Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0992924	08/24/2023
Name of Provider or Supplier	**Street Address, City, State**	
Nova Southeastern University -	3200 S University Dr - Ziff Bldg, Room 4343, Fort Lauderdale, 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 conducted on 08/24/2023 found the NOVA SOUTHEASTERN UNIVERSITY - ORAL PATHOLOGY SERVICES clinical laboratory not in compliance with 42 CFR Part 493, Requirements for 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 patient report, slides review and interview, the laboratory failed to have and record the negative control reactivity verification for the immunohistochemical (IHC) stain interpretation that the laboratory performed at least since 01/01/2022 to present for six out of six patients reviewed. Findings included: - The laboratory performed only the microscopic examination of the slides. -Review of the Form CLINICAL LABORATORY IMPROVEMENT AMMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION Form CMS-116 signed by the Laboratory Director on 08/19 /2023 revealed the following test menu for IHC: CD45 (Cluster of Differentiation 45 leukocyte IHC stain), CD3, CD20, Actin-HHF-35(Muscle Specific IHC stain), AE1 /AE3 (Epithelial IHC stain), Calponin, CD1a, CD4, CD8, CD68, Desmin, EMA (Epithelial Membrane Antigen IHC stain), Epstein-Barr virus latent membrane protein, Factor XIIIa, HMB45 (Anti-Human Melanosome IHC stain), Ki-67 (Nuclear Non-histone Protein IHC stain), MART-1/Melan-A (Melanocytic Marker IHC stain), Pan Keratin (Epithelial IHC stain), S100 (Neural Tissue/Lesion and Melanoma IHC

	stain), SOX-10 (Melanoma IHC stain), Synaptophysin (Neuroendocrine cell IHC Marker), Vimentin (Mesenchymal Cells IHC stain). - Review of six final reports and slides for the following cases revealed: a) Patient #1 (dated 06/03/2022). The report listed the use of IHC stain Epstein-Barr virus latent membrane protein, slide review revealed no negative control found. b) Patient #2 (dated 09/06/2023): The report listed the use of IHC stains Desmin, AE1/AE3 and Pan Keratin, slides review revealed no negative control. c) Patient #3 (dated 05/22/2023): The report listed the use of IHC stains EMA, Vimentin and Pan Keratin; slides review revealed no negative control used. d) Patient #4 (dated 06/09/2023): The report listed the use of IHC stains AE1 /AE3 and SMA, slides review revealed no negative control used. e) Patient #5 (dated 06/28/2023): The report listed the use of IHC stains SOX-10 and EMA, slides review revealed no negative control used. f) Patient #6 (dated 08/09/2023): The report listed the use of IHC stains SOX-10, mart-1 and hmb-45, slides review revealed no negative control used. During an interview on 08/24/2023 at 10:30 AM, the laboratory director confirmed that the laboratory failed to have and record negative control reactivity for the immunohistochemistry stains for the cases of reference.