

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2047513	(X3) Date Survey Completed 05/03/2023
Name of Provider or Supplier Sterling Urgent Care	Street Address, City, State 939 South State Highway 89 #2, Logan, 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
D5403	<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 review of the Standard Operating Procedures (SOPs) and interview with Testing Personnel #1 (TP #1), the laboratory failed to include panic values for the Nano Entek FRENDA assay for TSH, FT4, PSA and testosterone analytes since patient testing began on 2/26/2021 . The laboratory performs approximately 300 endocrinology tests annually. Findings include: 1. Review of procedure manuals on 5 /3/2023 at approximately 12:15 PM, revealed lack of panic values for the FRENDA assays for TSH, FT 4, PSA and testosterone since patient tsting began on 2/26/2021. 2. Interview with TP #1 on 5/3/2023 at approximately 12:15 PM, confirmed that the</p>

laboratory failed to include panic values for the FRENDA assays for TSH, FT 4, PSA and testosterone.