Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2105927	11/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Baystate Reference Laboratories	26 Queen St, Worcester, 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 Baystate Reference Laboratories pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory failed to follow a maintenance protocol for all laboratory microscopes as evidenced by the following: a) The laboratory utilizes five (5) microscopes in the various specialty areas of the laboratory. b) Interview with one laboratory technologist revealed that the microscopes were serviced on an annual basis c) Review of mainteance stickers on each of the microscopes on 11/20/19 at 12:31 PM revealed that one (1) of the five (5) microscopes utilized in hematology for white blood cell differential examinations had not been serviced since July of 2017. d) The laboratory technologist confirmed in an interview on 11/20/19 at 12:35 PM that the microscope in use had not been serviced along with the other four. e) The laboratory performs approximately 14,101 white blood cell differential annually. .
D5449	CONTROL PROCEDURES

	CFR(s): 493.1256(d)(3)(ii)(g) 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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform positive and negative controls each day qualitative serum pregnancy was performed as evidenced by the following: a) A review of serum and urine qualitative pregnancy testing for calendar year 2019 revealed that when serum pregnancy testing was performed positive and negative controls were not being performed concurrently with the patient serum samples Review of quality control revealed that external controls were run only on the following dates during 2019: 1/17/19, 1/30/19, 2/13/19, 2/21/19, 3/6/19, 3/20 /19, 4/4/19, 4/23/19, 5/1/19, 5/14/19, 5/28/19, 6/5/19, 6/18/19, 6/27/19, 7/8/19, 7/29 /19, 8/5/19, 8/14/19, 8/27/19, 9/5/19, 9/12/19, 10/2/19, 10/15/19, and 10/22/19. c) The general supervisor interviewed on 11/20/19 at 11:20 AM confirmed that external control testing was done only when a new box or shipment was opened not each day when patient serum pregnancy testing was performed. d) The laboratory performs approximately 154 serum pregnancy tests annually.