

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D2135849	<b>(X3) Date Survey Completed</b>  02/06/2019
<b>Name of Provider or Supplier</b>  Quantox Lab	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the PolyChem 180 urine toxicology analyzer, review of 80 of 80 patient test reports for Benzodiazepine (BENZ), Methadone (METH), Opiate (OPI), Ampethamine (AMP), Ethanol (ETH), Tetrahydrocannabinol (THC), Buprenorphine (BUP), review of quality control (QC), calibration records, and interview with the technical supervisor, the laboratory failed to retain QC and calibration documentation. Findings: 1. Observation of the PolyChem 180 analyzer for urine toxicology showed the analyzer was "turned on" and opened to the reagent screen. 2. Observation of the laboratory's reagent inventory, located in the refrigerator, revealed that the laboratory had in-date reagents for the PolyChem 180 analyzer. These reagents were marked as having been received in the laboratory in December 2018. 3. Review of 80 test reports showed the laboratory reported BENZ, METH, OPI, AMP, ETH, THC, BUP patient test results during the timeframe of August 9, 2018 through October 8, 2018. 4. No QC and calibration records were available for review. 5. Phone interview with the technical supervisor on February 4, 2018 at 4:00 PM and on February 6, 2018 at 2:50PM confirmed the laboratory failed to retain QC and calibration records.</p>
<b>D5200</b>	<p><b>GENERAL LABORATORY SYSTEMS</b> CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general</p>

laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:  
Based on review of patient reports, correlation studies, and proficiency testing records, the laboratory failed to verify the accuracy of 7 non regulated analytes (refer to D5217).

**D5217**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:  
Based on review of patient reports, proficiency testing (PT) documentation, correlation studies, and interview, the laboratory failed to verify the accuracy of the following non-regulated analytes: Amphetamine (AMP), Benzodiazepine(BENZ), Buprenorphine (BUP), Tetrahydrocannabinol (THC), Methadone (METH), Opiate (OPI), and Ethanol (ETH). Findings: 1. Review of available PT documentation showed the laboratory was not enrolled in any PT program. 2. Review of 80 of 80 patient reports from the PolyChem 180 urine toxicology analyzer showed the laboratory performed patient testing for the following analytes: AMP, BENZ, BUP, THC, METH, OPI, ETH. 3. No documentation was provided for accuracy two times a year for AMP, BENZ, BUP, THC, METH, OPI, ETH. 4. Interview with the technical supervisor on February 4, 2018 at 4:00 PM confirmed the laboratory failed to verify the 7 non-regulated analytes at least twice annually for 2018.

**D5400**

**ANALYTIC SYSTEMS**  
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:  
Based on review of patient and instrument reports, the laboratory failed to perform calibration on the PolyChem toxicology analyzer (refer to D5439); failed to perform two levels of quality control(QC) each day of patient testing (refer to D5447); failed to maintain a system to identify the personnel performing the Celiac antibody test (refer to D5787).

**D5435**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on the lack of available documentation and interview with the general supervisor #2, the laboratory failed to define a function check protocol to verify the accuracy of the timer and speed mechanisms on the laboratory centrifuge 5702 Eppendorf. Findings: 1. No documentation was available to show the laboratory defined a function check protocol to verify the accuracy of the timer and speed mechanisms on the 5702 Eppendorf centrifuge. 2. Interview with the general supervisor #2 on February 4, 2018 at 3:30 PM confirmed, the laboratory failed to have a protocol to verify the accuracy of time and speed on the laboratory centrifuge 5702 Eppendorf.

**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 observation, review of patient records, review of calibration records for the PolyChem 180 urine toxicology analyzer, and interview with the technical supervisor, the laboratory failed to perform calibration verification procedures. Findings: 1. Observation of the PolyChem 180 analyzer for urine toxicology showed the analyzer was "turned on" with a computer linked to it on the reagent screen. 2. Review of 80 test reports showed the laboratory reported out BENZ, METH, OPI, AMP, ETH,

THC, BUP test results during the timeframe of August 9, 2018 through October 8, 2018. 3. Review of calibration records revealed the laboratory failed to perform calibration for the PolyChem 180 urine toxicology analyzer for the analytes: BENZ, METH, OPI, AMP, ETH, THC, BUP. 4. Interview with the technical supervisor on February 4, 2019 at 4:00 PM confirmed the laboratory failed to perform calibration procedures on the PolyChem 180 toxicology analyzer.

**D5447**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on observation of the PolyChem 180 toxicology analyzer, review of patient reports, quality control (QC) documentation, and interview, the laboratory failed to perform and document at least 2 levels of external controls each day of patient testing for urine toxicology testing. Findings: 1. Observation of the PolyChem 180 analyzer for urine toxicology showed the analyzer was "turned on" with a computer opened to the reagent screen. 2. Review of 80 test reports showed the laboratory reported out Benzodiazepine (BENZ), Methadone (METH), Opiate (OPI), Ampethamine (AMP), Ethanol (ETH), Tetrahydrocannabinol (THC), Buprenorphine (BUP) test results during the timeframe of August 9, 2018 through October 8, 2018. 3. No QC documentation was available for review. 4. Phone interview with the technical supervisor on February 4, 2018 at 4:00 PM confirmed "JC setup and performed testing on the PolyChem. I do not know how to access the information in the analyzer." Phone interview with the technical supervisor on February 6, 2018 at 2:50 PM, confirmed the laboratory failed to perform 2 levels of QC each day of patient testing.

**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 review of patient records from December 12, 2018 through January 31, 2019 and interview with the technical supervisor, the laboratory did not maintain a record system that included the identity of four of four testing personnel performing celiac panel patient testing on the SQID instrument. Findings: 1. Review of patient records from the SQID instrumentation and test reports revealed the laboratory did not have a system that identified the testing personnel performing tests on the SQID instruments. 2. Interview with the technical supervisor on February 4, 2019 at 4:00

	<p>PM confirmed the laboratory did not have a system to show the identity of testing personnel performing celiac panels patient testing.</p>
<p><b>D5805</b></p>	<p><b>TEST REPORT</b> CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on review of three of three patient reports and interview with the technical supervisor, the laboratory failed to include the name and address where the test was performed. Findings: 1. Review of three patient test reports showed "Patient sample was processed on...". 2. Interview with the technical supervisor on February 4, 2019 at 4:00 PM confirmed the patient test report failed to include the name and address of the location where the test was performed.</p>
<p><b>D6076</b></p>	<p><b>LABORATORY DIRECTOR</b> CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of instrument documentation, the laboratory director failed to ensure the verification procedures were adequate on the PolyChem 180 (refer to D6086); failed to ensure the quality control programs were established and maintained for the PolyChem 180 (refer to D6093); failed to ensure prior to patient testing that all personnel have the required education and experience (refer to D6102); failed to ensure an approved procedure manual for the PolyChem 180 toxicology analyzer was available for testing personnel (refer to D6106).</p>
<p><b>D6086</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of verification procedures for the PolyChem 180 analyzer for urine toxicology, and interview with the general supervisor #2 and technical supervisor, the laboratory director failed to ensure verification procedures were adequate to determine</p>

accuracy, precision, reportable range, patient normal values, specificity and sensitivity. Findings: 1. Based on the lack of verification procedures for the PolyChem 180 chemistry analyzer for Benzodiazepine (BENZ), Methadone (METH), Opiate (OPI), Ampethamine (AMP), Ethanol (ETH), Tetrahydrocannabinol (THC), and Buprenorphine (BUP), showed the laboratory failed to perform accuracy, precision, reportable range, normal values, specificity and sensitivity prior to testing patient samples. 2. Interview with the general supervisor #2 and technical supervisor on February 4, 2019 at 4:30 PM confirmed the laboratory director failed to ensure adequate verification procedures for the PolyChem 180 analyzer.

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:  
Based on observation of the PolyChem 180 urine toxicology analyzer, review of 80 of 80 patient test reports for Benzodiazepine (BENZ), Methadone (METH), Opiate (OPI), Ampethamine (AMP), Ethanol (ETH), Tetrahydrocannabinol (THC), Buprenorphine (BUP), lack of quality control (QC) records, and interview with the technical supervisor, the laboratory director failed to ensure QC programs were established and maintained. Findings: 1. Observation of the PolyChem 180 analyzer for urine toxicology showed the analyzer was "turned on" and opened to the reagent screen. 2. Review of 80 test reports showed the laboratory reported out BENZ, METH, OPI, AMP, ETH, THC, BUP test results during the timeframe of August 9, 2018 through October 8, 2018. 3. No QC records were available for review. 4. Phone interview with the technical supervisor on February 4, 2018 at 4:00 PM and on February 6, 2018 at 2:50PM confirmed the laboratory failed to establish and maintain a QC program to assure quality of laboratory services.

**D6102**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:  
Based on review of personnel records, patient test records for December 2018 and January 2019 and interview with general supervisor # 2, the laboratory director failed to ensure four of seven testing personnel received appropriate training to perform high complexity testing on the SQID Elite instrument before reporting patient results. Findings: 1. The laboratory did not have documentation to show four testing personnel received appropriate training to perform celiac panel testing on the SQID Elite instrument. 2. Patient records from December 12, 2018 through January 31, 2019 showed four testing personnel tested patient specimens. The four testing personnel tested a combined 63 patient celiac panels with four analytes per panel ( tTG IgA, tTG

	<p>IgG, DGP IgA and DGP IgG). 3. Interview with general supervisor #2 on February 4, 2019 at 4:00 PM confirmed no documentation was available to show the testing personnel received training before reporting patient results.</p>
<p><b>D6106</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on review of procedure manuals and interview with the technical supervisor, the laboratory director failed to approve the PolyChem 180 (drug screen) procedure manual. Findings: 1. Review of the PolyChem 180 procedure manual revealed approval on January 17, 2017 by an individual not serving as laboratory director and never listed on the CMS Form-209. The laboratory did not have documentation to show the original and current laboratory director approved the manual. 2. The technical supervisor said the instrument was in use for patient testing from July 2, 2018 though September 4, 2018. Interview with the technical supervisor on February 4, 2019 at 4:00 PM confirmed the laboratory director did not approve the PolyChem 180 procedure manual prior to testing patients.</p>
<p><b>D6168</b></p>	<p><b>TESTING PERSONNEL</b> CFR(s): 493.1487</p> <p>The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.</p> <p>This CONDITION is not met as evidenced by: Review of personnel records revealed and interview with the technical supervisor confirmed, the laboratory did not have academic credentials required to qualify five of seven testing personnel performing high complexity testing. (Refer to # 6171)</p>
<p><b>D6171</b></p>	<p><b>TESTING PERSONNEL QUALIFICATIONS</b> CFR(s): 493.1489(b)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory</p>

training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview with the technical supervisor, the laboratory failed to provide academic credentials to qualify five of seven testing personnel performing high complexity testing. Findings: 1. The laboratory could not provide foreign equivalency credentials to show testing personnel #2 was qualified to perform high complexity testing in the United States. 2. The laboratory could not provide academic credentials to show testing personnel #4, #5, #6 and #7 were qualified to perform high complexity testing. 3. Interview with the technical supervisor on February 4, 2019 at 4:00 PM confirmed the laboratory did not have academic credentials required to qualify five testing personnel.