

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0990271	(X3) Date Survey Completed 08/06/2025
Name of Provider or Supplier New River Dermatology	Street Address, City, State 2617 Sheffield Drive, Blacksburg, 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 New River Dermatology August 5-6, 2025 by the Virginia Department of Health's Office of Licensure and Certification. New River Dermatology was found not in compliance with applicable Standards and Condition under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and include the Condition: D6076 - 42 CFR 493.1441 Condition: Laboratory Director.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of procedures, proficiency testing logs, lack of documentation, and interviews, the laboratory failed to perform mohs histopathology accuracy checks by peer review twice annually per laboratory policy during twelve (12) of twenty (20) months reviewed (timeframe: December 20, 2023 to August 6, 2025). **REPEAT DEFICIENCY Findings include: 1. Review of the laboratory's procedures revealed a quality assurance policy for proficiency testing (titled "Proficiency Testing - Post Analytical"). The policy stated "Proficiency testing is done to ensure accurate interpretation of mohs slides by the mohs surgeon. For proficiency testing, two cases are selected for review by an outside dermatopathologist. This process is done twice a year." 2. Review of the laboratory's peer review records for the 20 months of review (12/20/23-8/5/25) revealed the following documentation: Peer review 2024- 2 cases dated 4/8/24; Peer review 2025- 3 cases dated 5/20/25; The inspector requested to review additional peer review verified in the 12 months of calendar year 2024. No additional records were available. 3. The inspector inquired as to the reason peer review cases were not pulled twice annually as outlined in the quality assurance policy. The mohs staff members stated on 8/5/25 at 3:30 PM, "We had a couple of</p>

staff changes that occurred in 2024 that led to the lapse in pulling cases for peer review." 4. An interview with the mohs staff members on 8/5/25 at 3:30 PM and 8/6/25 at 10 AM confirmed the above findings.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
Based on review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form, policies, proficiency testing (PT) records, lack of documentation, and interviews, the laboratory director failed to identify PT quality assessment failures as they occurred when twice annual peer review assessment was not performed per policy in calendar year 2024 (a repeat deficiency). *Refer to D6093.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:
Based on review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification (CMS 116) and Statement of Deficiencies Plan of Correction (CMS-2567 POC) forms, quality assurance policy, proficiency testing (PT) peer review records, lack of documentation, and interviews, the laboratory director (LD) failed to identify PT quality assessment failure timely during twelve (12) of twenty (20) months reviewed (timeframe: December 20, 2023 to August 6, 2025). *Refer to D5217 a REPEAT DEFICIENCY Findings include: 1. Review of the CMS 116 report revealed that the LD identified high complexity histopathology mohs slide reading was performed during the 20 month review timeframe of 12/20/23 - 8/6/25. 2. Review of documentation revealed: Quality Assurance PT policy: The policy stated "Proficiency testing is done to ensure accurate interpretation of mohs slides by the mohs surgeon. For proficiency testing, two cases are selected for review by an outside dermatopathologist twice annually." CMS-2567 POC (LD signed/approved 12/21/23) procedure outlined a corrective action plan to ensure twice annual accuracy verification which stated "The laboratory director and testing personnel will monitor and verify that peer to peer is submitted and assessed every six months." 3. Review of the laboratory's 12 months of PT documentation in calendar year 2024 revealed one event of peer review (2 cases sent on 4/8/24). The inspector requested to review peer review documentation for additional cases performed in 2024. No additional records for the expected twice annual peer review in 2024 were provided. 4. The inspector inquired regarding identification/corrective action records for the failure to adhere to the LD approved PT and CMS-2567 POC protocols during the 12 month timeframe

outlined above. No corrective action documentation was available. 5. An interview with the mohs staff members on 8/5/25 at 3:30 PM and 8/6/25 at 10 AM confirmed the above findings.