Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0862936	01/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Bio Life Plasma Services Llc	3455 Quail Creek Dr, Denton, TX	

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 entrance conference was held with the laboratory representatives. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory procedures, review of laboratory records for the Reichert Protein Refractometers, and staff interview, it was revealed that the laboratory failed to retain documentation of instrument verification studies for 5 of 5 Reichert Protein Refractometers. Finding included: 1. During a tour of the testing area on 01/26/2021 at 12:36PM, the following 5 Reichert Protein Refractometers were observed to be in use: Serial Number 03447-0609 Serial Number 04251-0111 Serial Number 03446-0509 Serial Number 03448-0609 Serial Number

	03445-0509 2. The laboratory procedure titled "Refractometer Calibration Verification, Precision, and Specification Testing" (approval date 07/22/2020) stated the following: "7.0 Initiate Quality Control Record-Precision and Specification Testing form for new or repaired refractometer(s) for completion of precision testing. Note: The following procedure will be completed by six separate Medical Historians; two different testing personnel will perform each procedure twice over a period of three (3) days. A total of 36 results should be reported for each instrument (12 with distilled water, 12 with low control, and 12 with high control) ....7.3.1 New Centers must complete precision testing on all refractometers prior to center opening. Refractometer precision testing must be performed for all new refractometers as well after repairs." Further review of the laboratory procedure revealed a "Donor Screening Job Aid" which stated a "Verifiable reportable range: 4.4 - 10.5 grams/dL" for Total Protein. 3. Review of the laboratory record titled "Quality Control Record Refractometer Precision/Specification Testing" revealed documentation for "Equipment returned to Center" for the following refractometers: Serial Number 08093-1014; Dated 07/17/2018 Serial Number 08558-0115; Dated 08/23/2018 Serial Number 04252-0111; Dated 09/01/2018 These refractometer serial numbers were NOT any that were currently in use by the facility. The laboratory was asked to provide documentation of verification of performance specifications that included accuracy, precision, reportable range, and reference ranges before reporting patient test results for the 5 refractometers currently in use. No documentation was provided. 4. In an interview on 01/26/2021 at 12:36 PM in the conference room, the Center Manager and the Quality Management Representative were asked to provide documentation of verification of the reportable range of 4.4 - 10.5 grams/dL for the total protein. No documentation was provided. The laboratory representatives were then asked to provide the initial verification studies for each of the 5 refractometers in use. No documentation was provided. This confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (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 manufacturer's instructions for the Reichert Protein Refractometer, random review of laboratory environmental records (06/2020 and 12/2020), and confirmed in interview, the laboratory failed to define a humidity range in accordance with Reichert Protein Refractometer instructions for 2 of 2 months in 2020. Findings: 1. The manufacturer's instructions for the Reichert Protein Refractometer (13970000-100 Rev. E) stated in the section titled, "3.0 Environmental Conditions .....Max. Relative Humidity: 80% for temperatures to 31C ..." 2. A random review of the laboratory environmental records (06/2020 and 12/2020), revealed the laboratory failed to define a humidity range for the areas that the Reichert Protein Refractometers were stored. 3. In an interview on 01/26/2021 at 12:36 PM in the conference room, the Center Manager and the Quality Management Representative were asked to provide documentation of humidity levels for the areas that the Reichert Protein

	Refractometers were stored. The Center Manager stated that the facility did not measure humidity levels. This confirmed the above findings. Word Key: Max = maximum
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 direct observation, review of laboratory procedures, review of laboratory records for the Reichert Protein Refractometers, and staff interview, it was revealed that the laboratory failed to ensure instrument verification studies for precision, accuracy, reportable range, and reference intervals were performed for 5 of 5 Reichert Protein Refractometers. Findings included: 1. During a tour of the testing area on 01/26/2021 at 12:36PM, the following 5 Reichert Protein Refractometers were observed to be in use: Serial Number 03447-0609 Serial Number 04251-0111 Serial Number 03446-0509 Serial Number 03448-0609 Serial Number 03445-0509 2. The laboratory procedure titled "Refractometer Calibration Verification, Precision, and Specification Testing" (approval date 07/22/2020) stated the following: "7.0 Initiate Quality Control Record-Precision and Specification Testing form for new or repaired refractometer(s) for completion of precision testing. Note: The following procedure will be completed by six separate Medical Historians; two different testing personnel will perform each procedure twice over a period of three (3) days. A total of 36 results should be reported for each instrument (12 with distilled water, 12 with low control, and 12 with high control) ....7.3.1 New Centers must complete precision testing on all refractometers prior to center opening. Refractometer precision testing must be performed for all new refractometers as well after repairs." Further review of the laboratory procedure revealed a "Donor Screening Job Aid" which stated a "Verifiable reportable range: 4.4 - 10.5 grams/dL" for Total Protein. 3. Review of the laboratory record titled "Quality Control Record Refractometer Precision/Specification Testing" revealed documentation for "Equipment returned to Center" for the following refractometers: Serial Number 08093-1014; Dated 07/17/2018 Serial Number 08558-0115; Dated 08/23/2018 Serial Number 04252-0111; Dated 09/01/2018 These refractometer serial numbers were NOT any that were currently in use by the facility. The laboratory was asked to provide documentation of verification of performance specifications that included accuracy, precision, reportable range, and reference ranges before reporting patient test results for the 5 refractometers currently in use. No documentation was provided. 4. In an interview on 01/26/2021 at 12:36 PM in the conference room, the Center Manager and the Quality Management Representative were asked to provide documentation of verification of the reportable range of 4.4 - 10.5 grams/dL for the total protein. No documentation was provided. The laboratory representatives were then asked to provide the initial verification studies for each of the 5 refractometers in use. No documentation was provided. This confirmed the above findings.