

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 08D1086909	(X3) Date Survey Completed 07/31/2025
Name of Provider or Supplier Cadia Rehabilitation Pike Creek	Street Address, City, State 3540 Three Little Bakers Blvd, Wilmington, DE	
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
D0000	A Recertification Survey was conducted on July 31, 2025 at approximately 2:30 PM. The laboratory was surveyed according to 42 CFR Part 493 Clinical Laboratory Improvement Amendments (CLIA) requirements. Deficiencies were identified as follows:
D2014	<p>TESTING OF PROFICIENCY TESTING SAMPLES</p> <p>(b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review, interview, laboratory policy review, and review of the laboratory's Clinical Laboratory Improvement Amendments (CLIA) Application and Survey Summary (CASPER Report 0096D), the laboratory failed to maintain documentation of the steps in the processing of proficiency testing (PT) for arterial blood gas (ABG) for 3 (2023 ABG PT Event 3, 2025 ABG Event 1, and 2025 ABG Event 2) of 8 PT events reviewed. In addition, the laboratory failed to maintain a signed attestation form and instrument printouts for 1 (2025 ABG PT Event 2) of 8 PT events reviewed. Findings included: A laboratory policy titled, "Blood Gas Testing using a Handheld System," revised 01/31/2019, revealed the section titled, "Proficiency Testing" specified, "- Print results and enter results on [PT program] website and submit. After submission, [PT program] will return results in 1 - 2 weeks. Results are maintained in the [PT program] Binder." The laboratory's "CLIA Application and Survey Summary" (CASPER Report 0096D), with a run date of 07/22</p>

/2025, revealed no scores were found for the following PT events: 2023 ABG PT Event 3 and 2025 ABG PT Event 1. The laboratory was unable to provide documentation of the processing of 2023 ABG PT Event 3, 2025 ABG Event 1, or 2025 ABG Event 2. The laboratory was also unable to provide a signed attestation form and instrument printouts for 2025 ABG PT Event 2. During an interview on 07/31/2025 at 4:10 PM, Technical Consultant (TC)/ Testing Personnel (TP) #2 stated he had been in the position for only a month, and he was unable to locate the missing PT documentation.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

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.

This STANDARD is not met as evidenced by:
Based on interview and laboratory document and policy review, the laboratory failed to provide evidence of annual competency assessments for 2 (2023 and 2024) of 3 years reviewed for 20 testing personnel (TP) of 21 TP employee files reviewed for competency assessments. Findings included: A laboratory policy titled, "Blood Gas Testing using a Handheld System," revised 01/31/2019, revealed the section titled, "Training & [and] Competency" specified, "Staff are trained and complete competencies on obtaining and testing arterial blood gases upon hire using the Abbott iSTAT 1 handheld manual. Employees will demonstrate competency annually thereafter." Employee files for 20 of 21 employees identified as TP per the laboratory's CMS-209 revealed no documented evidence that annual competency assessments were completed in 2023 and 2024. During an interview on 07/31/2025 at 3:00 PM, Technical Consultant (TC)/Testing Personnel (TP) #2 stated he had been in the position for only a month and could not locate records of previous employee competency assessments.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:
Based on interview and facility document review, the laboratory failed to document the review and evaluation of proficiency testing (PT) results for arterial blood gas (ABG) for 3 (2023 ABG PT Event 2, 2024 ABG PT Event 1, and 2024 ABG PT Event 3) of 8 PT events reviewed. Findings included: Review of PT testing results documents for 2023 ABG PT Event 2, 2024 ABG PT Event 1, and 2024 ABG PT Event 3 revealed the Lab Director or designee had not signed off as having reviewed the results. During an interview on 07/31/2025 at 4:05 PM, Technical Consultant (TC) /Testing Personnel (TP) #2 stated he had been in the position for only a month, and he did not know why the review of PT results was not documented as required.