Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0227531	11/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Richmond Dermatology Specialists, Pc	9816 Mayland Drive, Richmond, 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 Richmond Dermatology Specialists, PC on November 13, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows and include the Condition under 42 CFR part 493 CLIA Regulation: D5200 -42 CFR. 493.1230 General Laboratory Systems.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services 116 form, procedures, proficiency testing records, lack of documentation, and interviews, the laboratory failed to retain documentation of twice annual accuracy verification for moderate complexity dermatological Potassium Hydroxide and high complexity histological pathology slide microscopy examinations during a recertification inspection's twenty-three months review timeframe (January 2022 to November 13, 2023). Cross Reference D5217.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) 116 form, procedures, proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to retain documentation of twice annual accuracy verification for dermatological Potassium Hydroxide (KOH) and histological pathology slide microscopy examinations during the twenty-three (23) months review timeframe (January 2022 to November 13, 2023). Findings include: 1. Review of the CMS 116 form revealed that the lab director (LD) identified three testing personnel qualified to perform moderate complexity patient dermatological Potassium Hydroxide (KOH) microscopy examinations and one testing personnel qualified to perform high complexity histological pathology slide reading. 2. Review of the laboratory's procedure manual revealed a LD approved protocol "Proficiency Testing" that outlined PT/accuracy verification for the nonwaived testing procedures outlined above. 3. Review of the laboratory's PT binder revealed no accuracy verification documentation for the 23 months of review (timeframe January 2022 to 11/13/23). The inspector requested to review twice annual accuracy documentation for Potassium Hydroxide (KOH) and pathology slide microscopy examinations. The documentation was not available for review. 4. An exit interview with the LD, executive director, and clinical lead on 11/13/23 at 3:30 PM confirmed the above findings.