Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

# Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2129156	**(X3) Date Survey Completed** 04/28/2025
Name of Provider or Supplier The Center For Cancer And Blood Disorders	**Street Address, City, State** 800 W Magnolia Avenue, Fort Worth, TX	
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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, and confirmed in interview, the laboratory failed to ensure one of one bottle of CD38-PC5.5 reagent did not exceed its expiration date. Findings included: 1. During a tour of the laboratory on 04/28/2025 at 12:34 p.m., the surveyor observed the following stored in the reagent refrigerator: 1 bottle of CD38-P5.5; Lot # 200072; expiration date: 05/06/2024 2. During an interview on 04/28/2025 at 12:49 p.m., the General Supervisor/Testing Person confirmed the laboratory failed to ensure one of one bottle of CD38-PC5.5 reagent did not exceed its expiration date.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the

	reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory policies, manufacturer's instructions, laboratory environmental logs, and confirmed in interview, the laboratory failed to document corrective action when room humidity ranges were not within the manufacturer's specifications for 4 of 13 days in 2024 (December) and 4 of 13 days in 2025 (January). Findings included: 1. Review of the laboratory's policy titled "LCI-CYTOMETER DAILY OPERATION" stated: "PROCEDURE Please note: Refer to the Beckman Coulter Flow Cytometer User Manual for more detailed descriptions of startup, cleaning and shutdown procedures [sic] Daily Startup: 1. Record the room temperature and humidity readings - manufacturer specifications states that the room temperature for ideal operation of the flow cytometers and all reagents should be between 16C and 25C (60F and 77F), and must not change more that 5F per hour. The humidity should be between 30% and 80%, without condensation." 2. Review of the Beckman Coulter Flow Cytometer User Manual stated: "INSTALLATION SPECIAL REQUIREMENTS ... Ambient Temperature and Humidity Keep the room temperature between 16C and 25C (60F and 77F), and do not let it change more that 5F per hour. Keep the humidity between 30% and 80%, without condensation." 3. Review of the laboratory's "ROOM TEMPERATURE PM LOG" revealed 4 of 13 days in 2024 (December) and 4 of 13 days in 2025 (January) when the room humidity was out of the manufacturer's acceptable range of 30% to 80% and no corrective action was documented as follows: 12/17/2024: minimum reading 29% 12/18/2024: minimum reading 27% 12/19/2024: minimum reading 29% 12/20/2024: minimum reading 29% 01/16/2025: minimum reading 28% 01/17/2025: minimum reading 29% 01/22/2025: minimum reading 28% 01/23/2025: minimum reading 27% 4. During an interview in the conference room on 04/28/2025 at 12:35 p.m., the General Supervisor after a review of records, confirmed the laboratory failed to document corrective action when room humidity ranges were not within the manufacturer's specifications for 4 of 13 days in 2024 (December) and 4 of 13 days in 2025 (January). Word Key: C- Celsius F- Fahrenheit
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) (e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid Services (CMS) 209 form, testing personnel records and staff interview, the laboratory director failed to specify in writing the responsibilities and duties for one of one Testing Persons (TP-1) performing high complexity testing and one of one General Supervisors (GS-1). Findings included: 1. Review of the CMS-209 form revealed TP-1 as a testing person performing high complexity laboratory testing and was also listed as the general supervisor (GS-1). 2. On 04/28/2025 at 11:00 a.m. in the conference room, the

	laboratory was asked to provide documentation of the delegation of responsibilities by the laboratory director for each testing person and general supervisor. No documentation was provided. 3. During the exit interview in the conference room on 04/28/2025 at 1:10 p.m., the GS-1/TP-1 confirmed the laboratory director failed to specify in writing the responsibilities and duties for one of one Testing Persons (TP-1) performing high complexity testing and one of one General Supervisors (GS-1).