Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D0993751	04/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Clinimmune	12705 E Montview Blvd, Ste 250, Aurora, CO	

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
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory instruments comparison documentation and an interview with the General Supervisor 1 (GS1) according to the Centers for Medicare and Medicaid Services (CMS) Form-209, the laboratory failed to perform biannual evaluations to define the relationship between its five of five thermocyclers used for histocompatibility molecular testing. Findings: 1. On April 14, 2025, at approximately 10:30 a.m., a direct observation of the post-PCR room revealed the presence of five Thermo Fisher Scientific Applied Biosystems VeritiPro Thermal Cyclers use for patient testing, identified as VeritiPro 3261, 3262, 3263, 3264, and 3265. 2. On April 14, 2025, at approximately 2:30 p.m., a review of instrument comparison documentation confirmed that no comparison studies had been performed for the five thermal cyclers to evaluate and document performance consistency. 3. On April 14, 2025, at approximately 3:00 p.m., an interview with GS1 confirmed that the laboratory had not conducted instrument comparison studies for the five thermal cyclers.