

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2254442	(X3) Date Survey Completed 03/12/2025
Name of Provider or Supplier Biotek America Llc DbA Freedom Plasma	Street Address, City, State 5651 38th Ave North, Saint Petersburg, FL	
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 announced CLIA validation survey was conducted at Biomat Holdings, LLC DBA Freedom Plasma on 03/12/2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory did not have a means of issuing a test report, for the analyte/test total protein, that contained the required elements for two of two years reviewed (03/12/2023 through 03/12/2025). Findings included: Review of the CMS-116, Application for Certification, signed by the Lab Director on 3/6/2025, showed the laboratory performed 57,361 total protein tests per year. A policy titled Maintaining Donor Privacy and Confidentiality, effective 06/15/2020, showed "For the donor, the test results may only be disclosed in person and in a private setting." The laboratory was unable to provide a printed patient test report. Interview with the Quality Systems Manager and the Center Manager on 3/12/2025 at 2:30 p.m., confirmed the lab verbally provided the results in person and did not have the ability to print a test report. The lab did not have a policy or procedure regarding printing test reports for total protein.</p>