

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2280252	(X3) Date Survey Completed 06/26/2025
Name of Provider or Supplier Nashville Gastroenterology & Hepatology	Street Address, City, State 330 Wallace Rd, Suite 103, Nashville, TN	
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 a review of the Department of Health and Human Services Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), the laboratory's procedure, laboratory personnel records, and staff interview, the laboratory failed to follow the procedure for competency assessment for testing person one that performed grossing procedures of patient tissue samples when the laboratory failed to perform the 2024 competency assessment and failed to include all six required procedures for the 2025 competency assessment. The findings include: 1. A review of Form CMS-209 revealed two testing personnel (testing person one performed grossing procedures, and testing person two performed tissue examination) who performed patient testing for histopathology. 2. A review of the laboratory procedure titled "Lab Personnel Competency Assessment Policies" revealed the following: "All personnels shall have an annual competency assessment done by the medical director based on their responsibilities in the lab". The personnel competency assessments included: 1. Direct observation of routine patient test performance; 2. Monitoring the quality of routine performance; 3. Review of all worksheets, quality controls, and preventative maintenance; 4. Direct observation of instrument maintenance and function checks; 5. Assessment of test performance through random peer review; 6. Assessment of problem-solving skills. 3. A review of the laboratory personnel records for testing person one, who performed grossing of patient specimens for histopathology testing, revealed the following: Documentation of the 2024 competency assessment was not available on the date of the survey (06/26/2025). The competency assessment performed on 06/23/2025 did not include</p>

documentation of (1) direct observation of routine patient test performance, (2) monitoring quality of routine performance, (3) direct observation of instrument maintenance and function checks, or (4) assessment of test performance through random peer review. Problem-solving indicated "NA." 6. An interview with the laboratory director on 06/26/2025 at 12:30 p.m. confirmed the survey findings. Word Key: CLIA- Clinical Laboratory Improvement Amendments NA- Not Applicable

D5473

CONTROL PROCEDURES

CFR(s): 493.1256(e)(2)(g)

(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.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's stain quality control log, stain protocol, and staff interviews, the laboratory failed to define the predicted characteristics of the Alcian Blue and Periodic Acid Schiff (AB/PAS), Hematoxylin and Eosin (H&E), or Giemsa stains used for histopathology patient testing in 2024 through the survey date (06/26/2025). The findings include: 1. A review of the laboratory's log titled "Stain Quality Control Log" for March 2024, August 2024, January 2025, May 2025, and June 2025 revealed no documentation of the predicted stain characteristics of the AB/PAS, H&E, or Giemsa stain quality. 2. A review of the laboratory stain protocol procedure revealed no definition of predictable stain characteristics of the AB/PAS, H&E, or Giemsa stain quality. 3. An interview with the laboratory director on 06/26/2025 at 12:30 p.m. confirmed the survey findings.