Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D2135849	10/30/2019
Name of Provider or Supplier	**Street Address, City, State**	
Quantox Lab	4633 World Parkway Circle Ste 103, Saint Louis, 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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on review of patient records and interview, the laboratory failed to retain all patient records for two years (refer to D3031).
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 and interview with the technical consultant (TC), the laboratory failed to include only the reference intervals (cutoff values) in use at the laboratory for one of 11 tests. Findings: 1. Review of the procedure manual revealed two cutoff values, 100 ng/ml and 300 ng/ml, for oxycodone for urine toxicology screening. 2. Interview with the TC on October 29, 2019 at 4:30 PM confirmed the only cutoff value in use at the laboratory for oxycodone is 100 ng/ml.
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 the performance verification procedures for the Olympus AU640e urine toxicology screening and interview with testing personnel (TP) #1, the laboratory failed to verify reference intervals (normal values) for 11 of 11 tests reviewed. Findings: 1. Review of the verification procedures for the Olympus AU640e chemistry analyzer for amphetamine, benzodiazepine, methadone, cannabinoid, opiate, buprenorphine, oxycodone, ethanol, specific gravity, pH, and creatinine showed no verification of normal values. 2. Interview with TP #1 on October 29, 2019 at 11:30 AM confirmed the laboratory failed to ensure the verification procedures for normal values for the Olympus AU640e chemistry analyzer were appropriate for the laboratory's patient population.
D6099	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(9) The laboratory director must ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions. This STANDARD is not met as evidenced by: Based on review of patient #1 email, laboratory "Patient Complaint Log", and interview with the technical consultant (TC), the laboratory director failed to ensure

	consultation was available to clients on matters relating to quality of test results for one of one patients. Findings: 1. Patient #1 contacted the Centers for Medicare & Medicaid Services Kansas City Regional Office (CMS) via email, and stated the following: a. Patient #1 emailed Quantox via a form located on the Quantox website between July 10-18, 2019. b. Patient #1 made two phone calls (and left two voicemails) to the number on Quantox's website between July 10-18, 2019. 2. Patient #1 forwarded to CMS a copy of an email sent to service@quantoxlab.com on July 18, 2019 at 8:36 AM expressing concern regarding their test results. 3. Review of the laboratory's patient call in/complaint log revealed patient #1's emails and phone calls were not logged. 4. In an email received at CMS from Patient #1 on October 29, 2019 at 327 PM, Patient #1 stated they never received a phone call or email in response to their questions about the quality of their test results. 5. Interview with the TC on October 29, 2019 at 4:00 PM confirmed the laboratory director failed to ensure that consultation was available to the laboratory's clients relating to quality test results.