

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 22D2059395	<b>(X3) Date Survey Completed</b> 03/03/2021
<b>Name of Provider or Supplier</b> Lawrence Medical Center	<b>Street Address, City, State</b> 320 Essex St, Lawrence, MA	
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>D0000</b>	A CLIA recertification survey was conducted for the Lawrence Medical Center laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
<b>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing review and interview, the laboratory failed to properly document the handling of proficiency testing samples as evidenced by the following: a) A review of proficiency testing records for calendar years 2019 and 2020 (3 testing events) revealed the fact that the program report forms and the attestation statements provided by the proficiency testing program were not completed for one (1) of the three (3) College of American Pathologists (CAP) proficiency testing events reviewed (UDS6 A 2020). The technical supervisor interviewed on 3/3/21 at 11:20 AM confirmed that the program report forms and the attestation statements for the above event were not completed by the laboratory director and the laboratory technologist. .</p>
<b>D5423</b>	<b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b>

CFR(s): 493.1253(b)(2)

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.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to provide documentation to verify that adequate validation studies to validate all aspects of test performance were performed as evidenced by the following: a) Sciex liquid chromatography-mass spectrometry (LC-MS) : In April of 2019 the laboratory put into place an LC/MS for the qualitative and quantitative testing of thirty two (32) high complexity toxicology analytes (7-aminoclonazapan, 6-acetylmorphine, benzoylecgonine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP), hydrocodone, lorazepam, 3,4-methylenedioxyamphetamine (MDA), 3,4-Methylenedioxy-N-ethylamphetamine (MDEA), buprenorphine, norfentanyl, nordiazepam, oxazepam, oxymorphone, oxycodone, tapentadol, gabapentin, tetrahydrocannabinol (THC) amphetamine, alpha-hydroxyalprazolam, codeine, fentanyl, hydromorphone, morphine, 3,4-Methylenedioxymethamphetamine (MDMA), methadone, methamphetamine, tramadol, norhydrocodone, temazepam, noroxycodone, norbuprenorphine, pregabalin, and ritalinic acid ). A review of the validation summary for the thirty two (32) analytes revealed the following issues: a) Precision: There was no indication in the validation summary that both intra- and inter-assay precision was performed. There was only one precision statistic given for each of the analytes. b) Accuracy: There was no indication in the validation summary that accuracy studies for the thirty two (32) analytes had been performed. An interview on 3/3/21 at 10 50 AM with the technical supervisor who had taken over from the previous technical supervisor in March of 2020 could not address the issues above as he was not involved in the initial validation of the LC/MS and the testing being implemented The laboratory performs 224,000 toxicology tests annually. .