

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2126807	(X3) Date Survey Completed 06/12/2019
Name of Provider or Supplier Lawrence Med Lab Llc	Street Address, City, State 395 West Cummings Park, Woburn, 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 Med Lab LLC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to follow manufacturer's instructions as evidenced by the following: The surveyor reviewed seventeen patient final test reports. Five of the seventeen reports reported semi-quantitative results for analytes that screened positive. The manufacturer, in their instructions for calibration for semi-quantitative results, indicates that a standard curve must be obtained by running all the calibrators for each test system. The laboratory's Standard Operating Procedure named "Calibration Verifications" states that the laboratory calibrated following manufacturer's instructions for qualitative results using one or two calibrators per test system. The general supervisor confirmed in an interview on 6/12 /19 at 2:10 P.M. that the laboratory did not follow manufacturer's instructions to report semi-quantitative results. The laboratory performs 189,000 toxicology tests annually.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the</p>

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 record review and interview the laboratory failed to perform calibration verifications as appropriate as evidenced by the following: The surveyor reviewed quality control records for calendar years 2018 and 2019. The review revealed that calibration verifications of at least 3 points were not performed once every six months for all end point methods performed on the Beckman Coulter AU400e chemistry analyzer. The laboratory's Standard Operating Procedure named "Calibration Verifications" states that calibration verification must be performed once every six months. The six month calibration verifications were performed on 12/12/17 and 6/11/19. There was no six month calibration verification performed in calendar year 2018. The director of operations and general supervisor confirmed through interview on 6/12/19 at 11:55 A.M. that six month calibration verification was not performed in calendar year 2018. The laboratory performs 189,000 toxicology tests annually.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on record review and interview, the technical supervisor failed to evaluate the competency of testing personnel and assuring that the staff maintains their competency to perform the test procedures promptly, accurately, and proficiently as evidenced by the following: The surveyor reviewed personnel records of the general supervisor/testing person. The review revealed that no annual competency assessments were performed for the one testing personnel performing high complexity testing for calendar year 2018. The laboratory's Standard Operating Procedure named

"Training and Competency/Competency Assessment" states that all employees will be tested annually. The competency assessments were performed on 4/3/17, 10/2/17, and 5/31/19. The director of operations confirmed through interview on 6/12/19 at 10:25 A.M. that the annually competency assessment was not conducted in 2018 to ensure procedures are performed promptly, accurately, and proficiently.