Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2101249	08/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
All Family Medicine Pc	365 Broadway, Suite 1, Amityville, NY	

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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on the surveyor's review of American Proficiency Institute (API) Proficiency Testing (PT) reports and an interview with the technical consultant/testing person, the laboratory failed to evaluate, perform and document remedial action for the PT scores of less than 100% for the following analytes: 2018 second event: UIBC = 60% 2018 first event: Total Calcium = 80% 2017 first event: Vit D = 0%
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a lack of policies and procedures and confirmed in an interview with the technical consultant/testing person at the time of this survey, the laboratory failed to establish and follow a written Quality Assessment (QA) policy and procedure for an ongoing mechanism to monitor, assess, and when indicated correct problems that may occur in the laboratory testing. PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEY CONDUCTED ON JANUARY 31, 2017.

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 a surveyor's review of the laboratory's calibration verification records and an interview with the technical consultant/testing person, the laboratory failed to perform calibration verification at least once every six months for all chemistry analytes on the AMS Liasys 450 analyzer. FINDINGS: 1. The calibrators for the analytes, tested on the AMS Liasys 450 analyzer have fewer than three points, therefore, the laboratory is required to perform calibration verification every six months. 2. At approximately 11: 00 AM on August 7, 2018, the technical consultant/testing person confirmed that the documentation of the calibration verification available for review was for calibration verification performed on 3/22/17 and 10/14/17. 3. The AMS Liasys 450 analyzer was out of calibration from 4/15/18 through the survey date. 4. Approximately 500 patient specimens were tested and reported for chemistry analytes when the AMS Liasys 450 analyzer was out of calibration verification.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor's findings and confirmed in an interview with the office manager, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the laboratory: 1. Maintained the plan of correction from the surveys conducted on 1/31/2017; 2. Laboratory's QA program was maintained, refer to D6021. PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEY CONDUCTED ON JANUARY 31, 2017.

D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on lack of Quality Assessment (QA) procedure and documentation and an interview with the technical consultant/testing person, the laboratory director failed to to establish a written Quality Assessment program for general laboratory systems. Refer to D5211, D5291, D5439 PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEY CONDUCTED ON JANUARY 31, 2017.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on a surveyor review of personnel records and confirmed in an interview with the technical consultant/testing person, the laboratory director failed to ensure that the one new testing person performing moderate complexity testing met the minimum educational requirements of a high school diploma and/or had foreign education diploma evaluated prior to performing patient testing. Refer to D6065
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a surveyor's review of personnel records and confirmed in an interview with the technical consultant/testing person at the time of the survey, the laboratory director failed to ensure that the one new testing person performing moderate

	complexity testing met the minimum educational requirements of a high school diploma and/or had foreign education diploma evaluated prior to performing patient testing.