

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2059395	(X3) Date Survey Completed 10/24/2018
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.
D5821	<p>TEST REPORT CFR(s): 493.1291(k)</p> <p>When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain a copy of the corrected report when errors in the reported patient test results were detected as evidenced by the following: a) In March and October of 2018 the laboratory had to correct results that were erroneously reported due to the wrong cut-off values for fentanyl and ethanol being entered incorrectly into the laboratory information system (LIS) by the technical representative for the toxicology analyzer. This affected 61 fentanyl test results reported between 1/19/18 and 10/12/18 as well as 190 ethanol test results reported between 1/19/18 and 3/20/18. b) A review of two corrected reports from 1/8/18 and 8/20/18 revealed that the reports failed to indicate that they were in fact corrected results. c) Interview with the laboratory technologist on 10/24/18 at 11:45 am revealed that the final reports were archived in the laboratory's LIS after one month. After that time they could not be altered. d) Based on this evidence there was no assurance the medical care providers were provided with most updated test results to ensure proper diagnosis and care. The laboratory performs approximately 76,932 toxicology tests annually.</p>

D6040

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(2)

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:

Based on record review and interview, the technical consultant failed to fulfill the responsibility for verification of the laboratory's test performance characteristics as evidenced by the following: a) The technical consultant failed to ensure that validation studies were reviewed and approved prior to implementing new test methodologies. b) A review of two (2) test validations (fentanyl and ethanol) implemented in January of 2018 revealed that the technical consultant failed to review and approve them for patient testing. Review of the validation study documentation revealed that the laboratory director, who does not qualify as technical consultant, had documented a review of the validation studies. c) The laboratory technologist confirmed in an interview on 10/24/18 at 10:34 AM that the validation studies for the two toxicology tests had been reviewed and approved by the laboratory director, not the technical consultant. .

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on record review and interview, the technical consultant failed to evaluate the competency of the staff through review of quality control records as evidenced by the following: a) A review of toxicology quality control records for calendar years 2017 and 2018 revealed that the technical consultant had not documented a review of quality control results for testing performed under hematology. b) The laboratory technologist confirmed in an interview on 10/24/18 at 10:34 AM that cumulative quality control results were being reviewed by the laboratory director who does not qualify as a technical consultant.