Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2259687	06/18/2026
Name of Provider or Supplier	**Street Address, City, State**	
Life Plasma	5438 Perkiomen Ave, Reading, PA	

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
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (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. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records, lack of documentation and interview with the head of quality and regulatory (HQR), the laboratory failed to maintain 4 of 4 AAB-MLE PT attestation statements signed by the analyst and laboratory director (LD) for Chemistry/Hematology testing events performed in 2025 and 2026. Findings include: 1. On the day of the survey, 6/18/2026 at 11:00 am, review of the laboratory's AAB-MLE PT records revealed the laboratory failed to maintain attestation statements signed by the analyst and LD documenting that PT samples were tested in the same manner as patient specimens for the following 4 of 4 AAB-MLE Chemistry and Hematology PT events performed in 2025 and 2026: - 2025: AAB-MLE M1, M2, M3 events - 2026: AAB-MLE M1 event 2. The HQR confirmed the finding above on 6/18/2026 at 1:15 pm.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 review of the laboratory's temperature logs, lack of documentation and interview with the head of quality and regulatory (HQR) the laboratory failed to monitor and document room humidity (RH) as required to ensure reliable test system operation and test result reporting for 1 of 1 instrument used to perform Chemistry testing from 03/19/2026 to date of survey. Findings include: 1. On the date of the survey, 06/18/2026 at 12:30 pm, review of the laboratory's temperature logs revealed the laboratory failed to document room humidity (manufacturer's acceptable range 80% RH for temperatures to 88 degrees F) to ensure operating conditions were met for the following 1 of 1 instrument used to perform total protein (TP) testing from 03/19/2026 to 06/18/2026: - Reichart Refractix DSP digital refractometer (S/N 01034-1125) 2. Review of the laboratory's test logs revealed the laboratory performed 2,298 TP tests using the Reichart Refractix DSP digital refractometer from 3/19/2026 to 6/18/2026. 3. The HQR confirmed the findings above on 06/18/2026 at 1:30 pm.