Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0265755	11/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Medical Associates Of Albany Pc	101 Oakland Crossing Dr, Leesburg, GA	

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 Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on November 12, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on the review of the Implementation documents for the ABX Pentra XL80 /XLR (ABX) hematology analyzer, and staff interview the Laboratory Director (LD) failed to approve the Implementation documents, before testing was initiated. Findings: 1. Review of the Implementation documents for the ABX hematology analyzer, showed that the LD had not approved and signed the documents before patient testing had started. 2. Interview with staff #2 (CMS 209 form), on November 12, 2019, at approximately 12pm in the lab office, confirmed that the LD had not approved the and signed the implementation documents for the ABX, Hematology analyzer.