Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0914294	04/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
Tanner Clinic - Kaysville	380 N 400 W, Kaysville, 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
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 manufacturer's specifications review, lack of documentation and confirmation by staff, the laboratory failed to document they monitored the percent Humidity (H%) documenting they met the Medonic counting instrument manufacturer's specifications for instrument operation for complete blood count (CBC) tests. The laboratory performed approximately 3 to 5 CBC tests per day. Findings include: 1. The manufacture specified H% to be less than 80%. 2. The laboratory failed to document humidity % was monitored to ensure the environmental specifications were met. 3. In an interview with staff on 04/11/2018 at approximately 12:45 P.M., staff confirmed they did not monitor humidity for CBC testing.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on quality control record review, lack of documentation, and interview with staff, the laboratory failed to perform two levels of quality control each day of testing for 1 of 2 serum pregnancy (hCG) test days reviewed. The laboratory tested approximately 1 serum pregnancy tests every week and a half. Findings include: 1. Quality control record review failed to include documentation the laboratory performed two levels of qualify control testing on 06/20/2017 for performing hCG testing for patient 710503. 2. In an interview with staff on 04/11/2018 at approximately 12:30 P.M. staff stated the laboratory had not performed an Individualized Quality Control Plan for the laboratory location in Kaysville. Staff confirmed they did not perform 2 levels of quality control each day of patient testing for serum hCG testing from January 1, 2016 to April 11, 2018.