

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2112746	(X3) Date Survey Completed 06/02/2021
Name of Provider or Supplier Octapharma Plasma Inc	Street Address, City, State 8420 N Armenia Ave, 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	<p>An unannounced complaint survey for complaint number 2021006863 and 2021007764, was conducted on 06/02/2021 at Octapharma Plasma Inc. The facility was not in compliance with 42 CFR 493, Requirement for clinical laboratories. Complaint #2021007764 had a deficiency cited at D3011. Complaint #2021006863 had no deficiencies cited. The following is a description of the standard level deficiency:</p>
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 observations, record review, and interview the laboratory failed to clean and decontaminate all equipment after contact with blood or plasma. Findings Included: During a tour of the laboratory on 06/02/21 at 1:30 PM dried blood was observed on 1 of 4 hematocrit instruments in the screening area. Blood was also observed in the bottom of the capillary holder of the centrifuge of the same hematocrit instrument. Review of the "Exposure Control Plan" policy (NC-SAFETY-002) states in section 5.5.1.8 to "Clean and decontaminate all equipment after contact with blood or plasma immediately or as soon as possible." Interview on 06/02/21 at 1:42 PM with the Quality Assurance Supervisor and the Assistant Manager confirmed the blood on and in the hematocrit instrument and stated that it should have been cleaned prior to being used again. During the tour on 06/02/21 at 1:30 PM, a brownish red substance was observed on the side of 1 bed in bay 2 of the treatment floor. Interview on 06/02/21 at 2:00 PM with the Quality Assurance Supervisor revealed that the substance observed was iodine and immediately had a staff member clean it off the side of the chair.</p>