

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2159388	(X3) Date Survey Completed 05/03/2023
Name of Provider or Supplier Sterling Urgent Care	Street Address, City, State 609 S Highway 91 #A, Richmond, 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. 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</p>

testosterone. 2. Interview with TP #1 on 5/3/2023 at approximately 12:15 PM, confirmed that the laboratory failed to include panic values for the FRENDA assays for TSH, FT 4, PSA and testosterone.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on record review and interview with Testing Personnel #1 (TP #1), the laboratory failed to ensure verification of performance specifications after relocating the Nano Entek FRENDA instrument on 7/6/2022, which tests TSH, FT 4, PSA and testosterone analytes. The laboratory performs approximately 300 endocrinology tests annually. Findings include: 1. Record review on 5/3/2023 at approximately 2:30 PM, revealed the laboratory failed to verify performance specifications after relocating the FRENDA instrument on 7/6/2022. 2. Interview with TP #1 on 5/3/2023 at approximately 2:30 PM, confirmed the laboratory failed to perform verification of performance specification for the FRENDA instrument after being relocated on 7/6/2022.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on record review and interview with Testing Personnel #1 (TP #1) the laboratory failed to list the correct address of the laboratory's location on the test report since relocating the lab on 7/6/2021. The laboratory performs approximately 300 endocrinology tests annually. Findings include: 1. Record review of the test report on 5/3/2023 at approximately 2:55 PM, revealed the old address of 700 South Highway 89, Richmond, UT 84333 on the test report rather than the correct address of 609 South Highway 91, Richmond, UT 84333. 2. Interview with Testing Personnel #1 (TP #1) on 5/3/2023 at approximately 2:55 PM, confirmed the test report listed the incorrect address of 700 South Highway 89, Richmond, UT 84333 on the test report rather than the correct address of 609 South Highway 91, Richmond, UT 84333.