

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2007043	(X3) Date Survey Completed 06/23/2026
Name of Provider or Supplier Lifesouth Community Blood Centers Inc	Street Address, City, State 219 Compass Way, Cullman, 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 Document a Donor-Related Incident (DDRI) policy, and interviews with the Regional Manager (RM), the District Director (DD), and the Assistant Donor Service Manager (ADSM) the surveyors determined the personnel failed to follow established safety procedures regarding documenting a donor incident report post donation. The surveyors noted 1 of 1 DDRI not documented and donor felt faint post donation. This deficiency is the result of a complaint investigation, with complaint number AL00052042, conducted on June 23, 2026. The findings include: 1. The Alabama Department of Public Health, Bureau of Health Provider Standards received one voicemail message from the Complainant on 06-10-2026 regarding a donor fainting post donation with "no adequate response on how to resolve the situation". 2. The CLIA State Agency conducted a phone interview with the Complainant on 06-10-2026 at 11:15 AM. The Complainant stated she was donor recruiter for LifeSouth Community Blood Centers. On 11/17/2025, the complainant was at a high school blood drive and noticed a student unresponsive post blood donation. The complainant wanted to call an ambulance, and she was told to stand down by the RM, DD, and ADSM. 3. An on-site complaint investigation was conducted on 06-23-2026. A review of the Document a Donor-Related Incident (DDRI) form revealed the following: (A) Page 2, 5.5.2, Incidents Reported After Donation: Document incident reports after the donation 4. During an interview with the ADSM on 6-23-26 at 11:58 AM, the ADSM confirmed the donor was on the floor when she entered the room. The surveyor asked if a Donor-Related Incident (DRI) form would have been filled out and the ADSM confirmed yes

	a form is filled out anytime there is an incident post donation. 5. During an interview with the RM and DD on 6-23-26 at 12:14 PM the surveyor requested the DRI form for the donor in question and the DD told the surveyor there are no incident reports for that location on that day. The RM and DD confirmed a DRI form needed to be documented for the donor post donation and there was no evidence of documentation.
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 Document a Donor-Related Incident (DDRI) form policy, and interviews with the Regional Manager (RM), the District Director (DD), and the Assistant Donor Service Manager (ADSM), the surveyors determined the laboratory failed to have an effective mechanism in place to ensure donor incident information was entered into the Post Donation Donor Incident program (PDDIP). This deficiency is the result of a complaint investigation, with complaint number AL00052042, conducted on June 23, 2026. The findings include: 1. The Alabama Department of Public Health, Bureau of Health Provider Standards received one voicemail message from the Complainant on 06-10-2026 regarding a donor fainting post donation with "no adequate response on how to resolve the situation". 2. The CLIA State Agency conducted a phone interview with the Complainant on 06-10-2026 at 11:15 AM. The Complainant stated she was donor recruiter for LifeSouth Community Blood Centers. On 11/17/2025, the complainant was at a high school blood drive and noticed a student unresponsive post blood donation. The complainant wanted to call an ambulance, and she was told to stand down by the RM, DD, and ADSM. 3. An on-site complaint investigation was conducted on 06-23-2026. After explaining the purpose of the unannounced survey, at 10:00 AM the surveyors requested the following documentation: (A) Documentation of the Post Donation Donor Incident Report (PDDIR) (B) Documentation of the Document a Donor-Related Incident (DDRI) policy and procedure 4. A review of the Document a Donor-Related Incident (DDRI) policy and procedure revealed the following: (A) Page 2, 5.5.2, Incidents Reported After Donation: Document incident reports after the donation 5. During an interview with the ADSM on 6-23-26 at 11:58 AM, the ADSM confirmed the donor was on the floor when she entered the room. The surveyor asked if a Donor-Related Incident (DRI) form would have been filled out and the ADSM confirmed yes a form is filled out anytime there is an incident post donation.