Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1002070	09/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Skin Center Of Northern Virginia, The	3700 Joseph Siewick Drive - Suite 404, Fairfax, VA	

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	An announced CLIA recertification survey was conducted at The Clinical Skin Center of Northern Virginia on September 4, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
D5427	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(c) (c) Documentation. The laboratory must document all activities specified in this section. This STANDARD is not met as evidenced by: Based on a tour, review of the laboratory's performance validation/verification records, patient test logs, and interviews, the laboratory failed to document the validation of the Vector PNI IHC (CK) Immunohistochemical (IHC) stain kit prior to reporting twenty-two (22) patient results using the new IHC staining kit from June 12, 2019 to the date of survey on September 4, 2019. Findings include: 1. During a tour of the laboratory at approximately 10:00 AM, the surveyor noted IHC reagents for the Vector PNI IHC (CK) IHC kit (lot ZE1121 exp. 9/20) in use for patient IHC staining for the detection of CK. The surveyor asked when the laboratory began using the Vector PNI IHC kit in the laboratory. TP F stated they began patient testing for CK in June 2019. 2. Review of the laboratory's performance validation/verification documentation records revealed a lack of documentation of the validation of the new Vector PNI IHC (CK) IHC stain kit. The inspector requested to review documentation that the laboratory had performed validation of the new IHC stain kit prior to patient testing. The laboratory provided no documentation of the new IHC stain validation for review. 3. In an interview with TP B, TP F, TP G and Mohs Technician (MT) A at approximately 1:15 PM, TP B stated they performed the validation but they did not have the documentation. 4. Review of patient test logs revealed that the laboratory reported 22 patient PNI CK IHC stain results using the Vector PNI IHC (CK) stain kit

	from June 12, 2019 to the date of the survey on September 4, 2019. 5. In an exit interview with the TP F at approximately 2:00 PM, the above findings were confirmed.