

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 46D1010297	<b>(X3) Date Survey Completed</b> 11/13/2020
<b>Name of Provider or Supplier</b> Tanner Clinic - Syracuse	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation, reagent quality control records review, and interview with staff, the laboratory failed to document human chorionic gonadotrophin (hCG) test cartridges and Medonic complete blood cell (CBC) counter reagent cell diluent and red blood cell lyse reagent were not used past their expiration dates. Medonic complete blood cell (CBC) counter reagent cell diluent and red blood cell (RBC) lyse reagent reviewed from April 2019 to November 2020 and hCG test kits reviewed from July 2019 to November 2020 lacked a record of the lot number and expiration dates and the dates the cartridges were placed in use. The laboratory performed approximately 3 to 5 hCG tests per month and 3 to 5 CBC tests per day. Finding include: 1. Quality control records review for hCG testing for patient 621424 on 07/02/2020 and for patient 689985 on 01/07/2020 failed to include the hCG test cartridge lot number, expiration date and the date the test kit was in use to match quality control to the timeframe the patient tests were performed. 2. The laboratory lacked documentation they recorded the lot number, expiration date and date the reagents were placed in use for the Medonic cell counter reagents (RBC Lyse and cell diluent). 3. In an interview with staff on 11/13/2020 at approximately 4:50 P.M., the laboratory director confirmed the hCG and cell counter diluent and lyse reagents were not recorded.</p>
<b>D6053</b>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p>

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on personnel records review, competency records review, lack of documentation, and confirmation by staff, the laboratory technical consultant failed to evaluate 2 of 2 new testing personnel semiannually the first year of testing for complete blood count and serum human chorionic gonadotrophin (hCG) testing.

Findings include: 1. Personnel records review included 2 new testing personnel were hired in 2019 (testing person A and testing person B). 2. Competency records review lacked documentation new testing person A, and new testing person B lacked semiannual competency evaluations in 2019. 3. In an interview with the laboratory director on 11/13/2020 at approximately 4:45 P.M. the laboratory director confirmed semiannual competency was not performed for 2 new testing persons in 2019.