Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D1010297	04/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Tanner Clinic - Syracuse	2038 W 1900 S, Syracuse, 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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on Micros ABX manufacturer's instructions review, lack of documentation and interview with staff, the laboratory failed to follow the hematology cell counter manufacturer's instructions to perform calibration every six months for 2 of 2 six month time frames reviewed from April 2016 through April 2018. The laboratory performed approximately 4 complete blood counts per day. Findings include: 1. The ABX micros CBC instrument reviewed included instructions for calibration performance once every 6 months of use. 2. The laboratory failed to record calibration performance from May 2016 to July 1, 2017. 3. In an interview conducted on 04/25 /2018 at approximately 1:00 P.M. staff confirmed calibration documentation for ABX calibrations were not available on the day of survey.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

	This STANDARD is not met as evidenced by: Based on patient test records review, Individualized Quality Control Plan (IQCP) review, quality control records review, lack of documentation, and interview with staff, the technical consultant failed to ensure the laboratory maintained the quality control plan for 1 of 2 test systems reviewed, serum pregnancy tests, (hCG) for 1 of 3 months of hCG test results reviewed. The laboratory tests approximately 3 samples per month for serum hCG tests. Findings include: 1. Patient test records review included documentation the laboratory performed serum hCG testing for patient 776714 on 07/25/2017. 2. IQCP review included, in the quality control plan states to perform external liquid positive and negative controls monthly and with each new lot number of hCG test kit. 3. Quality control records review failed to include documentation the laboratory performed external liquid positive and negative controls from 06/26/2017 to 09/01/2017. 4. In an interview with staff on 04/25/2018 at approximately 1:15 P.M., staff confirmed the IQCP was not maintained for this time period for serum hCG testing.