

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0990271	(X3) Date Survey Completed 12/19/2023
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 the New River Dermatology on 12/19/23 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:
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 the review of policy and procedures (P&P), peer review records, lack of documentation and interview, the laboratory failed to follow the established P&P for professional review for accuracy of at least two Mohs histological samples at the date of survey on 12/19/23. Findings include: 1. Review of the P&P revealed the policy "The professional review is performed to ensure accurate interpretation of Mohs frozen sections by the Mohs surgeon. Two random Mohs cases each year will be reviewed for slide interpretation accuracy. This will be done by a dermatopathologist. A Mohs Professional Quality Assurance Report shall be submitted with the comments of the Mohs surgeon and dermatopathologist and filed in the Quality assurance manual." 2. Review of available peer review records for the calendar year 2022 revealed four samples sent to a dermatopathologist for review. The date of review by the dermatopathologist was 01/23/23. The inspector inquired about the delay in the review of four cases for the calendar year 2022 with the clinical coordinator on 12/19/23 at noon. The clinical coordinator stated, "I mailed the slides and forms to our dermatopathologist in November of 2022 and did not receive a timely response. We have had issues with getting the reports returned in a timely manner." The inspector requested to review the peer review records for the calendar year of 2023 or records pending review by the dermatopathologist. The clinical coordinator stated, "we have</p>

not sent any slides or records for peer review as of today for our 2023 review." 3. An exit interview with the clinical coordinator on 12/19/23 at 12:30 confirmed the findings.

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 the review of daily quality control (QC) logs, patient testing logs for the Mohs histological samples, policy and procedure (P&P), lack of documentation, and interview, the lab failed to document the intended reactivity of the Hematoxylin and Eosin (H&E) stain on 07/21/22 and 08/25/23, reporting seven patients and one patient respectively. Record review beginning 01/01/22 up to date of survey on 12/19/23. Findings include: 1. Review of daily H&E Stain QC and patient testing logs for the Mohs histological samples revealed lack of documentation of intended reactivity of the H&E stain for the following: 07/21/22- seven patients reported, and 08/25/23- one patient reported. 2. Review of the P&P revealed the following statements, "Quality Assurance- the first case submitted to the Mohs lab which consists of NORMAL tissue will be stained for H&E and documented on the control sheet as the QA." 3. An exit interview with the clinical coordinator on 12/19/23 at 12:30 confirmed the findings.