

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D2135849	(X3) Date Survey Completed 02/21/2018
Name of Provider or Supplier Quantox Lab	Street Address, City, State 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
D5423	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's manual, review of the verification of performance specifications, and interview with the laboratory director and technical supervisor, the laboratory failed to provide documentation of accuracy, precision, analytical sensitivity and reportable range for 15 of 58 analytes and failed to provide documentation of analytical specificity and reference intervals for 58 of 58 analytes for a modified test system, Shimadzu LCMS 8040 for toxicology testing labeled "For research use only. Not for use in diagnostic procedures." 1. Review of the Shimadzu LCMS 8040 manual for toxicology testing revealed "For research use only. Not for use in diagnostic procedures." 2. Review of the laboratory's validation reports for performance specifications of the Shimadzu LCMS 8040 toxicology instrumentation revealed the laboratory failed to verify accuracy, precision, analytical sensitivity, reportable range that are appropriate for the laboratory's patient population for the following analytes: Clomipramine, N-Desmethyloclopramine, Nortriptyline, MDEA, Ritalinic acid, Mitragynine, Fluoxetine HCL, Norfluoxetine, Norhydrocodone,</p>

Naloxone, Noroxycodone, Pregabalin, Zaleplon, MDPV, a-PVP. 3. Review of the laboratory's validation report for performance specifications of the Shimadzu LCMS 8040 toxicology analyzer revealed the laboratory failed to verify analytical specificity to include interfering substances and reference intervals(normal values) for the following analytes: Mitragynine, Citalopram, N-Desmethylecitalopram, Fluoxetine HCL, Norfluoxetine, Amphetamine, Methamphetamine, Alprazolam, a-OH-Alprazolam, 7-Aminoclonazepam, Nordiazepam, Oxazepam, Lorazepam, Temazepam, Codeine, Hydrocodone, Morphine, Hydromorphone, Norhydrocodone, Amitriptyline, Clomipramine, N-Desmethylclomipramine, Nortriptyline, THC-COOH, UR-144 5-pentanoic acid, Benzoylcegonine, Fentanyl, Norfentanyl, Gabapentin, 6-MAM, Methadone, EDDP, MDMA, MDA MDEA, Ritalinic Acid, Buprenorphine, Pentazocine, Meperidine, Normeperidine, Norbuprenorphine, Naloxone, Oxycodone, Noroxycodone, Oxymorphone, PCP, Pregabalin, Propoxyphene, Norpropoxyphene, Zaleplon, Zolpidem-COOH, Carisoprodol, Meprobamate, MDPV, a-PVP, Tapentadol, Tramadol, O-Des-methyltramadol. 4. Interview with the laboratory director and the technical supervisor on February 21, 2018 at 11:00 AM confirmed the laboratory failed to provide the performance specifications for accuracy, precision, analytical specificity, analytical sensitivity, reportable range and reference intervals before using a modified system approved "for research use only."