

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2044578	(X3) Date Survey Completed 02/06/2023
Name of Provider or Supplier Nashville Gastrointestinal Specialists, Inc	Street Address, City, State 4230 Harding Pike, Suite 400, 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 review of the laboratory's procedure manual, employee personnel records, and interview with the Laboratory Director, the laboratory failed to have a procedure to include all six criteria for assessing personnel competency. The findings include: 1) Review of the laboratory procedure manual revealed the following six criteria were not included in the laboratory's "Competency Assessment for Grossing" procedure and competency documentation: a. Direct observation of routine patient test performance b. Monitoring the recording and reporting of test results c. Review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records. d. Direct observation of performance of instrument maintenance and function checks e. Assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f. Assessment of problem solving skills. 2) Review of the employee personnel records revealed no documentation of competency assessment for the six required criteria in 2021 and 2022. 3) Interview on 02/06/2023 at 11 a.m. with the Laboratory Director confirmed the testing personnel competency procedure did not include the six criteria for testing personnel competency assessment required by the Centers for Medicare and Medicaid Services (CMS).</p>
D6128	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the</p>

performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on review of the competency assessment records for the laboratory testing personnel and interviews with the Laboratory Director and General Supervisor, the Technical Supervisor failed to document the evaluation of the testing personnel performing histopathology grossing in 2021 and 2022. The findings include: 1. Review of the competency assessment records for testing personnel revealed one of one testing personnel performing histopathology grossing failed to have a documented competency assessment by the Technical Supervisor for 2021 and 2022. 2. Interview with the Laboratory Director and General Supervisor on 02/06/2023, at approximately 11:00 a.m. confirmed the Technical Supervisor (and Laboratory Director) failed to document a competency assessments for testing personnel number one performing histopathology grossing in 2021 and 2022.