| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number**<br><br>49D2131489 | **(X3) Date Survey Completed**<br><br>08/29/2023 |
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| **Name of Provider or Supplier**<br><br>Dermatology Associates Of Virginia | **Street Address, City, State**<br><br>10800 Midlothian Turnpike - Suite 310, 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** |
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| **D0000** | An announced CLIA recertification survey was conducted at Dermatology Associates of Virginia (Midlothian) on August 24-25, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The inspection also included a follow up review of personnel records and interviews with the clinical administrator and laboratory supervisor on 8/28/23-8/29/23. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiency cited is as follows: |
| **D6115** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(2)<br><br>The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), personnel files, newly installed histopathology tissue processing analyzers' performance qualification records, lack of documentation, review of user guide, and interviews, the technical supervisor (TS) failed to document an approval evaluation/verification for one (1) of two (2) new tissue sample processors after installation in May 2023 as reviewed on the date of the inspection August 24-25, 2023. Findings include: 1. Review of the laboratory's CMS 209 personnel form and personnel files revealed that Testing Personnel (TP) #1 qualified and performed responsibilities of Lab Director (LD) and identified TP #2 qualified and performed responsibilities of TS. * See Personnel Code Sheet. 2. A review of the histopathology analyzer validation records revealed the following 2 new automated processors were installed by field service technical specialists in May 2023: Tissue Tek Sakura Prisma Plus for Histological Hematoxylin & Eosin (H & E - Serial Number 617101041217) on 5/25/23; Roche Benchmark Ultra Plus for |

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| | Immunohistochemistry (IHC - Serial Number 1100222) on 5/30/23. 3. The inspector noted that the initial Roche Benchmark Plus installation validation studies were not evaluated by the LD or TS. The inspector noted a Roche field service specialist notation (dated 5/30/23), "Installation performance qualification completed. All 20 vimentin stained slides show appropriate staining." 4. The inspector requested to review a record of an evaluation/approval of validation studies for reaction/stain quality observations for the new analyzer system outlined above by the TS or LD. The clinical administrator and laboratory supervisor stated on 8/25/23 at 2 PM, "We will get the lab director and technical supervisor to review and sign the initial and preceding validations." 5. Review of the Roche Benchmark Ultra Plus user guide revealed statement, "Product validations should be interpreted by qualified pathologist personnel in conjunction with histological examination, relevant clinical information, and proper controls." 6. A follow up interview with the clinical administrator on 8/29 /23 at 11 AM confirmed the above findings. |