Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2176390	01/04/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pinnacle Dermatology - Hedgewood	13875 Hedgewood Drive Suite 210, Woodbridge, 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 Pinnacle Dermatology-Woodbridge on January 4, 2023 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 deficiency is as follows:
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, slide quality control log sheet, Mohs Surgery specimen logs, lack of documentation and interviews, the laboratory failed to follow their established policy and document the intended reactivity for Hematoxylin and Eosin (H&E) stain for one (1) day of twenty (20) days of Mohs surgery during the review timeframe of May 6, 2021 until December 16, 2021 while reporting nine (9) patients. Findings include: 1. Review of the laboratory's procedure manual revealed a policy, "Policy on Quality Assurance and Procedure-Mohs Surgery", which stated: "b. The stains for each Mohs day are evaluated for intended reactivity. i. A quality control slide is rendered at the beginning of each day to assess quality of staining solutions and techniques." 2. Review of the slide quality control log sheet and Mohs patient log sheets from May 6, 2021 until December 16, 2021 revealed a lack of documentation of the intended reactivity for the H&E QC slide for July 15, 2021 while reporting 9 patients. The surveyor requested to review the H&E QC slide and documentation of the intended reactivity for the H&E stain for

	July 15, 2021. The laboratory was unable to provide the H&E QC slide and documentation of the intended reactivity of the H&E stain for July 15, 2021. 3. In an exit interview with the Mohs Technician on January 4, 2023 at approximately 11:15 AM, the above findings were confirmed.