

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0522746	(X3) Date Survey Completed 11/16/2020
Name of Provider or Supplier Tanner Clinic - Layton	Street Address, City, State 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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on new lot number verification documentation review, instrument settings review, lack of documentation, and interview with staff, the laboratory failed to follow Sysmex CA600 manufacturer's instructions to perform Innovin reagent new lot number verification using the new lot number of reagent and the new lot number's International Sensitivity Index (ISI) to calculate the normal patient geometric mean. Then use the newly determined geometric mean as the denominator for the calculation of the International Normalized Ratio for coagulation measurement of the Prothrombin time for 1 of 1 new lot number of Innovin received from November 2018 to November 2019 (lot number 549752). The lab performed approximately 8 to 14 INR calculations per day. Findings include: 1. The new lot number verification included the calculation for the new patient mean of 15.5.. The normal patient geometric mean was not obviously stated as such in the verification record 2. Sysmex CA 600 instrument settings observed on 11/18/2020 at approximately 12:00 Noon. Was 10.1, the same as the previous lot number of 10.1455 rounded down. 3. In an interview with staff on 11/18/2020 at approximately 12:45 staff confirmed they could not determine if the new normal patient geometric mean was correctly calculated and entered into the Sysmex CA600 instrument for INR calculation.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p>

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on patient test records review, quality control records review, lack of documentation, and interview with staff, the laboratory failed to record the lot number and expiration dates of qualitative serum pregnancy test kits, the dates the kits were placed into use, and the date the kits expired for 2 years of testing reviewed. Findings include: 1. Patient test records review for patient 759865 included a negative qualitative serum pregnancy test. 2. Quality control record review for serum qualitative pregnancy tests performance on 06/01/2019 failed to include the lot number or expiration date of the the test kit in use. 3. In an interview on 11/16/2020 at approximately 6:45 P.M. the laboratory director confirmed serum qualitative pregnancy tests kit lot numbers were not recorded in the test system from November 2018 to November 2020.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on personnel competency evaluations review, lack of documentation, and interview with the technical supervisor, the laboratory failed to evaluate 10 of 10 testing personnel annually for 1 of 2 years of testing reviewed, 2019. Findings include: 1. Personnel records review failed to include competency evaluations for 10 testing personnel performing high complexity testing for more than one year. 2. In an interview conducted on 11/16/2020 at approximately 4:00 P.M. the director confirmed annual competency evaluations were not performed in 2019.