

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2299056	(X3) Date Survey Completed 09/09/2025
Name of Provider or Supplier Moses Cone Physician Services, Inc DbA	Street Address, City, State 719 Green Valley Road Suite 306, Greensboro, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of personnel records, and interview with TP (testing personnel) #1 on 9/9/25, the laboratory failed to follow their policy for competency assessment of two of two providers (TP #3, TP #4) who perform KOH (potassium hydroxide) tests. Findings: Review of the laboratory's "General Laboratory Quality System" policy revealed "... 5. PERSONNEL COMPETENCY ASSESSMENT ... Each employee's written job description will clearly outline their responsibilities, and competency assessments will be based on these descriptions. The laboratory director will conduct an annual performance review for each employee to ensure continued competency. A written summary of the review will be placed in the employee's personnel file. ..." Review of personnel records for TP #3 and TP #4 revealed no documentation of competency evaluations during 2024 or 2025. During interview at approximately 3:15 p.m., TP #1 confirmed that competency evaluations had not been performed for TP #3 and TP #4 during 2024 or 2025.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test</p>

performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies and procedures, review of two random patient test reports, and interview with TP #1 on 9/9/25, the laboratory's test reports did not include the address of the laboratory. Findings: Review of the "General Laboratory Quality Systems" policy revealed " ... Postanalytic Systems ... 1. Test Reports ... The information will include ... name and address of the testing facility ..." Review of a patient KOH test report and a patient Mohs map revealed the test reports did not include the laboratory's address. During interview at approximately 2:30 p.m., TP #1 confirmed the laboratory's address was not included on the test reports.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)(ii)

(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies and procedures, review of MART-1 validation records, and interview with TP #1 on 9/9/25, the laboratory director failed to ensure that verification procedures used were adequate to verify the performance specifications of the MART-1 immunohistochemical stain. Findings: Review of the laboratory's quality assessment plan revealed "...8. Test Systems ... For new test systems, we will verify performance specifications to ensure reliability and accuracy. This includes evaluating: Accuracy Precision Sensitivity Specificity These measures will help confirm that the system performs as expected and meets clinical and regulatory standards. ..." Review of MART-1 validation records revealed the records did not indicate include a summary/timeline of the steps taken to validate the MART-1 immunohistochemical stain, did not include the laboratory director's signature, and did not include the date it was approved for patient testing. During interview at approximately 2:00 p.m., TP #1 stated the first patient was tested using the MART-1 immunohistochemical stain on 2/10/25.