Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2259687	09/23/2024
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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the procedure manual, and interview with the Quality Assurance Director (QAD), the laboratory director failed to sign revised procedures from November 11, 2022 to the day of survey. Findings include: 1. On the day of survey, 9/23/2024 review of the procedural manual revealed that the laboratory director failed to sign and review all revised procedures from November 11, 2022 to the day of survey. 2. The following laboratory procedures were observed on the day of survey to have been revised and not signed by the laboratory director: - "Equipment Validation Plan." Last revised 02/07/2023. - "Facility Maintenance." Last revised 06/11/2024. - "Refractometer Semi-Annual Evaluation." Last revised 03/03/2023. - "Quality Assurance Program." Last revised 05/03/2024. - "Supplies and Consumables Policy." Last revised 05/28/2024. 3. The QAD confirmed the findings above on 9/23/2024 at 11:00 AM.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's Reichart TS meter-DPS verification of performance specifications records, lack of documentation, and interview with Quality Assurance Director (QAD), the laboratory failed to provide complete validation records for the required performance specifications for 1 of 1 analytes tested on the Reichart TS meter-DPS before reporting patient results from 02/09/2023 to the day of the survey. Findings Include: 1. On the day of survey, 09/23/2024 at 10: 00 am, the laboratory's validation documentation failed to include a study for accuracy, precision, reportable range of test results for the test system, and verification that the manufacturer's reference intervals (normal values) were appropriate for the laboratory's patient population, for the chemistry analyte total protein performed on the Reichart TS meter-DPS from 02/09/2023 to 09/23/2024. 2. QAD confirmed the findings above on 09/23/2024 at 10:00 AM.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's "Refractometer Semi Annual Evaluation Form" and interview with the Quality Assurance Director (QAD), the laboratory failed to perform calibration verification at least every six months for total protein performed on the Reichart TS Meter-DSP refractometers from 11/21/2022 to the day of survey. Findings include: 1. On the day of survey, 9/23/2024 at 11:30 AM, review of the laboratory's "Refractometer Semi Annual Evaluation Form" revealed that the laboratory failed to perform calibration verifications at least every six months from 11 /21/2022 for: a. Reichart TS Meter-DSP Refractometers: R1, R2, R3, R4, and R5. 2. The laboratory performed 17,004 chemistry tests in 2023 (CMS-116 annual volume). 3. The QAD confirmed the findings above on 9/23/2024 at 11:30 AM.
D5775	COMPARISON OF TEST RESULTS

	CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Quality Assurance Director (QAD), the laboratory failed to evaluate, twice a year, the relationship between test results for 5 of 5 Reichart TS Meter-DSP analyzers from 11/21/2022 to the day of the survey. Findings include: 1. On the day of the survey, 09/23/2024 at 11:30 AM, the laboratory could not provide documentation of the biannual comparison of test results between 5 of 5 Reichart TS Meter-DSP analyzers for Total Protein performed from 11 /21/2022 to the date of the survey. 2. The laboratory performed 17,004 chemistry tests in 2023 (CMS-116 annual volume). 3. The QAD confirmed the findings above on 09 /23/2024 at 11:30 AM.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient tests reports and interview with the Quality Assurance Director (QAD), the laboratory failed to include the laboratory's address on all patient test reports from June 19, 2024 to the day of survey. Findings include: 1. On the day of survey, 9/23/2024 document review of patient test reports revealed that the laboratory failed to include the laboratory's address on all patient reports from June 19, 2024 to the day of survey. 2. The laboratory performed 17,004 chemistry tests in 2023 (CMS-116 annual volume). 3. The QAD confirmed the evidence above on 9/23 /2024 at 11:00 AM.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of competency assessment records, and interview with the Quality

	Assurance Director (QAD) the laboratory failed to evaluate test performance through either blind samples, proficiency testing or previously analyzed samples from 11/21 /2022 to the day of survey. Findings include: 1. On the day of survey, 9/23/2024 review of testing personnel (TP) competency assessments, revealed the laboratory failed to evaluate test performance through either blind samples, proficiency testing, or previously analyzed samples for 7 of 7 TP (CMS 209 TP #2, #3, #4, #5, #6, #7, and #8) from 11/21/2022 to 9/23/2024. 2. The QAD confirmed the evidence above on 9/23 /2024 at 10:30 AM.