

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2020561	(X3) Date Survey Completed 03/07/2025
Name of Provider or Supplier Raleigh Neurology Associates, Pa	Street Address, City, State 1520 Sunday Drive, Raleigh, 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
D6125	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v)</p> <p>(b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedure, 2024 "Competency Assessment - Toxicology Data Analysis and Data Review" testing personnel (TP) competency records and interview with chief quality officer 03/04/25, TS #2 failed to documentation the assessment of the test performance of 15 of 15 data analysis and data review TP. Findings: Review of laboratory procedure "SYSTEM LEVEL PROCEDURE: Competency" revealed "5.3...Competency testing includes the following six areas of assessment: 5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and...". Review of 2024 "Competency Assessment - Toxicology Data Analysis and Data Review" TP competency records revealed a checklist, with 7 tasks. The "tasks" are given a "N" - Does not meet standard and/or expectation; "Y" - Meets standard and/or expectation; or n/a - Not applicable. Review of 15 of 15 TP Task #7 - Blinded Sample Assessment - Data Review revealed a "Y". The assessment failed to include documentation of the results obtained by TP and a comparison of the results obtained from the "Blinded Sample". The assessment also fails to include the expectation or standard that is to be met to determine test performance. Interview with chief quality officer at approximately 9:45 a.m. confirmed the competency assessment records failed to include documentation of the results obtained by TP and the comparison of the results obtained from the blind sample. She also confirmed the assessment records fail to include the expectation or standard that is to be met to determine test performance.</p>