

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2107932	(X3) Date Survey Completed 12/13/2022
Name of Provider or Supplier Csl Plasma Inc	Street Address, City, State 2041 George Jenkins Blvd Ste 7, Lakeland, 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, #2022016038, was conducted on 12/09/2022 - 12/13/2022 at CSL Plasma Inc. The facility was not in compliance with 42 CFR 493, Requirement for clinical laboratories.
D5205	<p>COMPLAINT INVESTIGATIONS CFR(s): 493.1233</p> <p>The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to follow their complaint process on 12/09/2022. Findings Included: Review of the policy dated 8/30/2022 and titled "Handling Donor Inquiries and Complaints" revealed "It is important that you investigate each inquiry or complaint and a [sic] provide prompt, thorough resolution. Since a timely response is essential to providing good customer service and ensuring compliance with our procedures and processes, the Center Manager or Assistant Center Manager has 5 calendar days to provide a resolution. Remember, this process notifies the Center Manager and the Assistant Center Managers. If someone is out-of-office or on PTO [paid time off], the others are notified.... If there is no response within 5 days, your regional managers will also receive an email notification. They will follow-up with you accordingly. It's all an important part of being accountable and being responsive." Interview on 12/09/2022 at 2:30 PM with the Center Manager revealed there has not been any complaints since she took over last July 2021. Interview on 12/09/2022 at 2:45 PM via telephone with the Medical Staff Associate responsible for fielding phone calls earlier in the day revealed she had received a complaint that morning, and it was not forwarded on to the Center Manager.</p>