

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2142655	(X3) Date Survey Completed 09/19/2019
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	A recertification survey was conducted on September 19, 2019. 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 record review and staff 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 2018 using a blind peer review. Findings: Review of the laboratory's policy titled "Proficiency Program" noted that "slides sent out for a second opinion will be used to assess then performance of the pathologist. The laboratory's form titled "Anatomic Pathology Consultation / Peer Review" listed slides sent out for second opinions. The laboratory used the consults to evaluate the accuracy of the reading and interpretation of the H&E stain, special stains and IHC stains. The laboratory directory evaluates the following special stains: AFB (Acid Fast Bacilli, Mycobacterium stain), Alcain Blue (mucopolysaccharides and glycoproteins 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: AE1/AE3 (Epithelial IHC stain), 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</p>

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), 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), pHH3 (Phosphohistone H3 Protein IHC stain), S100 (Neural Tissue/Lesion and Melanoma IHC stain), SOX-10 (Melanoma IHC stain), and Synapto (Neuroendocrine IHC stain). During an interview on 9/19/19 at 1244 PM, the Testing Personnel B acknowledged that the slides and diagnosis on patients were sent out when a second opinion was requested. Testing Personnel B also acknowledged that the use of the consult slides for the peer review wasn't a blind peer review and that the "Anatomic Pathology Consultation / Peer Review" didn't provide a space to indicate if the two doctors agreed on the diagnosis.

D5805

TEST REPORT
CFR(s): 493.1291(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 record review and interview, the laboratory's patient final report failed to list the correct address of the laboratory where the histopathology testing was performed for 4 out of 4 patient final reports examined, (#1, #2 #3 and #4). Findings: Review of the "Surgical Pathology Report" for patient #1, #2, #3 and #4 showed that the laboratory's address was incorrect. During an interview on 9/19/19 at 1:34 PM, the Testing Personnel B acknowledged that the surgical report did not have the correct address.