Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2121334	04/06/2022
Name of Provider or Supplier	**Street Address, City, State**	
Tanner Clinic - East Layton	1750 E 3100 N, Layton, 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 record review and an interview with the laboratory director, the laboratory failed to have a policy or procedure to assess the competency for four out of four technical consultants for the position of technical consultant. Findings Include: 1. The laboratory performed approximately 14,951 moderately complex hematology and chemistry tests a year. 2. A review of the laboratory procedures revealed the laboratory failed to have a policy or procedure to assess the competency of the position of technical consultant for four out of four technical consultants. 3. An interview on 04/06/2022, at 1:40 PM, with the laboratory director, confirmed the laboratory failed to have a policy or procedure to assess the competency for the position of technical consultant.
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 a review of patient test reports, laboratory procedure manual, and an interview with the laboratory director, the laboratory failed to include reference intervals in the laboratory procedure manual for eight of fifteen Complete Blood Count (CBC) values Findings include: 1. Review of the patient reports revealed that the CBC panel has fifteen components with reference ranges. WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT CT, RDW, -GRAN%, -LYM%, -MONO%, GRAN#, -LYM#, and -MONO# 2. Review of the "CBC SATELLITE-Medonic M-Series Hematology Analyzer" procedure revealed the failed to include reference ranges for HCT, MCV, MCH, MCHC, RDW, GRAN#, -LYM#, and -MONO# 3. Interview with the laboratory director on 04/06/2022 at approximately 3:55 PM, confirmed the lab failed to provide reference ranges for several values included in the CBC panel.
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 and interview with the laboratory director, the laboratory failed to store test kit components and specimens at temperatures consistent with the manufacturer's instructions for the Chemstrip Microalbumin test strips, CLINITEK Urinalysis samples, the Medonic M-Series Hematology Analyzer, One Step + hCG Combo Test (serum), urine cultures media, ESR on the Excyte Mini, Alere i RSV CLSI, and Alere i Strep A CLSI assays. Findings include: 1. Record review of Chemstrip Micral for the Semiquantative Determination of Microalbumin procedure revealed Chemstrip Microalbumin test strips are to be stored at 2-8C. 2. Record review of the Urinalysis (CLINITEK Status+ Analyzer) procedure revealed that refrigerated urine samples must be brought to room temperature, 20-30C, before testing. 3. Record review of the Medonic M-Series Hematology Analyzer instrument manual revealed instruments specifications require a temperature between 64-90F (18-32C). 4. Record review of the One Step + hCG Combo Test (serum) procedure revealed that specimens are to be stored at 2-8C. 5. Record review of the Urine Cultures - General Setup procedure revealed that all media is stored in the refrigerator

	at 4-8C. 6. Record review of the ESR on the Excyte Mini manufactures instructions revealed specimens at room temperature should be between 18-25C and specimens should be refrigerated at temperatures between 2-8C. 7. Record review of the Alere i RSV CLSI manufactures instructions revealed specimens refrigerated at temperatures between 2-8C. 8. Record review of the Alere i Strep A CLSI manufactures instructions revealed specimens refrigerated at temperatures between 2-8C. 9. Record review of the laboratory temperature log revealed that room temperature is considered acceptable between 60-80F (15-26C) and that acceptable refrigerated temperature is between 2-8C. 10. The laboratory performed approximately 14,951 moderately complex hematology and chemistry tests a year. 11. An interview on 04/06/2022, at 2: 45 PM, with the laboratory director, confirmed the laboratory failed to monitor room and refrigerator temperatures that were consistent with laboratory procedures and manufacturer's instruction.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of patient test reports, laboratory procedure manual, and an interview with the laboratory director, the laboratory failed to include the correct normal ranges for complete blood counts (CBC) on four out of seven values. Findings include: 1. Review of the patient reports revealed four of the seven reference ranges did not correctly match those reference ranges for the CBC test in the procedure manual. 2. The procedure manual showed: Parameter Reference Range Red Blood Count (RBC) 4.2-5.4 X 106/l Hemoglobin (HGB) 12.0-18.0 G/dL White Blood Count (WBC)4.3-10.8 X 103/l Platelets (PLT) 144-4.44 X 103/l 3. The patient report showed: Parameter Reference Range Red Blood Count (RBC) 4.50-5.30 X 106/l Hemoglobin (HGB) 13.0-16.0 G/dL White Blood Count (WBC)4.5-13.0 X 103/l Platelets (PLT) 150-400 X 103/l 4. In an interview on 04/06/2022 at 3:55 PM, the laboratory director confirmed the lab failed to provide pertinent normal ranges on the test report.