Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2117115	06/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Kbmo Diagnostics	1a Business Way, Hopedale, 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 My Allergy Life dba All Lab Solutions laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on procedure review and interview the laboratory failed to have a procedure manual which included the following: a) A review of the laboratory procedure manual revealed that there was no specific policy and procedure outlining the criteria for reporting critical or panic values and the procedure for reporting them to the

	authorized individual ordering the test. b) The technical consultant interviewed on 6/13 /18 at 11:04 AM. confirmed that a critical values reporting policy was not available in the laboratory procedure manual. .
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions 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 interview, the laboratory director failed to ensure that the physical plant and environmental conditions provided a safe environment in which employees were protected from physical, chemical, and biological hazards as evidenced by the following: Emergency Eyewash Station: On the day of the survey the maintenance records of the emergency eyewash were requested. The technical consultant interviewed on 6/13/18 at 11:40 AM confirmed that the emergency eyewash was not being routinely checked and maintained on a weekly basis.