

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2073060	(X3) Date Survey Completed 04/24/2018
Name of Provider or Supplier Tanner Clinic - Roy	Street Address, City, State 3443 W 5600 S, Roy, 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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing records review, lack of documentation, and interview with staff, the laboratory failed to ensure Hematology and Serum Pregnancy proficiency testing results were reviewed and evaluated for 3 of 6 American Proficiency Institute (API) events surveyed (events 1, 2, and 3 of 2016). Findings include: 1. Proficiency testing records failed to include documentation test results were reviewed by staff to identify problems in complete blood count test accuracy. The laboratory scored 80% for red blood cell count, Hematocrit, and Hemoglobin tests for the 3rd event of 2016. No corrective actions or identification of the sources of error were noted. 2. In an interview conducted on 04/24/2018 at approximately 11:45 A.M. staff confirmed proficiency testing records available did not include a review and evaluation of API test reports for 2016 hematology and serum pregnancy testing.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by:</p>

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 review of the Individualized Quality Control Plan (IQCP), quality control records review, and interview with staff, the technical consultant failed to ensure the laboratory maintained the levels of analytic performance for serum pregnancy (hCG) tests for two years of testing reviewed, from April 2016 to April 2018. The laboratory tested approximately 12 specimens per year. Findings include: 1. The IQCP review included the instructions to perform two levels of quality control (QC) with each new lot number of test kits and monthly. 2. Quality control record review included documentation the laboratory performed quality control with each new lot number of serum pregnancy test kits. 3. In an interview conducted on 04/24/2018 at approximately 11:45 A.M. staff confirmed the laboratory had not followed the IQCP to perform QC monthly and with each new lot number of hCG test kit.