

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2159618	(X3) Date Survey Completed 01/19/2021
Name of Provider or Supplier Tanner Clinic - Westside	Street Address, City, State 1477 N 2000 W, Ste C, Clinton, 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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on procedure review, lack of documentation, and interview with the director, the director failed to sign and date as approved 1 of 6 new tests reviewed, sensitive estradiol. The laboratory performed approximately 2 to 5 tests per week. Findings include: 1. The new test procedure failed to include the approval by the laboratory director prior to testing patient's specimens for the concentration of Estradiol. 2. In an interview conducted on 01/19/2021 at approximately 5:15 P.M. the director confirmed the procedure was not signed and dated as approved for Estradiol concentration prior to patient testing in March 2020.</p>
D6013	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;</p> <p>This STANDARD is not met as evidenced by: Based on SARS 2 Covid 19 IgG test verification studies review, lack of</p>

documentation and interview with staff, the laboratory director failed to sign and date as approved the accuracy and precision studies for Sars Covid 19 IgG presence or absence. The number of patients tested was not determined. Findings include: 1. The laboratory studies included comparison studies to verify the accuracy and precision for Sars 2 Covid 19 IgG testing. The study included verification of at least two separate studies: one with 7 true positive 1 false positive, 1 true negative and 2 false negative. The second group of specimens included 10 of 10 negative results, and of 31 previously tested negative specimens the laboratory study results was 13 negative. The remainder of the 31 negative results were not accounted for and of 11 known positive samples the laboratory reported 5 as negative. The reconciliation was not documented. 2. In an interview conducted on 01/19/2020 with the laboratory director confirmed the laboratory study was conducted with 2 other laboratories verifying the same test on the same instrument combining specimens in order to provide sufficient positive specimens to be statistically valid. The laboratory lacked information to support the specimen integrity ensuring the specimens maintained IgG reactivity in transit and in storage until testing was performed and that the study documented test accuracy and precision.