

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2200341	(X3) Date Survey Completed 02/26/2026
Name of Provider or Supplier Atrium Health Wfb General Dermatology Laboratory -	Street Address, City, State 5826 Samet Drive Suite 103, High Point, NC	
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
D6086	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)</p> <p>(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of SOX10 validation records 2/26/26, the laboratory director failed to ensure that verification procedures used were adequate to verify the performance specifications of the SOX10 immunohistochemical stain prior to use for patient testing. Findings: Review of the laboratory's "Sry-related HMg-Box gene 10 (SOX10) Validation Procedure" revealed "... Interpretation of Results: The completed slides and Immuno Checklist and QC sheet are given to the Mohs surgeon for interpretation. Changes are made based on their interpretation of the slides provided. The stains are repeated based on recommendations/comments from the Mohs surgeon(s). Once all have come to agreement on the quality and reproducibility of the SOX10 staining is sufficient for patient testing, the full validation packet is provided to the Laboratory Director for approval and final signature. ..." Review of SOX10 validation records revealed a log with a list of ten cases used to perform the validation and a notation that each case was acceptable. The records did not include a summary/timeline of the steps taken to validate the SOX10 immunohistochemical stain, did not include any changes or adjustments made to the original protocol, and did not indicate the date that patient testing began.</p>
D6107	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)</p> <p>(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each</p>

supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of policies and procedures, review of job descriptions, review of 2024 and 2025 competency evaluation records, and interview with the laboratory director 2/26/26, the laboratory director failed to specify in writing the duties and responsibilities for 3 of 3 histotechnicians. Review of the laboratory's "Quality Assurance Procedure" revealed "... Personnel All laboratory personnel are Histology Technicians who are ASCP certified and meet requirements for High-Complexity testing according to CLIA guidelines. ... The laboratory director performs direct observation for annual competency evaluation reviews and documentation is kept in the policy and procedure manual. ..." Review of the laboratory's "Testing personnel responsibilities" revealed general duties such as "Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results ...". The responsibilities did not indicate that histotechnicians are authorized to perform grossing. Review of 2024 and 2025 histotechnician competency evaluations revealed the competency evaluations for 3 of 3 histotechnicians did not indicate review of grossing competency by the laboratory director. During interview at approximately 10:00 a.m., the laboratory director stated that she performs most of the grossing in the laboratory, but histotechnicians do occasionally perform grossing. The laboratory director confirmed that grossing was not specifically listed as one of the histotechnician job duties.