

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2151738	(X3) Date Survey Completed 01/21/2026
Name of Provider or Supplier Carlos Portu Md Pllc DbA Shoreline	Street Address, City, State 950 Manatee Rd, Naples, FL	
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	An announced CLIA recertification survey was conducted at CARLOS PORTU MD PLLC DBA SHORELINE PHYSICIAN GROUP on January 21, 2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to rotate one of the two Testing Personnel (TP) performing Proficiency Testing (PT), for Hematology specialty for four out of four events reviewed. Findings included: 1-Review of FORM CMS-209 signed and dated by the Laboratory Director (LD) on 01/20/2026 revealed the laboratory had two TP listed (TP#1 and TP#2). 2- Review of personnel records for TP#2 revealed that the Initial Competency had a date of 08/21/2024. 3-Review of American Proficiency Institute (API) PT records for the Hematology specialty attestations signed in the following dates in year 2024, (11/11/2024) and 2025 (03/16 /2025, 07/21/2025 and 11/05/2025), revealed that TP#2 did not participated in any of the events listed. During an interview on 01/21/2026 at 01:55 PM, TP#1 confirmed that the laboratory failed to rotate PT in the Hematology specialty, and that TP#2 failed to participated in the following events during last event of 2024 and the three events of 2025.</p>
D6047	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(i)</p>

(b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;

This STANDARD is not met as evidenced by:

Based on record review and staff interview revealed that the Technical Consultant (TC) or a qualified designee failed to observe patient testing during competency evaluation for one out of two Testing Personnel (TP) for one year reviewed. Findings included: 1-Review of FORM CMS 209 signed by the Laboratory Director on 01/20/2026, revealed the following: Laboratory Director (LD) was also Clinical Consultant and TC for Hematology and Chemistry specialties and two TP (TP#1 and TP#2). 2- Review of personnel records revealed that six months Competency on 02/12/2025 was observed by TP#1. TP #1 did not meet the qualification for Technical Consultant. 3- During an interview on 01/20/2026 at 02:00 PM, LD/TC confirmed that the TC failed to observe patient testing observation during six months Competency for TP#2 in 2025

D6050

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(iv)

(b)(8)(iv) Direct observation of performance of instrument maintenance and function checks;

This STANDARD is not met as evidenced by:

Based on record review and staff interview revealed that the Technical Consultant (TC) or a qualified designee failed to observe of instrument performance and function check during competency evaluation for one out of two Testing Personnel (TP) for one year reviewed. Findings included: 1-Review of FORM CMS 209 signed by the Laboratory Director on 01/20/2026, revealed the following: Laboratory Director (LD) was also Clinical Consultant and TC for Hematology and Chemistry specialties and two TP (TP#1 and TP#2). 2-Review of personnel records revealed that six months Competency on 02/12/2025 was observed by TP#1. TP #1 did not meet the qualification for Technical Consultant. 3- During an interview on 01/20/2026 at 02:00 PM, LD/TC confirmed that the TC failed to observe instrument performance and function check during six month Competency for TP#2 in 2025.