Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0953866	12/29/2025
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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of procedure, 2024 and 2025 proficiency testing (PT) results, and interview with the general supervisor (GS) #3, the laboratory failed to evaluate PT results that did not reflect laboratory test performance. Findings: 1. Review of the procedure titled "Proficiency Testing" for ungraded PT results states, "If the method is quantitative, TEN Healthcare's results should be compared with the median and range reported by the PT supplier. Acceptability limits should be established for each analyte at the discretion of the laboratory director. If the method is qualitative, TEN Healthcare's results should be compared to the consensus results of the other participants". 2. Review of College of American Pathologists (CAP) and American Proficiency Institute (API) PT records showed no corrective action documentation was available to show the laboratory investigated ungraded PT results for the following events: CAP C-C 2024 General Chemistry/Therapeutic Drugs CHM-11, CHM-12 , CHM-13 , CHM-14 and CHM-15 API 2024 Microbiology 1st Event RSP-01, RSP-03, UTI-01, UTI-02, UTI-03, UTI-04 and UTI-05 API 2024 Microbiology 2nd Event UTI-06, UTI-07, UTI-08, UTI-09, UTI-10 and VGP-03 API 2024 Microbiology 3rd Event RSP-13, UTI-11, UTI-12, UTI-13, UTI-14 and UTI-15 3. Review of the procedure titled "Proficiency Testing" for educational challenge PT results states, "The PT supplier typically provides an intended response and calculates statistics based on the participants' results. TEN Healthcare's results should be compared to these statistics and evaluated for acceptability by the laboratory director

	or designee. If TEN Healthcare's results align with at least 50% of participants, results may be deemed acceptable. For cases where this is not a participant consensus, results should be evaluated on an individual basis for acceptability. If TEN Healthcare's results align with at least 50% of participants, results may be deemed acceptable. If not, the laboratory director or designee should investigate and try to determine the reason for the lack of consensus and if the results from other participants can be used for accuracy measurement of the sample/assay. This investigation should be documented in a CAPA which is to be housed in the QA department". 4. Review of College of American Pathologists (CAP) and American Proficiency Institute (API) PT records showed no corrective action documentation was available to show the laboratory investigated education challenge PT results for the following events: CAP BCP-A 2025 Blood Cell Identification BCP 06, BCP-07, BCP-08, BCP-09 and BCP-10 5. Interview with the GS #3 on December 29, 2025 at 4:30 PM confirmed the laboratory failed to evaluate PT results that did not reflect the laboratory test performance in 2024 and 2025.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: A. Based on review of laboratory procedures, urine toxicology screening quality control (QC), and interview the technical supervisor (TS) #3, the laboratory failed to follow the written procedure for urine toxicology screening quality control. Findings: 1. Review of laboratory procedure "TOX-30-BS480 Screening" states "Quality Control Acceptance Criteria: The result of the Quality Control samples must fall within 20% of the expected value unless specified by the manufacturer". 2. Review of tetrahydrocannabinol (THC), methylenedioxymethamphetamine (MDMA), and fetanyl urine toxicology screening QC showed QC ranges were greater than 20%. 3. Interview with the technical supervisor (TS) #3 on December 29, 2025 at 3:00 PM confirmed the laboratory failed to follow the written procedure for quality control acceptability. 44735 B. Based on review of laboratory procedures, complete blood count (CBC) patient results, and interview the technical supervisor (TS) #1, the laboratory failed to follow the written procedure for complete blood count (CBC) specimen stability for 105 of 575 patients in November 2025. Findings: 1. Review of laboratory procedure "Blood Stability by Assay" states "Complete Blood Count (CBC) sample stability 1 day." 2. Review of complete blood count (CBC) patient results for November 2025 showed 105 patients tested and resulted when the specimen was greater than 1 day old. 3. Interview with the technical supervisor (TS) #1 on December 29, 2025 at 3:00 PM confirmed the laboratory failed to follow the written procedure for complete blood count (CBC) specimen stability.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based on observation of blood laboratory room temperature supplies, and interview with the technical supervisor (TS) #1, the laboratory failed to ensure laboratory supplies were not used when they had exceeded their expiration date. Findings: 1. Observation of blood laboratory room temperature supplies showed the following still in use: 1 flat of Becton Dickinson Vacutainer Sodium Fluoride 3 mg blood tubes Lot 3016622 exp 5/31/24 1 box of Reli Safety Blood Collection Set Lot 20220211 exp 2 /10/25 1 box of Becton Dickinson Safety Lock Blood Collection Set Lot 2250731 exp 8/31/24 2. Interview with the TS #1 on December 29, 2025 at 11:30 AM confirmed the laboratory failed to ensure laboratory supplies were not used when they had exceeded their expiration date.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on review of the Mindray BS480 toxicology screening analyzer quality control (QC) records for November 2025 to date December 29, 2025, and interview with the technical supervisor (TS) #3, the laboratory failed to perform a positive control each day of patient testing for four of fourteen analytes. Findings: 1. Review of Mindray BS480 toxicology screening analyzer QC records from November 2025 to date December 29, 2025 showed the laboratory failed to have a positive quality control range above the cut-off value for the analytes tetrahydrocannabinol (THC), methylenedioxymethamphetamine (MDMA), Fentanyl and Phencyclidine. 2. Interview with the TS #3 on December 29, 2025 at 2:30 PM confirmed the laboratory failed to perform a positive control each day of patient testing for four analytes.
D5807	TEST REPORT CFR(s): 493.1291(d) (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 review of urine LC/MS procedure manual, review of patient test reports, and interview with the technical supervisor (TS) #3, the laboratory failed to ensure pertinent haloperidol cutoff value matched the cutoff value on the patient reports.. Findings: 1. Review of the "LC-MS/MS Analysis of Urine Pain Panel" stated "Haloperidol cutoff 50 ng/ml". 2. Review of patient report showed "Haloperidol cutoff 100" 3. Interview with the TS #3 on December 29, 2025 at 3:00 PM confirmed the discrepant cutoffs for haloperidol.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) (e)(8) Ensure that reports of test results include pertinent information required for

	interpretation; This STANDARD is not met as evidenced by: Based on review of patient test reports printed on December 29, 2025 for the laboratory developed urine drug confirmation testing and interview with the general supervisor (GS) #3, the laboratory director failed to ensure that test reports include pertinent information required for interpretation. Findings: 1. Review of patient test reports printed on December 29, 2025 for the laboratory developed urine drug confirmation testing showed the laboratory director failed to include a statement on the patient test report stating that the performance characteristics of the urine drug confirmation testing were determined by the laboratory and have not been cleared or approved by the U.S. Food and Drug Administration. 2. Interview with the general supervisor (GS) #3 on December 29, 2025 at 4:00 PM confirmed the laboratory director failed to ensure that test reports include pertinent information required for interpretation.