

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 46D2073060	<b>(X3) Date Survey Completed</b> 11/13/2020
<b>Name of Provider or Supplier</b> Tanner Clinic - Roy	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5293</b>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</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 monitor potassium hydroxide (KOH) proficiency to review effectiveness of the corrective actions taken to prevent recurrence for 4 of 6 proficiency testing failures. Findings include: 1. The laboratory failed potassium hydroxide (KOH) on the 3rd American Proficiency Institute (API) event of 2018, the 1st and 2nd events of 2019, and 1st event of 2020. 2. Proficiency testing quality assessment records lacked documentation the laboratory had reviewed the effectiveness of corrective actions taken for initial and subsequent failures to prevent failing a 3rd and 4th time. 2. In an interview with staff on 11/13/2020 at approximately 1:00 P.M. the director confirmed the laboratory repeatedly failed KOH testing and that the laboratory had not monitored corrective actions to determine corrective actions taken did not prevent recurrence.</p>
<b>D5791</b>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p>

This STANDARD is not met as evidenced by:  
Based on quality assessment documentation, lack of documentation and interview with the director, the laboratory director failed to monitor the Individual Quality Control Plan annually in 2019 for problems found in Human Chorionic Gonadotrophin (hCG) testing to ensure reducing the frequency of hCG Quality Control testing to once per lot number was sufficient to detect problems in testing for hCG testing reviewed from January 2019 to August 11, 2020. The laboratory performed approximately 5 serum hCG tests per month. Findings include: 1. Quality assessment documentation failed to include a record the laboratory director reviewed the established IQCP for hCG testing in 2019. 2. In an interview conducted on 11/13 /2020 at approximately 12:50 P.M. the director confirmed the IQCP for serum hCG tests was not reviewed for quality critical componet presence in 2019.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

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 testing personnel competence evaluations review, lack of documentation, and interview with the laboratory director/technical consultant, the laboratory technical consultant failed to evaluate 1 of 1 testing person annually for competency in 2019. Findings include: 1. Personnel competency records review included one testing person performed testing for more than one year and lacked documentation of competency performance in 2019. 2. In an interivew conducted on 11/13/2020 at proximately 12 :45 P.M. the director/technical consultant confirmed annual competency was not performed for personnel with more than one year of moderate test performance in 2019.