Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2166137	05/05/2025
Name of Provider or Supplier	**Street Address, City, State**	
Csl Plasma Inc	7509 B Crestwood Boulevard, Birmingham, AL	

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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on a telephone interview with a complainant, a review of the Center Exposure Control Plan (CECP), footage from a plasma donation video from 04-01-2025, and interviews with the Assistant Manager of Quality (AMQ), and the Center Manager (CM), the surveyors determined Testing Personnel 1 (TP1) and Testing Personnel 2 (TP2) failed to follow established safety procedures regarding spills clean up and post-exposure protocol. The surveyors noted 1 of the 16 beds was not cleaned and disinfected after each donation on 04-01-2025. This deficiency is the result of a complaint investigation, with complaint number AL00050971, conducted on May 5, 2025. The findings include: 1. The Alabama Department of Public Health, Bureau of Health Provider Standards received two voicemail messages from the Complainant on 04-10-2025 and 04-16-2025 regarding exposure to blood from a previous donor, and stating the facility had given "no adequate response on how to resolve the situation". 2. The CLIA State Agency conducted a phone interview with the Complainant on 04-17-2025 at 10:00 AM. The Complainant stated he was a routine plasma donor, and after the completion of a donation on 04-01-2025, the complainant noticed blood underneath the armrest, on the bed and on the floor. He realized the blood was not his, and blood had soaked thru his clothing and onto his skin. The Floor Manager (also TP2) also noted the blood, and tried to wipe it off the Complainant's pants. The Complainant stated afterward he was concerned because "there was so much blood", and he wondered if he "might have caught something"; the Complainant further stated the facility had not checked to ensure the exposure would not make him sick, and had only offered to dry clean his clothes. 3. An on-site complaint investigation was

	conducted on 05-05-2025. A review of the Center Exposure Control Plan (CECP) revealed the following: (A) Pages 15-16: "Equipment Cleaning and Decontamination Workpractice Controls "...Equipment that is or becomes contaminated with blood during normal operations will be cleaned and disinfected..." (B) Page 18-19: "Personnel Protective Equipment (PPE) ...Employees and donors are never permitted to wear contaminated clothing away from [the Facility name] site...If personal articles of clothing are contaminated, the donor will be asked to relinquish those item to [Facility name] for proper disposal as regulated medical waste. ..." (C) Pages 24-25: "Employee Post Exposure Incident Care..."...If an employee, donor, or other person's clothing is saturated, provide a uniform set...to the donor to wear out of the center. The saturated clothing must be disposed in a biohazard waste container. ..." (D) Page 25: "Physician Assessment and Counseling by an authorized treating physician are vital components of the required post-exposure follow up procedure". (E) Page 24: "Post Exposure Incident Event Investigation...All incidents are investigated per [Facility Policy number]..." (F) Page 27: "Donor Post Event Investigation...The exposed donor Enablon Event Investigation report must be forwarded to the Divisional Medical Director within 24-hours." 4. A review of the video footage of the donor area of the facility on 04-01-2025 revealed the following sequence of events: (A) Approximately 4:08 PM: The bed and armrest were decontaminated before the donor donation was started. The donor arrives and lays back in the donation chair, however the phlebotomist is observed having problems with the venipuncture. Blood spills onto the bed, armrest pillow, and the phlebotomist's lab coat. The surveyors observed the phlebotomist in the video wiping off the sides of the bed and the armrest during the donation. (B) The phlebotomist checked to ensure there were no other problems, and then left to change her lab coat and perform other tasks in another area. After the allotted time the plasma donation was terminated, and the needle was removed by TP1. However, the video does not show TP1 decontaminating the bed, armrest and surrounding area as per the CECP protocol. (C) Approximately 6:00 PM: Donor #13676371 (the Complainant) arrived in the plasmapheresis area for his donation. Donor #13676371 lay in the same bed used by the the previous donor that had not been decontaminated. After the allotted collection period, TP2 terminated the donation and removed the needle. (D) 6:51 PM: In the video, the surveyors observed when donor #13676371 stood upright, he observed he had come in contact with some of the blood on the bed under the armrest pillow. TP2 was observed trying to wipe the donor's clothing with the disinfecting wipes, however TP2 allowed Donor #13676371 to leave the facility in the contaminated clothing. TP2 failed to follow the required procedures specified in the CECP protocol to protect donors when an exposure occurs. 5. During an interview on 05-05-2025 at 1:30 PM, the AMQ and CM confirmed donor # 13676371 (the Complainant) was exposed to blood from the previous donor, and TP1 and TP2 had not followed procedures as specified in the CECP protocol. When as asked if the facility had documented the incident, the CM stated on 04-01-2025 at around 7:30 PM, TP2 contacted her about the incident. TP2 had left the donor's number (13676371) on her desk, but did not document the event in the Electronic Event Management System known as ENABLON.
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 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.

This STANDARD is not met as evidenced by:
Based on a telephone interview with a complainant, a review of the Center Exposure Control Plan (CECP), footage from a plasma donation video from 04-01-2025, a lack of documentation of resolution to the complainant's concerns, and interviews with the Assistant Manager of Quality (AMQ), and the Center Manager (CM), the surveyors determined the laboratory failed to have an effective mechanism in place to ensure valid complaints are investigated and documented. This deficiency is the result of a complaint investigation, with complaint number AL00050971, conducted on May 5, 2025. The findings include: 1. The Alabama Department of Public Health, Bureau of Health Provider Standards received two voicemail messages from the complainant on 4-10-2025 and 4-16-2025 regarding exposure to blood from a previous donor, and stating the facility had given "no adequate response on how to resolve the situation". 2. The CLIA State Agency conducted a phone interview with the Complainant on 4/17 /205 at 10:00 AM. The Complainant stated he was a routine plasma donor, and after the completion of a donation on 4-1-2025, the Complainant noticed blood underneath the armrest, the bed and on the floor. He realized the blood was not his, and blood had soaked thru his clothing and onto his skin. The Floor Manager (also TP2) also noted the blood, and tried to wipe it off the Complainant's pants. The Complainant stated afterward he was concerned because "there was so much blood", and he wondered if he "might have caught something"; the Complainant further stated the facility had not checked to ensure the exposure would not make him sick, and had only offered to dry clean his clothes. 3. An on-site complaint investigation was conducted on 05-05-2025. After explaining the purpose of the unannounced survey, at 9:09 AM the surveyors requested the following documentation: (A) Documentation of the Donor's complaint or event incident report (B) Infection Control Policy and Procedure (CECP) (C) Complaint Policy and Procedure 4. A review of the Center Exposure Control Plan (CECP) revealed the following: (A) Pages 15-16: "Equipment Cleaning and Decontamination Workpractice Controls "...Equipment that is or becomes contaminated with blood during normal operations will be cleaned and disinfected..." (B) Page 18-19: "Personnel Protective Equipment (PPE) ...Employees and donors are never permitted to wear contaminated clothing away from [the Facility name] site...If personal articles of clothing are contaminated, the donor will be asked to relinquish those item to [Facility name] for proper disposal as regulated medical waste. ..." (C) Pages 24-25: "Employee Post Exposure Incident Care..."...If an employee, donor, or other person's clothing is saturated, provide a uniform set...to the donor to wear out of the center. The saturated clothing must be disposed in a biohazard waste container. ..." (D) Page 25: "Physician Assessment and Counseling by an authorized treating physician are vital components of the required post-exposure follow up procedure". (E) Page 24: "Post Exposure Incident Event Investigation...All incidents are investigated per [Facility Policy number]..." (F) Page 27: "Donor Post Event Investigation...The exposed donor Enablon Event Investigation report must be forwarded to the Divisional Medical Director within 24-hours." 5. A review of the video footage of the donor area of the facility on 4/1/2025 confirmed the following: (A) The phlebotomist had problems with the venipuncture during the previous donation before the Complainant arrived. Blood spilled onto the bed, armrest pillow, and the phlebotomist's lab coat. The phlebotomist wiped off the sides of the bed and the armrest pillow during the donation, checked to ensure there were no other problems, and then left to change her lab coat and perform other tasks in another area. (B) The plasma donation was terminated, and the needle was removed by TP1. TP1 was not observed decontaminating the bed, armrest pillow and surrounding area as per the CECP protocol. (C) Donor #13676371 (the Complainant) arrived in the plasmapheresis area for his donation, and lay in the same bed used by the the previous donor that had not been decontaminated. After the allotted collection period, TP2

	terminated the donation and removed the needle. When donor #13676371 stood upright, he observed he had come in contact with some of the blood on the bed. The donor also noticed blood underneath the armrest pillow. TP2 tried to wipe the donor's pants with the disinfecting wipes, and then allowed Donor #13676371 to leave the facility in the contaminated clothing. TP2 failed to follow the required procedures specified in the CECP protocol to protect donors when an exposure occurs. 5. During an interview on 05-05-2025 at 10:03 AM the AMQ explained the Donor's complaint had not been documented. The CM explained that on 4/1/2025 at around 7:30 PM, TP2 had contacted her about the incident. TP2 had left the donor's number (13676371) on her desk, but did not document the event in the Electronic Event Management System known as ENABLON. 6. During the exit interview on 05-05-2025 at 1:30 PM, the AMQ and CM confirmed donor # 13676371 (the Complainant) was exposed to blood from the previous donor, and TP1 and TP2 had not followed procedures as specified in the CECP protocol. In addition, the facility had failed to document and investigate the complaint as per the protocol in the CECP procedure.