

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2072032	(X3) Date Survey Completed 10/26/2021
Name of Provider or Supplier Csl Plasma Inc-Tampa	Street Address, City, State 10061 E Adamo Dr, Tampa, 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 unannounced complaint survey for complaint number 2021013895, was conducted on 10/26/2021 at CSL Plasma Inc. - Tampa. The facility was not in compliance with 42 CFR 493, requirements for clinical laboratories. The following is a description of the standard level deficiencies:
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and staff interview, the laboratory failed to ensure 2 (#B and #C) out of 4 (#A-#D) laboratory staff followed the safety procedure for hand hygiene and glove changes. Findings included: 1. Review of the laboratory's safety procedures revealed a "Daily Huddle" dated 10/28/20, titled "Hand Sanitizing or Glove Change Between Donors." The procedure stated "Glove changes or sanitizing shall be used between donors,..." and "REMINDER: Hands must be washed or sanitized between glove changes." 2. Observation of the donor reception area on 10/26/21 at 9:45 am revealed that Testing Personnel (TP) #B performed total protein and hematocrit testing on one donor. TP #B did not change her gloves or sanitize her gloves prior to performing testing on the next donor. 3. Observation of the donor processing area on 10/26/21 at 10:00 am revealed that Phlebotomist #C was preparing a donor on the equipment to begin plasmapheresis (process for separating the plasma from the blood). During this process, another donor, who was in the process of plasma donation, called Phlebotomist #C over for assistance. Phlebotomist #C was not observed to change gloves or perform hand hygiene/glove sanitation between physical contact with both donors. 4. On 10/26/21 at 10:15 am, Phlebotomist #C confirmed he had not changed his gloves or sanitized before moving on to the next donor.</p>

Phlebotomist #C then changed his gloves but did not wash or sanitize his hands between glove changes. 5. On 10/26/21 at 10:25 am, the Center Manager confirmed that TP #B did not change her gloves between donors. 6. On 10/26/21 at 10:45 am, the Center Manager and Assistant Manager of Quality reported that staff have to change gloves between donors or use hand sanitizer on the nitrile gloves in the screening /donor reception areas.