Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0522746	04/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Tanner Clinic - Layton	2121 N 1700 W, 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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff the laboratory failed to verify the reportable range for Au 680 tests for which the instrument used a two point calibration for 2 of 4 six month time frames after March of 2017 through April 2018 for 8 of approximately 20 tests reviewed. The laboratory performed approximately 800,000 routine chemistry tests per year using the Au 680 instrument. Findings include: 1. Calibration test records reviewed included a two point calibration, as

	specified by the manufacturer, for Sodium, Potassium, Chloride, Creatinine, Triglycerides, Alanine transaminase, Aspartate transaminase, and Alkaline phosphatase. 2. The laboratory failed to document at least once every 6 months they verified the reportable range of the 8 tests listed in finding 1 at the zero or minimal value, at the mid-level, and at the upper level of the reportable range for each test. 3. In an interview conducted on 04/27/2018 at approximately 4:45 P.M. the laboratory staff stated they did not have documentation they verified the tests reportable range at least once every 6 months of testing in September of 2017 and April of 2018. ,