Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2206631	12/06/2021
Name of Provider or Supplier	**Street Address, City, State**	
Utah Cancer Specialists	425 E 5350 S Suite 101, Ogden, UT	

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
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 a record review and an interview with the technical consultant, the laboratory failed to have a policy or procedure to assess the competency of testing personal for tests performed on the Beckman-Coulter DxH 520 hematology analyzer and the position held by the technical consultant. The laboratory performed approximately 5,500 hematology tests annually. Findings include: 1. A review of the laboratory procedures revealed the laboratory failed to have a procedure or policy to assess all six procedures for the assessment of eight of eight testing personnel. 2. A review of the laboratory procedures revealed the laboratory failed to have a policy or procedure to assess the position of two of two technical consultant. 3. An interview on 12/06/2021, at 1:30 PM, with the technical consultant, confirmed the laboratory failed to have a policy or procedure to assess the competency for testing personnel and the technical consultant.
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 record review, direct observation, and interview with testing personnel the laboratory failed to follow the manufacturer's instructions to monitor and document the humidity of the laboratory space which performed approximately 5,500 hematology tests on the Beckman-Coulter DxH analyzer. Findings include: 1. No criteria was established for the monitoring of room humidity. 2. No hygrometer was present in the laboratory during observation on 12/06/2021 at approximately 4:00 PM. 3. Beckman Coulter DxH instrument manual states "The instrument meets performance claims when operated at a maximum of 80% relative humidity". 4. In an interview on 12/06/2021 at approximately 3:00 PM, the testing personnel confirmed humidity was not monitored.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on record review, direct observation, and interview with testing personnel, written expiration dates were not on three of three Beckman-Coulter quality control materials. The laboratory performs approximately 5,500 hematology test annually on the Beckman Coulter DxH instrument. Finding include: 1. The package insert for the Beckman Coulter DxH 500 Hematology Controls states that open tubes are stable for 14 days. 2. An observation on 12/06/2021, at 3:30 PM, revealed the expiration dates failed to be written on three of three controls. 3. In an interview on 12/06/2021 at approximately 3:30 PM, testing personnel confirmed that expiration dates are not written on the controls.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on record review and interview with testing personnel, the laboratory did not establish a maintenance protocol for the Beckman Coulter DxH instrument. The laboratory performs approximately 5,500 hematology tests annually. Findings include: 1. A record review of the laboratory procedures revealed the laboratory failed to

	document and have a protocol for maintenance activities for the Beckman-Coulter DxH. 2. In an interview on 12/06/2021 at approximately 3:00 PM, the testing personnel confirmed there was not a maintenance protocol for the Beckman Coulter DxH instrument.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review, direct observation, and interview with laboratory staff, the laboratory director failed to provide management and direction to the laboratory by failure to ensure corrective actions were taken when the laboratory received an performance of "unacceptable" for the Analyte Basophils sample DXH-03 in the American Proficiency Institute 2021 Hematology/Coagulation - 1st event (See D6019); failure to ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur for the Beckman Coulter DxH instrument (See D6022); and the failure to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process (See D6031).
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and interview with technical consultant, a corrective action plan was not followed when proficiency testing was unacceptable. The laboratory performs approximately 5,500 tests annually on the Beckman-Coulter DxH 500. Findings include: 1. American Proficiency Institute 2021 Hematology/Coagulation - 1st event review found a performance of "unacceptable" for the Analyte Basophils sample DXH-03. 2. The laboratory failed to follow its corrective action plan procedure for unacceptable proficiency testing results. 3. In an interview on 12/06 /2021 at approximately 2:10 PM, the technical consultant confirmed that no corrective action was followed.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

	and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Consultant. The laboratory failed to identify failures in quality in their DxH quality control samples for the Beckman Coulter DxH instrument. The laboratory performs approximately 5,500 hematology tests annually. Findings include: 1. The Quality Assurance manual states in Section VI E "Controls must be reviewed and analyzed to assure that the controls are not trending towards the established upper or lower limits and that the controls are not hovering around, and failing, established limits." 2. A record review revealed 13 out of 37 days the Abnormal Low control was out of the acceptable reference range. 3. Record review failed to show any investigation or corrective action was performed when the controls were out of range. 4. In an interview on 12/06/2021 at approximately 2:30 PM, the Technical Consultant confirmed that no investigation or corrective action was performed to address the controls that were running out of range.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review, direct observation, and interview with testing personnel, the laboratory director failed to ensure that testing personnel could access the Beckman-Coulter DxH 520 Hematology Analyzer procedure. The laboratory performs approximately 5,500 hematology tests annually. Findings include: 1. Direct observation conducted on 12/06/2021 at approximately 3:10, testing personnel was not able to access the Beckman-Coulter DxH 520 Hematology Analyzer procedure when asked to locate it. 2. In an interview conducted on 12/06/2021 at approximately 3:10, the testing personnel confirmed that they did not know where the procedure manual was located and did not know if there was a procedure manual available.
D6067	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Each individual performing moderate complexity testing must have training to ensure that the individual has-- (A) the skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (B) the skills required for implementing all standard laboratory procedures; (C) the skills required for performing each test method and for proper instrument use; (D) the skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed; (E) a working knowledge of reagent

	stability and storage; (F) the skills required to implement the quality control policies and procedures of the laboratory; (G) an awareness of the factors that influence test results; and (H) the skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the Training Procedure for Testing Personnel procedure, the Beckman-Coulter DxH 520 Hematology Analyzer procedure, training documentation, and staff interview, the laboratory failed to provide evidence that training assessed the skills required for patent testing. The laboratory performs approximately 5,500 hematology tests annually. Findings include: 1. The Training Procedure for Testing Personnel and the Beckman-Coulter DxH 520 Hematology Analyzer procedure failed to include skills required to accurately perform patient testing. 2. Training documentation failed to include the skills required to assess and perform patient testing. 3. In an interview conducted on 12/06/2021 at approximately 1:15 PM, the technical consultant confirmed that initial training documentation for testing personnel does not contain details on what skills were assessed.