

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2059395	(X3) Date Survey Completed 12/22/2022
Name of Provider or Supplier Lawrence Medical Center	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	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. Refer to Conditions of Participation for Clinical Laboratories 42 CFR Part 493.
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on procedure, record review and interview, the laboratory failed to define all statistical parameters for quality control utilized in the performance of toxicology testing as evidenced by the following: a) The laboratory runs three levels of quality control at the beginning and end of urine toxicology screens performed by Liquid Chromatography/Mass Spectroscopy (LC/MS) . The criteria for quality control acceptability in the procedure manual was stated as plus or minus twenty five percent of the mean. The procedure also included the mean of each individual quality control level for the tests performed. b) A review of quality control for calendar year 2022</p>

was performed. The review revealed the fact that there were no calculated ranges (upper and lower limits) available to compare to the quality control results obtained for each of the drug screen runs performed. c) The laboratory director confirmed in an interview on 12/22/22 at 10:45 AM that the calculated upper and lower limits were not available for each of the toxicology analytes performed. d) The laboratory performs forty seven (47) drugs of abuse and metabolites with a total annual volume of approximately 159,198.