Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0946653	09/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ludlow Medical Center	200 Center Street, Ludlow, 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 Ludlow Medical Center laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the 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 every six months or, as appropriate, as evidenced by the following: a) A

	review of quality control records for calendar years 2018, and 2019 was performed. b) The review revealed that calibration verifications of at least 3 points was not performed once every six months for one (1) of one (1) chemistry analytes requiring calibration verification on the Tosoh G8 chemistry analyzer. Six month calibration verifications for Hemoglobin A1C were not performed every six months (initially performed 6/2018 and then on 7/17/19. c) The technical consultant interviewed on 9 /13/19 at 9:20 AM, confirmed that calibration verifications on Hemoglobin A1C had not been performed every six months. d) The laboratory performs approximately 4,263 Hemoglobin A1C tests annually. .
D6011	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(2) and provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to provide a safe environment environment in which employees are protected from chemical and biological hazards as evidenced by the following: a) A review of maintenance records for calendar year 2017 revealed that there were no records to confirm that the eyewash was checked, at least weekly, for proper operation. b) The technical consultant confirmed in an interview on 9/13/19 at 11:15 AM that the eyewash was being checked weekly but could not confirm that they were being documented.