

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2112698	(X3) Date Survey Completed 02/10/2023
Name of Provider or Supplier Eurofins Donor & Product Testing, Llc	Street Address, City, State 1700 Enterprise Way, Suite 114, Marietta, GA	
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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on February 10, 2023. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 document review of the Standard Operating Procedure (SOP) and staff interview, the laboratory failed to make changes in procedure, on a bi-annual basis, as stated in the Procedure manual. The Findings include: 1. Document review of the Procedure Manual revealed that the laboratory is using MediaLab to store the procedures electronically. The procedures reviewed revealed several procedures that were not updated, approved, signed, and dated by the current laboratory director before use. 2. The procedures that were reviewed and were not updated by the Laboratory Director: - Customer Test Requisition Creation and Review Process (07/06 /2021) -Pipette Maintenance and Verification (05/14/2020) -Thermometer and Hygrometer Calibration (05/14/2020) -ABO Rh Cord Blood Typing Using ORTHO Column Agglutination Card using LabVantage (05/10/2021) 3. During an interview with the Technical Consultanta(CMS-209) on February 10, 2023 at 11:50AM, in a cubicle space, in the front of the building, confirmed that the Laboratory Director was not updating, approving, signing, or dating the procedures bi-annually as stated in the SOP.</p>