Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2252890	03/27/2025
Name of Provider or Supplier	**Street Address, City, State**	
Biotek America, Llc (Dba Freedom Plasma)	7750 Scott Street, White Settlement, 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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on review of laboratory policies, quality control (QC) records, and confirmed in interview the laboratory failed to retain all QC records for three of three months reviewed (October through December 2024) for two of two refractometers. Findings included: 1. Review of laboratory policies revealed the laboratory did not have a policy for the retention of laboratory records. 2. Review of QC records from October through December 2024 for two refractometers (Serial #'s 15730-1221 and 15727-1221) revealed the laboratory did not document the lot numbers for the abnormal and normal levels of QC material. The laboratory was asked on 03/27/2025 at 11:45 a.m. and at 1:20 p.m. for the documentation of the abnormal and normal QC lot numbers used from October through December 2024. No documentation was provided. Without complete QC records QC performance and acceptability could not be verified. 3. During an interview on 03/27/2025 at 1:20 p.m., the laboratory representatives confirmed the above findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 laboratory policies, the laboratory's submitted CMS 116 application, the lack of calibration verification records, and staff interview, it was revealed that the laboratory failed to have documentation of performing calibration verification every six months for testing of the total protein analyte on six of six Reichert TS Meter-DSPs in 2023 and 2024. Findings included: 1. Review of laboratory policies revealed the laboratory did not have a policy for performing calibration verifications every six months for testing of the total protein analyte. 2. A review of the laboratory's submitted CMS 116 application on the date of the survey revealed the laboratory performed total protein testing on the Reichert TS Meter-DSP. 3. On 03/27/2025 at 11:20 a.m., the laboratory was asked to provide calibration verification records for the six Reichert TS Meter-DSPs used in 2023 and 2024. The following were the six Reichert TS Meter-DSPs used by the laboratory: Serial #15722-1221 Serial #15727-1221 Serial #15721-1221 Serial #15724-1221 Serial #15730-1221 Serial #15720-1221 4. A further review of the laboratory's submitted CMS 116 application revealed an annual test volume of 93099 total protein tests performed. 5. During an interview on 03/27/2025 at 11:20 a.m., the laboratory representatives confirmed the above findings.