

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2278008	(X3) Date Survey Completed 04/23/2024
Name of Provider or Supplier Abo Plasma Llc	Street Address, City, State 169 N State Street, Orem, UT	
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	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Quality Assurance Manager, the current laboratory director failed to sign and date the laboratory procedure manuals for Quality Assurance, Competency Assessment and Total Protein testing. The laboratory performs approximately 50,000 chemistry tests per year. Findings include: 1. Record review of procedures on 4/22/2024 at approximately 12:45 PM, revealed the Quality Assurance procedure, the Competency Assessment procedure and the Total Protein Testing procedure were not signed or dated by the current laboratory director. 2. In an interview conducted with the Quality Assurance Manager on 4/22/2024 at approximately 12:45 PM, confirmed that the Quality Assurance, Competency Assessment and Total Protein testing procedures were not signed or dated by the current Laboratory Director.</p>