Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2174873	01/12/2021
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	An initial certification survey was conducted on January 12, 2021. Southwest Cancer Center clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
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. Findings: Cross Reference D5201: Based on observation and interview, the laboratory failed to ensure that confidential patient information was securely (encrypted) emailed to and from the pathologist from 11/21/19 to 1/12/21. Cross Reference D5209: Based on record review and interview, the laboratory failed to establish and follow a written procedure to access the training and competency of 1 out of 1 (Testing Personnel A). 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 from 11/21/19 to 1/12/21.
D5201	CONFIDENTIALITY OF PATIENT INFORMATION CFR(s): 493.1231 The laboratory must ensure confidentiality of patient information throughout all

	phases of the total testing process that are under the laboratory's control. This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory failed to ensure confidential patient information was securely (encrypted) emailed to and from the pathologist from 11/21/19 to 1/12/21. Findings: During an observation on 1/12/21 at 11:40 AM, the Technical Supervisor emailed Patient #1's flow cytometry reports with confidential information to the pathologist for interpretation. The email was not encrypted and the patient's name was typed in the subject line. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 1/21/21, the laboratory had an estimated annual test volume of 11,000. During an interview on 1/12/21 at 11:40 AM, and 3:14 PM, the Technical Supervisor stated she put the patient's name in the subject line of the email and had not encrypted the email.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview, the laboratory failed to establish and follow a written procedure to access the training and competency of 1 out of 1 staff, (Testing Personnel A). Findings: Review of the laboratory's procedure manual, signed by the Laboratory Director on 1/12/21, showed that there was no procedure on training and competency. Review of the laboratory's records showed the laboratory failed to have documentation of the initial training on the Beckman Coulter Navios Flow Cytometer and a competency evaluation after six months. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 1/21/21, the laboratory had an estimated annual test volume of 11,000. During an interview on 1/12/21 at 2: 22 PM, the Technical Supervisor stated there was no procedure on training and competency. During an interview on 1/12/21 at 1:30 PM, the Technical Supervisor stated she did not have the documentation on her training and no competency evaluation was performed on her.
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 from 11/21 /19 to 1/12/21. Findings: Review of the procedure manual showed there was no procedure on PT. No documentation was available that showed the laboratory performed PT. The Clinical Laboratory Improvement Amendments (CLIA)

	Application for Certification, signed and dated by the Laboratory Director on 1/21/21, 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 1/21/21, the laboratory had an estimated annual test volume of 11,000. During an interview on 1/12/21 at 2:26 PM, the Technical Supervisor stated the laboratory did not have a procedure on PT. During an interview on 1/12/21 at 1:21 PM, the Technical Supervisor stated the laboratory had not performed any PT.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory's quality assessment program failed to monitor and evaluate the overall quality of the analytic system and correct identified problems. Findings: Cross Reference D5403. Based on record review and interview, the laboratory procedure manual failed to include a procedure on specimen labeling. Cross Reference D5413. Based on observation, record review and interview, the laboratory failed to record the temperature of the refrigerator, freezer, and the room and humidity of the room where the testing was performed from 11/21/19 to 1 /12/21.. Cross Reference D5429. Based on record review and interview, the laboratory failed to document the maintenance performed on Beckman Coulter Navios Flow Cytometer from 11/21/19 to 1/12/21.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results.

	(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory procedure manual failed to include a complete procedure on patient specimen labeling. Findings: Review of the procedure manual, signed and dated by the Laboratory Director on 1/12/21, showed there was no procedure on the labeling of the ClearLLab tubes that patient specimens were added to and run on the Beckman Coulter Navios Flow Cytometer. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 1/21/21, the laboratory had an estimated annual test volume of 11,000. During an interview on 1/12/21 at 2: 19 PM, the Technical Supervisor stated there was no procedure on labeling patient specimens run on the flow cytometry instrument.
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 observation, record review and interview, the laboratory failed to record the temperatures for the refrigerator, freezer, and the room and humidity of the room where the testing performed from 11/21/19 to 1/12/21. Findings: 1. Observation of the flow cytometry reagents, 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, showed a storage temperature of 2 - 8 degrees C (Celsius). No temperature logs for the refrigerator were available for review. 2. Observation of the Fetal Bovine Serum used for patient sample preparation stored in the freezer, showed a storage temperature of 2-8 degrees C (Celsius). No temperature logs for the freezer were available for review. 3. Review of the Beckman Coulter Navios Flow Cytometer instruction manual noted the room temperature should be between 15.5 degrees C and 32 degrees C, and the humidity between 30% and 85%. No temperature or humidity logs for the room where testing was performed were available for review. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for

	Certification signed and dated by the Laboratory Director on 1/21/21, the laboratory had an estimated annual test volume of 11,000. During an interview on 1/12/21 at 1: 23 PM, the Technical Supervisor stated she did not record the temperature for the refrigerator, freezer, or the room temperature and humidity of the room where the testing was performed.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document the maintenance performed on Beckman Coulter Navios Flow Cytometer from 11/21/19 to 1/12/21. Findings: Review of the Beckman Coulter Navios Flow Cytometer instructions manual notes "Use the Maintenance Log to record daily and periodic maintenance." Review of the instruments maintenance log showed that nothing had been filled in. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 1 /21/21, the laboratory had an estimated annual test volume of 11,000. During an interview on 1/12/21 at 1:30 PM, the Technical Supervisor stated she did not record the maintenance performed on the flow cytometer.
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 flow cytometry reports failed to provide all the required information for laboratory test reports for 2 of 2 patients, (#1, #2). Findings: Review of the flow cytometry reports sent to the pathologist for interpretation failed to have the correct address where the technical component was performed. Review of the final flow cytometry with the pathologist's interpretation failed to state where the technical component was performed. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 1/21/21, the laboratory had an estimated annual test volume of 11,000. During an interview on 1/12/21 at 11:25 AM, the Technical Supervisor stated the reports did not mention where the technical component was performed.
D6076	LABORATORY DIRECTOR

	CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to provide overall management and direction. Findings: Cross Reference D6082: Based on record review and interview, the Laboratory Director failed to ensure that testing systems used in the laboratory provided quality laboratory services for all aspects of testing performance, including analytic and postanalytic phases of testing from 11/21 /20 to 1/12/21. Cross Reference D6103: Based on review of the procedure manual and interview, the Laboratory Director failed to ensure the laboratory established and followed a written procedure to access training and competency 1 of 1 staff, (Testing Personnel A). Cross Reference D6107: Based on review of the procedure manual and interview, the Laboratory Director failed to specify in writing the responsibilities and duties (job descriptions) of the Laboratory Director, Clinical Consultant, Technical Supervisor, General Supervisor, and Testing Personnel.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure that testing systems used in the laboratory provided quality laboratory services for all aspects of testing performance, including analytic and postanalytic phases of testing from 11/21/20 to 1/12/21. Findings: The Laboratory Director failed to ensure the laboratory procedure manual had a procedure on specimen labeling. (See D5403) The Laboratory Director failed to ensure the temperatures for the refrigerator, freezer, and the room and humidity of the room where the testing performed from 11/21/19 to 1/12 /21 was recorded. (See D5413) The Laboratory Director failed to ensure the maintenance performed on Beckman Coulter Navios Flow Cytometer from 11/21/19 to 1/12/21 was documented. (See D5429) The Laboratory Director failed to ensure the flow cytometry reports provided all the required information for laboratory test reports for 2 of 2 (#1, #2) patients. (See D5805)
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

	This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview, the Laboratory Director failed to ensure the laboratory established and followed a written procedure to access the training and competency of 1 out of 1 staff, (Testing Personnel A). Findings: The Laboratory Director failed to ensure the laboratory established and followed a written procedure to access the training and competency of 1 out of 1 (Testing Personnel A). (See D5209)
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must 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 the procedure manual and interview, the Laboratory Director failed to specify in writing, the responsibilities and duties (job descriptions) of the Laboratory Director, Clinical Consultant, Technical Supervisor, General Supervisor, and Testing Personnel. Findings: Review of the laboratory's procedure manual, signed by the Laboratory Director on 1/12/21, showed there was no job descriptions for the Laboratory Director, Clinical Consultant, Technical Supervisor, General Supervisor, and Testing Personnel. The Laboratory Personnel Report, signed and dated by the Laboratory Director on 1/10/21, listed 1 laboratory director, 1 clinical consultant, 1 technical supervisor, 1 general supervisor and 1 testing personnel. During an interview on 1/12/21 at 3:26 PM, the Technical Supervisor stated there were no job descriptions.