| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 49D0227531 | 09/12/2019 |
| **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 |
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| **D0000** | An announced CLIA Recertification survey was conducted at the Richmond Dermatology and Laser Specialists on September 12, 2019 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: |
| **D5200** | GENERAL LABORATORY SYSTEMS<br>CFR(s): 493.1230<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on a review of the policy and procedure (P&P) and an interview with the laboratory director, the laboratory failed to verify the accuracy of the Potassium Hydroxide (KOH) and dermatological Wet Preparation (Prep) microscopic examinations at least twice annually in the calendar year 2018 and 2019. (Repeat Deficiency and Cross Reference D5217.) |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>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. |

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| | This STANDARD is not met as evidenced by:<br>**Repeat Deficiency** Based on a review of the policy and procedure (P&P) and an interview with the laboratory director, the laboratory failed to verify the accuracy of the Potassium Hydroxide (KOH) and dermatological Wet Preparation (Prep) microscopic examinations at least twice annually in the calendar year 2018 and 2019. Findings include: 1. Review of the P&P and interview with the laboratory director at approximately 10:00 AM revealed the laboratory performs dermatological Wet Prep and KOH microscopic slide examinations. The inspector requested to review the documentation of twice a year accuracy verification for the aforementioned tests. The documentation was not available for review. 2. An interview with the laboratory director at approximately 11:00 AM confirmed the findings. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the policy and procedure (P&P), lack of documentation, and an interview with the laboratory director, the laboratory failed to establish a written P&P for performing the twice-annual accuracy verification for the Potassium Hydroxide (KOH) and dermatological Wet Preparation (Prep) microscopic examinations at the date of survey on September 12, 2019. (Cross Reference D5217.) Findings include: 1. Review of the current P&P revealed lack of documentation of an established P&P for performing the twice-annual accuracy verification for the KOH and dermatological Wet Prep microscopic examinations. 2. An interview with the laboratory director at approximately 11:00 AM confirmed the findings. |