Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2101942	07/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Levine Cancer Institute - Transplantation	Carolinas Medical Center, 1000 Blythe Boulevard, Charlotte, NC	

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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview with the TS (technical supervisor) 7/27/23, all procedures had not been approved, signed, and dated by the current laboratory director. Findings: Review of the laboratory's policies and procedures revealed the procedures were signed and dated by the TS, the Chair of the Network Cancer Committee, and the Quality/Accreditation Coordinator. The procedures had not been signed and dated by the current laboratory director to indicate review and approval. During interview at approximately 11:10 a.m., the TS confirmed that the current laboratory director had not signed and dated all procedures. He stated they did not realize it was required.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions and review of 2020, 2021, 2022, and 2023 temperature and humidity logs, the laboratory failed to establish acceptable ranges for room temperature and humidity that were consistent with the ranges specified by the manufacturer for operation of the Beckman Coulter FC500 flow cytometer. Findings: Review of manufacturer's instructions for the Beckman Coulter FC500 flow cytometer revealed the manufacturer specifies operation of the analyzer in an environment with a room temperature of 16-32 degrees Celsius and a humidity range of 30-80%. Review of 2020, 2021, 2022, and 2023 temperature and humidity logs revealed the logs did not include acceptable ranges for room temperature and humidity until December 2021. The acceptable ranges added in December 2021 were 15-30 degrees Celsius for room temperature and 20-85% for humidity which were not consistent with manufacturer's instructions for operation of the Beckman Coulter FC500 flow cytometer.
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 manufacturer's instructions and review of 2020, 2021, 2022, and 2023 temperature and humidity logs, the laboratory failed to take and document corrective action for humidity readings that were outside the acceptable range specified by the manufacturer for operation of the Beckman Coulter FC500 flow cytometer. Findings: Review of manufacturer's instructions for the Beckman Coulter FC500 flow cytometer revealed the manufacturer specifies operation of the analyzer in an environment with a humidity range of 30-80%. Review of the laboratory's 2020, 2021, 2022, and 2023 temperature and humidity logs revealed the laboratory documented current, maximum, and minimum humidity readings daily. Current humidity readings were below the acceptable limits on multiple days with no corrective action documented. Examples: 1. February 3, 14, 21, 24, 27, 28, 2020 (6/20 days); 2. December 3, 8, 9, 18, 23, 24, 28, 30, 2020 (8/22 days); 3. January 6, 7, 11, 13, 18, 19, 21, 29, 2021 (8/20 days); 4. March 2, 3, 4, 5, 8, 9, 10, 15, 2021 (8/23 days); 5. February 1, 2, 7, 8, 9, 10,11, 14, 15, 16, 21, 2022 (11/20 days); 6. November 9, 14, 15, 17, 18, 21, 22, 23, 2022 (8/21 days); 7. February 6, 7, 8, 13, 14, 2023 (5/20 days).
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8)

	Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of personnel records and interview with the GS (General Supervisor) 7/27/2023, the Technical Supervisor failed to perform annual competency assessments on the GS in the years 2019, 2020, 2021 and 2022. Findings: Review of the laboratory's policy "E.102.2 Personnel Management-Training, Proficiency and Competency Assessment" states in "Section c. Ongoing (Annual) Competency...i. Outcome of tasks/procedures performed or direct observation of personnel performing the task/procedure serves as the basis for ongoing competency. ii. Use form E. 102D Ongoing (Annual) Competency..." Review of the laboratory's personnel records revealed the absence of a documented competency for the GS in the years 2019, 2020, 2021 and 2022. An interview with the GS at approximately 10:35 a.m. confirmed the absence of these documents. The GS stated there was no one to perform her competency during those times.