Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2108732	04/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Sterling Urgent Care	630 E 1400 N #150, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory failed to retain quality control assay sheets for each new lot number of control materials reviewed for 4 of 4 tests performed: Complete Blood Count (CBC), Thyroid Stimulating Hormone (TSH), Free Thyroxine (FT4), and Prostate Specific Antigen (PSA) testing. Findings include: 1. The laboratory failed to retain CBC quality control assays for low, normal, and high levels of quality control materials tested from 09/22 /2016 to 04/16/2018. 2. The laboratory failed to document the assay values for FT4, TSH, and PSA tests prior to QC lot number 1411070A (normal) and 1411071A (high) expiration date 12/2017 for patient 01211987 for a TSH test performed on 07/21 /2016. 3. In an interview conducted on 04/16/2018 at approximately 3:30 P. M. staff stated they did not retain the quality control assay informantion for quaity contrls for CBC, TSH, FT4, and PSA testing beyond the lot number in use.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in

	electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on FREND Thyroid Stimulating Hormone (TSH) and Free Thyroxine (FT4) testing records review, temperature records review, manufacturer's instructions review, and interview with staff, the laboratory failed to document they followed manufacturer's instructions to incubate FT4 specimens at 37 degrees C for 2 of 2 specimens reviewed. Findings include: 1. Patient testing records review for TSH testing performed on 11/16/2017 for patient date of birth 01/10/57 and on 03/12/2018 for patient date of birth 01/10/86 included documentation the laboratory reported TSH results on these dates. 2. Temperature record review failed to include documentation the laboratory recorded the heat block and cartridge warming plate temperature was 37 degrees C on 11/16/2017 and 03/12/2018. 3. Manufacturer instructions review included instructions to warm FT4 cartridges at 37 degrees on the warming plate and to incubate 70ul of the specimen in the Gold T-4 Antibody tube in the 37 degree heat block tube for 5 minutes.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory failed to evaluate Free Thyroxine (FT4), Thyroid Stimulating Hormone (TSH), and Prostate Specific Antigen (PSA) quality control over time to monitor accuracy and precision of FT4, TSH, and PSA tests that may be influenced by changes in test system performance and environmental conditions and variance in operator performance from 09/22/2016 when testing began to 04/16/2018. The laboratory performed 5 to 10 TSH and FT4 tests per week and less than one PSA tests per month. Findings include: 1. The laboratory failed to document quality control results were monitored over time for FT4, TSH, and PSA tests. 2. In an interview with staff on 04/16/2018 at approximately 4:15 P.M. laboratory staff confirmed they did not have a process to monitor FT4, TSH and PSA tests over time.
D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive

	maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of reagent test record documentation, package insert review, patient test records review, and interview with testing staff, the laboratory failed to document quality control performance for new lot numbers of FREND test cartridges for TSH and Free T 4 testing from 09/22/2016 to 04/16/2018. The laboratory performed approximately 5 to 10 tests per week (250 per year). Findings include: 1. The laboratory failed to record the dates new lot numbers of TSH and Free T4 test cartridges were placed into use. 2. Package insert review included the fact that each box of cartridges contains 25 (FT4) or 30 (TSH) individual test cartridges (equaling approximately 25 boxes per year.) 3. The laboratory failed to document quality control performance prior to testing patients when new lot numbers of TSH and FT4 cartridges were placed into use. 4. Patient test records review for patient 06201987 tested on 09/27/2018 failed to include documentation quality control was performed prior to 09/27/2016 for the TSH lot number in use. 5. In an interview with testing staff on 04/16/2018 at approximately 4:00 P.M., staff confirmed they did not record the dates new lot numbers of FT4 an TSH cartridges were placed into use and did not document that quality control was performed prior to testing patient samples for new lot numbers or shipments.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on patient test record review and interview with staff, the laboratory failed to maintain an information or record system that included the identity of the personnel who performed complete blood count (CBC), Free Thyroxine (FT4), Thyroid Stimulating Hormone (TSH), and Prostate Specific Antigen (PSA) testing. The laboratory listed nine testing personnel currently trained to perform moderately complex testing. Findings include: 1. The laboratory testing staff initialed patient test reports to identify the person performing the tests. 2. The laboratory did not have a record or information system to identify the person to whom the initials matched. 3. In an interview conducted on 04/16/2018 at approximately 4 :30 P.M., staff confirmed the identification of initials was dependent on existing staffs' memory for whom the initials matched for personnel who no longer performed testing.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

	This STANDARD is not met as evidenced by: Based on patient test report review and interview with staff, the laboratory failed to ensure the laboratory normal range of values for Thyroid Stimulating Hormone (TSH), Free Thyroxine (FT4) and Prostate Specific Antigen tests were made available to the authorized person ordering the tests for 3 of 7 non waived tests performed (TSH, FT4, and PSA). Findings include. 1. The laboratory test report for TSH, FT4 and PSA tests included the test instrument print out scanned into the patient's chart record with the test result and the units of measure. 2. In an interview with staff on 01 /16/2018 at approximately 4:00 P.M., staff stated the laboratory had not distributed the laboratory's normal range for TSH, FT4 and PSA tests performed on the FREND analyzer and confirmed the normal range was not on the report entered into the patient's chart record.