

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  46D2073060	<b>(X3) Date Survey Completed</b>  03/15/2023
<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>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the "CBC, Satellite Medonic M-series Hematology Analyzer" procedure and an interview with the laboratory directory, the laboratory failed to include panic values for Complete Blood Count (CBC) testing. The laboratory performed 25,996 CBC tests annually. Findings include: 1. Review of the procedure manual on March 15th, 2023 at 3:00 PM revealed a lack of panic values for CBC testing. 2. Interview with the laboratory director on March 15th, 2023 at 3:10 PM confirmed the laboratory failed to include panic values in the procedure manual.</p>