Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0953866	05/22/2018
Name of Provider or Supplier	**Street Address, City, State**	
Thyroid Specialty Laboratory, Inc	1636 Headland Dr, Fenton, MO	

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	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on review of the procedure manual revealed and interview with the technical supervisor on May 22, 2018 at 2:00 PM confirmed, the laboratory failed to have reference intervals(normal values) for urine creatinine, pH, oxidants, specific gravity, and reference intervals(cutoff values) for 60 of 60 analytes for oral fluid specimens for high complexity toxicology testing.
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 review of validations and interview with the technical supervisor on May 22, 2018 the laboratory failed to complete a validation after laboratory moved to a new location on the Olympus AU400e and no laboratory director approval for validation's on AB Sciex Q trap 4500 and AB Sciex Q trap 5500 after laboratory moved. Findings: 1. Laboratory moved in spring 2017. No validation was completed on the Olympus AU400e after instrument was moved. 2. No laboratory director approval for validations on the AB Sciex Q trap 4500 and AB Sciex Q trap 5500 after instruments were moved. 3. Interview with the technical supervisor on May 22, 2018 at 2:00 PM confirmed the laboratory failed to complete a validation after laboratory moved locations on the Olympus AU400e and failed to have laboratory director approval for validation's on the AB Sciex Q trap 4500 and AB Sciex Q trap 5500 after instruments were moved.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of chemistry calibration verification and interview with the technical supervisor, the laboratory failed to perform a calibration verification every six months in 2017 on the Olympus AU400e. Findings: 1. Review of Olympus AU400e chemistry calibration verification for pH, creatinine, specific gravity and oxidants

	showed no calibration every six months in 2017 that included a minimal value, a mid-point value and a maximum value. 2. Interview with the technical supervisor on May 22, 2018 at 2:00 PM confirmed the laboratory failed to perform a calibration verification on the Olympus AU400e.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of instrument comparisons and interview with the technical supervisor on May 22, 2018 at 2:00 PM confirmed the laboratory failed to perform instrument comparisons on the AB Sciex Q Trap 5500 and the AB Sciex Q Trap 4500 in 2017 to date May 22, 2018
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of competency performance documentation revealed and interview with the laboratory director on May 22, 2018 at 2:00 PM confirmed, the director failed to assure 6 of 6 testing personnel maintained competency for high complexity toxicology testing for 2017 and to date May 22, 2018.