Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2259687	11/21/2022
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 a review of the laboratory's procedure manuals and an interview with the quality manager (QM), the laboratory failed to ensure that all procedures were approved, signed, and dated by the current laboratory director (LD) before use from 05/31/2022 to the date of the survey. Findings include: 1. On the date of the survey, 11/21/2022 at 10:01 am, a review of the laboratory's procedure manuals revealed that the laboratory director did not review and approve the current procedures in use from 05/31/2022 to 11/21/2022. 2. The Backup Medical Director & Lab Director Job Spec states, "Review and approve the CLIA-defined moderate complexity test procedures, as required." 3. Patient testing was performed from 05/31/2022 to the date of the survey. 4. The QM confirmed the finding above on 11/21/2022 around 11:45 am.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by:

	Based on a review of the laboratory's quality assurance (QA) and quality control (QC) records, laboratory director (LD) job specifications, and an interview with the quality manager (QM), the LD failed to ensure QA programs were established and maintained to assure the quality of laboratory services provided from 05/31/2022 to the date of the survey. Findings Include: 1. On the date of the survey, 11/21/2022 at 10:45 am, a review of the QA and QC documents revealed no documented review was performed by the LD for the following from 05/31/2022 to 11/21/2022: -Monthly and weekly QA reports -Monthly QC records for 2 of 2 Reichert TS meter-DPS refractometers -Refractometer Validation Plan for 2 of 2 Reichert TS meter-DPS refractometers performed on 05/04/2022 2. The Backup Medical Director & Lab Director Job Spec document states, "Review the QA reports for timely and appropriate actions on moderate complexity procedures for test problems." 3. The QM confirmed the findings above on 11/21/2021 around 11:45 am.