Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2174873	08/18/2022
Name of Provider or Supplier	**Street Address, City, State**	
Southwest Cancer Center	7436 Docs Grove Circle, Orlando, 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	Recertification survey was conducted from August 11-18, 2022. Southwest Cancer Center clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D3007	FACILITIES CFR(s): 493.1101(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs. This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory failed to use certified thermometers to record the temperatures of the refrigerator and the freezer used to store reagents from 04/19/2021 to 08/11/2022. Findings: On 08/11/2022 at 9:24 AM, the following flow cytometry reagents were observed in the refrigerator: Flow-Check Pro Fluorospheres, Flow-Set Pro Fluorospheres, ClearLLab Control Cells Normal and Abnormal, ClearLLab Compensation Beads, IO Test 3 Lysing Solution, and IO Test 3 Fixation Solution. On 08/11/2022 at 9:24 AM, Fetal Bovine Serum was observed in the freezer. Review of the package insert for the Digital Fridge/Freezer Thermometer showed there was no date listed on the thermometer of when it was calibrated and no indication of when the calibrations were due. On 08/11/2022 at 10:27 AM, the Technical Supervisor stated the thermometers were not certified.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

	This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to retain daily Quality Control (QC) log on the Beckman Coulter Navios Flow Cytometer from 03/19/2021 to 04/04/2022. Findings: The laboratory performed daily controls consisting of Flow-Check Pro Fluorospheres, Flow-Set Pro Fluorospheres, ClearLLab Controls Cells Normal and ClearLLab Controls Cells Abnormal. Documentation of the controls were kept on the flow cytometer and in the form of paper in Levey-Jennings (L-J) charts. The records on the flow cytometer were corrupted between 03/19/2021 to 04/04/2022 and could not be viewed using the protocols of the lot numbers used for the daily controls. The laboratory did not provide the paper L-J charts from 03/19/2021 to 04/04 /2022. According to the Clinical Laboratory Improvement Amendment (CLIA) Application for Certification, signed and dated by the Laboratory Director on 08/16 /2022, the laboratory had an annual test volume of 10,800 tests. On 08/11/2022 at 11: 25 AM, the Technical Supervisor stated a previous testing personnel employee corrupted the files on the flow cytometer and she was working to recreate the charts. On 08/18/2022 at 5:16 PM, the Technical Supervisor stated the last day in 2021 they had the L-J charts for was 03/18/2021 and the first day in 2022 they had the L-J charts was 04/05/2022.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to monitor and evaluate the overall quality of the general laboratory system and correct identified problems. Cross Reference D5217. Based on record review and interview, the laboratory failed to verify the accuracy (proficiency testing - PT) of 29 analytes (antibodies) at least twice annually in 2021. This is a repeat deficiency from the initial survey on 01/12 /2021.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to verify the accuracy (proficiency testing - PT) of 29 analytes (antibodies) at least twice annually in 2021. This is a repeat deficiency from the initial survey on 01/12/2021. Findings: The laboratory chose to perform PT with the College of American Pathologists (CAP). Review of the CAP PT records showed the attestation, instrument printouts, and performance review for two of two events in 2021 were not available for review. The

	Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, signed and dated by the Laboratory Director on 08/21/2022, noted the laboratory performed flow cytometry using 29 different antibodies. The laboratory evaluated the following antibodies: CD8 (T cells marker), CD10 (follicle center cells marker), CD11b (granulocytes and monocytes marker), CD13 (myeloid cells marker), CD14 (monocytes and macrophages marker), CD15 (granulocytes and Hodgkin's lymphoma marker), CD16 (granulocytes and natural killer cell marker), CD19 (B cell marker), CD20 (B cell marker), CD30 (B cell and Hodgkin's lymphoma marker), CD33 (monocytes and macrophages marker), CD34 (hematopoetic stem cells marker), CD38 (plasma cells and activated T and B cells marker), CD45 (leukocyte marker), CD56 (natural killer cells marker), CD64 (monocytes and macrophages marker), CD117 (stem cell and plasma cells marker), CD123 (progenitor cell marker), CD200 (myeloid cell marker), HLA-DR (Human Leukocyte Antigen - DR isotype T cell marker), Light chains (kappa and lambda, B cell marker), and TCR-gd (T cell receptor - gamma delta marker). According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 08/16/2022, the laboratory had an estimated annual test volume of 10,800. On 08/11/2022 at 10:18 AM, the Technical Supervisor stated the testing personnel who worked in 2021 did not perform proficiency testing.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to document corrective action when the refrigerator and freezer temperatures were out of acceptable range for the reagents stored in them from 04/19/2020 to 06/16/2022. Findings: 1. On 08/11/2022 at 9:24 AM, the following flow cytometry reagents were observed in the refrigerator: Flow-Check Pro Fluorospheres, Flow-Set Pro Fluorospheres, ClearLLab Control Cells Normal and Abnormal, ClearLLab Compensation Beads, IO Test 3 Lysing Solution, and IO Test 3 Fixation Solution. The boxes containing the reagent showed a storage temperature of 2-8 degrees C (Celsius) for all reagents. The temperature range of 2-8 degrees C is equivalent to 35.6-46.4 degrees F (Fahrenheit). Review of the temperature logs showed the following dates the temperatures were out of the acceptable range and no corrective action was taken. 04/19/2021 temperature 34.5 degrees F 04/27/2021 temperature 34.1 degrees F 05/11 /2021 temperature 35 degrees F 07/15/2021 temperature -3.9 degrees C 07/22/2021 temperature -5.1 degrees C 09/21/2021 temperature 8.3 degrees C 12/02/2021 temperature 1.7 degrees C 12/21/2021 temperature 1.7 degrees C 12/30/2021 temperature 1.3 degrees C 01/06/2022 temperature 1.1 degrees C 01/13/2022 temperature 1.2 degrees C 01/18/2022 temperature 1.7 degrees C 01/25/2022 temperature 1.7 degrees C 02/01/2022 temperature 1.2 degrees C 02/08/2022 temperature 1.8 degrees C 02/12/2022 temperature 1.9 degrees C 02/19/2022 temperature 1.8 degrees C 2. On 08/11/2022 at 9:24 AM, the Fetal Bovine Serum used for patient sample preparation was observed in the freezer. The label on the bottle of the Fetal Bovine Serum showed a storage temperature of -10 to -40 degrees C. Review of the temperature logs showed the following dates the temperatures were out of the acceptable range and no corrective action was taken. 06/24/2021

	temperature -2.3 degrees C 06/28/2021 temperature -3.9 degrees C 06/29/2021 temperature 5 degrees C 07/15/2021 temperature -3.6 degrees C 07/20/2021 temperature -3.6 degrees C 07/22/2021 temperature -4.4 degrees C 07/27/2021 temperature -3.6 degrees C 07/29/2021 temperature -6.1 degrees C 08/03/2021 temperature -5.1 degrees C 08/05/2021 temperature -5.9 degrees C 08/10/2021 temperature -6.5 degrees C 08/12/2021 temperature -5.6 degrees C 08/17/2021 temperature -6 degrees C 08/19/2021 temperature -6.3 degrees C 08/24/2021 temperature -6.8 degrees C 08/26/2021 temperature -4.8 degrees C 08/31/2021 temperature -6.9 degrees C 09/02/2021 temperature -7.7 degrees C 09/07/2021 temperature -0.6 degrees C 09/09/2021 temperature -8.9 degrees C 09/14/2021 temperature -5.3 degrees C 09/16/2021 temperature -8.3 degrees C 09/21/2021 temperature -7 degrees C 09/23/2021 temperature -7.3 degrees C 09/30/2021 temperature -5.2 degrees C 10/06/2021 temperature -6.7 degrees C 10/07/2021 temperature -5.7 degrees C 10/14/2021 temperature -7.6 degrees C 10/19/2021 temperature -7.4 degrees C 10/21/2021 temperature -6.4 degrees C 10/28/2021 temperature -5.7 degrees C 11/02/2021 temperature -7.1 degrees C 11/04/2021 temperature -5.2 degrees C 11/09/2021 temperature -4.5 degrees C 11/11/2021 temperature -8 degrees C 11/16/2021 temperature -9 degrees C 11/18/2021 temperature -2.9 degrees C 11/23/2021 temperature -4.3 degrees C 12/02/2021 temperature -4.7 degrees C 12/07/2021 temperature -2.1 degrees C 12/09/2021 temperature -2.4 degrees C 12/14/2021 temperature -3.2 degrees C 12/16/2021 temperature -4.9 degrees C 12/21/2021 temperature -5.8 degrees C 12/30/2021 temperature -6.5 degrees C 01/06/2022 temperature -6.3 degrees C 01/11/2022 temperature -6.8 degrees C 01/13/2022 temperature -7.6 degrees C 01/18/2022 temperature -6.9 degrees C 01/20/2022 temperature -7.8 degrees C 01/27/2020 temperature -8.2 degrees C 02/01/2022 temperature -5.1 degrees C 02/03/2020 temperature -6.2 degrees C 02/08/2022 temperature -1.4 degrees C 02/10/2022 temperature -2.3 degrees C 02/12/2020 temperature -4.1 degrees C 02/15/2022 temperature -5.2 degrees C 02/17/2022 temperature -2.3 degrees C 02/19/2020 temperature -4.2 degrees C 02/22/2022 temperature -4.8 degrees C 03/01/2022 temperature -6.3 degrees C 03/15/2022 temperature -1.7 degrees C 03/29/2022 temperature -8.8 degrees C 03/31/2022 temperature -9.0 degrees C 04/05/2022 temperature -6.3 degrees C 04/07/2022 temperature -1.4 degrees C 04/19/2022 temperature -9.3 degrees C 04/21/2022 temperature -6.5 degrees C 05/03/2022 temperature -4.8 degrees C 05/05/2022 temperature -4.2 degrees C 05/10/2022 temperature -8 degrees C 05/12/2022 temperature -4.8 degrees C 05/19/2022 temperature -7.4 degrees C 06/01/2022 temperature 6.5 degrees C 06/16/2022 temperature -8.8 degrees C According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 08/16/2022, the laboratory had an estimated annual test volume of 10,800. On 08/11/2022 at 11:25 AM, the Technical Supervisor acknowledged there were temperatures out of range and no corrective action was documented.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for

	acceptability. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to include name and address of the laboratory where the professional component was performed for five (#1, #2, #3, #4, #5) of six patients' Flow Cytometry Report, (#1, #2, #3, #4, #5, #6). Findings: Review of patients' "Flow Cytometry Report" showed the name and address of the laboratory where the professional component was performed was not listed on five (#1, #2, #3, #4, #5) of six patient reports reviewed, (#1, #2, #3, #4, #5, #6). According to the Clinical Laboratory Improvement Amendment (CLIA) Application for Certification, signed and dated by the Laboratory Director on 08/16/2022, the laboratory had an annual test volume of 10,800 tests. On 08/11/2022 at 11:25 AM, the Technical Supervisor stated the name and address was on the reports but someone removed it.