelial Antigen IHC stain), Chromogranin (Neuroendocrine cell IHC Marker), CD1A (Cluster of Differentiation 1A gastrointestinal epithelium and cytoplasmic hepatocytes 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</p>

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), CEA (Carcinoembryonic Antigen IHC stain), CD68 (Cluster of Differentiation 68 transmembrane glycoprotein), CK7 (Cytokeratin 7 Protein IHC stain), CK20 (Cytokeratin 20 IHC stain), D-240 (Podoplanin, lymphatic endothelial IHC stain), EMA (Epithelial Membrane Antigen IHC stain), Factor XIIIa (Factor XIIIa protein IHC stain), Fite (Microorganism IHC stain), HMB-45 (Melanoma-associated marker IHC stain), KI-67 (Cell proliferation marker IHC stain), Melan-A/MART-1 (Melanocytic Marker IHC stain), MITF (Microphthalmia Transcription Factor IHC stain), Pank-AE1/3 (Epithelial IHC stain), pHH3 (Phosphohistone H3 Protein IHC stain), PRAME (Melanoma IHC stain), S100 (Neural Tissue/Lesion and Melanoma IHC stain), SOX-10 (Melanoma IHC stain), and Synapto (Neuroendocrine IHC stain). Review of the peer review records revealed the peer review was done once in 2022 on 09/09/2022. On 03/11/2024 at 3:45 PM, Testing Personnel A acknowledged the peer review was done only once in 2022.