Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2101249	06/10/2024
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
D0000	The plan of correction, found All Family Medicine, PC Physician Office Laboratory (POL) in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare & Medicaid Services (CMS) PT Certification and Survey Provider Enhanced Reporting system (CASPER 0096D and 0155D) and American Proficiency Institute (API) Proficiency Testing (PT) summary reports, as well as interview with the Testing Person (TP), the laboratory failed to retain copies of the signed attestation and PT result forms for the API 2023 second event. FINDINGS: 1. There was no documentation of summary report LD review and date of review for the API 2023 Chemistry Miscellaneous second event. 2. The TP confirmed the findings on June 10, 2024, at 12:00 P.M. 3. It was noted that the laboratory scored 100% for the API 2023 Chemistry Miscellaneous second event Sex Hormone Binding Globulin analyte.
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 review of CMS PT CASPER 0096D, 0155D, and API PT summary reports from 2023 as well as interview with the TP, the laboratory failed to document evidence of review and evaluation of the API 2023 Chemistry Miscellaneous second event. Refer to D2015. PLEASE NOTE: THIS IS A RECTIED DEFICIENCY FROM THE SURVEY CONDUCTED ON AUGUST 7, 2018.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of CMS PT CASPER 0096D, 0155D, and API PT summary reports from 2022 as well as interview with the Laboratory Supervisor (LS), the laboratory failed to document review and perform corrective action for API 2022 Chemistry Core Second Event unsatisfactory scores. FINDINGS: 1. A review of the API 2022 Chemistry Core Second Event, Endocrinology subspecialty, DHEA-S analyte revealed unsatisfactory score of 60%. 2. There was no documentation of review and corrective action performed for API 2022 Chemistry Core Second Event, Endocrinology subspecialty, DHEA-S analyte. 3. The LS confirmed the findings on June 10, 2024, at approximately 12:00 P.M.
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 review of current, approved Quality Assessment (QA) policy, lack of QA documentation, and interview with the LS, the laboratory failed to establish frequency of laboratory QA review performance. FINDINGS: 1. There was no documentation of laboratory QA review performance from calendar year 2022 through the date of survey. 2. The QA policy did not include instructions for frequency of laboratory QA review performance. 3. The LS confirmed the findings on June 10, 2024, at approximately 12:00 P.M. PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEYS CONDUCTED ON AUGUST 7, 2018, AND JANUARY 31, 2017.
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 lack of thermometer calibration procedures and records, and interview with the TP, the laboratory failed to retain approved instructions for the calibration of thermometers. FINDINGS: 1. There was no documentation of Acurite humidity, Elitech freezer, and Fisherbrand refrigerator thermometer calibration certificates as well as manufacturer's instructions for calibration of thermometers. 2. The current, approved standard operating procedures did not include written instructions for performing calibrations of thermometers. 3. The TP confirmed the findings on June 10, 2024, at approximately 12:30 P.M.
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 review of current, approved QA policy, lack of QA documentation, lack of API PT summary report documentation and corrective action, as well as interview with the TP, the laboratory director (LD) failed to maintain policies and procedures for monitoring all phases of testing to assure the quality of laboratory services. Refer to D2015, D5211, D5221, and D5291. PLEASE NOTE: THIS IS A RECITED DEFICINCY FROM THE SURVEYS CONDUCTED ON AUGUST 7, 2018, AND 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 review of current, approved QA policy, lack of QA documentation, and interview with the LS, the LD failed to establish frequency of laboratory QA review performance to assure quality of laboratory services provided. Refer to D5291 and D6000. PLEASE NOTE: THIS IS A RECITED DEFICINCY FROM THE SURVEYS CONDUCTED ON AUGUST 7, 2018, AND JANUARY 31, 2017.