Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	53D2147193	08/21/2018
Name of Provider or Supplier	**Street Address, City, State**	
Sterling Urgent Care Of Wyoming	47 Doc Perkes Rd, Afton, WY	

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
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on new testing verification studies review, lack of documentation, and interview with staff, the laboratory failed to verify the accuracy, precision, and reportable range for 1 of 4 tests performed on the Nano Entek FREND instrument, Free Thyroxine. The laboratory tested one patient over 3 months of testing reviewed from May to August 2018. Findings include: 1. New test verification studies failed to include documentation the laboratory verified Free Thyroxine accuracy, precision, and reportable range prior to testing a patient on 08/20/2018 reporting a result of 1.62. 2. In an interview conducted on 08/21/2018 at approximately 8:00 P.M., staff confirmed the verification documentation for Free Thyroxine was not present.
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 quality control records review, lack of documentation, and confirmation by staff, the laboratory quality control procedures for non-waived routine chemistry and endocrinology testing failed to include a method to monitor over time the accuracy and precision for 4 of 4 tests performed, Free Thyroxine (FT4), Thyroid Stimulating Hormone (TSH), Prostate Specific Antigen (PSA), and Testosterone (Testo). The laboratory performed approximately 1 to 3 tests per month. Findings include: 1. The laboratory Individual Quality Control Plan for FT4, TSH, PSA, and Testo failed to include a method to monitor weekly performance of one level of quality control over time. 2. In an interview with staff on 08/21/2018 at approximately 7:15 P.M., staff confirmed the laboratory had not yet set up a method to monitor quality control for the 4 moderate complexity chemistry tests performed over time to monitor shifts and trends that may affect patient test results.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on new tests verification studies review, lack of documentation, and interview with staff, the director failed to document verification procedures used were adequate to determine accuracy and precision for 1 of 4 new tests - Free Thyroxine (FT4) performed on the Nano Entek FREND instrument and failed to sign and date as approved the verification studies for 3 of 4 tests met the manufacturer's specifications for accuracy, precision, and reportable ranges for Thyroid Stimulating Hormone (TSH), Prostate Specific Antigen (PSA), and Testosterone (Testo). The laboratory tested and reported Free T4 for 1 patient since opening of the laboratory in May of 2018 and tested and reported approximately 8 to 12 results for TSH, PSA, and Testosterone. Findings include: 1. New test verification studies for Free Thyroxine testing failed to include accuracy and precision studies. 2. New test verification studies review failed to include documentation the director approved verification studies for TSH, PSA, and Testo. 3. In an interview conducted on 08/21/2108 at approximately 8:15 p.m., staff confirmed the director had not approved, by signing and dating, the 05/09/2018 study results.