

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2003025	(X3) Date Survey Completed 03/06/2024
Name of Provider or Supplier Physician's Plasma Alliance	Street Address, City, State 124 Old Gray Station Rd, Johnson City, 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 center manager, the laboratory failed to have a procedure to include all six criteria for assessing personnel competency in 2023. The findings include: 1. Review of the laboratory procedure manual revealed the laboratory's "Training Process" procedure and competency documentation did not include the following six required criteria: 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 employee personnel records revealed eight of eight testing personnel competency assessments reviewed did not include the six required criteria in 2023. 3. Interview on 03.06.2024 at 12:30 p.m. with the center manager 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) in 2023.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p>

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on observation of the donor screening areas, review of the manufacturer's user's guide, lack of documentation, and interview with the center manager, the laboratory failed to monitor relative humidity in the areas where total protein donor testing was performed in 2023 and 2024. The findings include: 1. Observation of two donor testing areas on 03.06.2024 at 9:30 a.m. revealed two Reichert TS Meter D Refractometers (serial numbers 033880409 and 044680611) were in use for total protein donor testing. 2. A review of the manufacturer's user's guide revealed the following for environmental conditions; maximum relative humidity: 80% for temperatures up to 31 degrees Celsius decreasing linearly to 50% (relative humidity at 40 degrees Celsius). 3. The laboratory could not provide records of relative humidity monitoring for January 2023 through the date of the survey, March 6, 2024. 4. An interview on 03.06.2024 at 12:30 p.m. with the center manager confirmed the above survey findings.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on a review of testing personnel competency assessment records and an interview with the center manager, the technical consultant failed to perform competency assessments for seven of eight testing personnel in 2023. The findings include: 1. A review of testing personnel competency assessment records revealed the technical consultant did not perform the 2023 competency assessments for nine of nine competencies performed on seven of eight testing personnel. 2. An interview with the center manager on 03.06.2024 at 12:30 p.m. confirmed the above survey findings.