Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2068454	01/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Internal Medicine, Pc	935 Northern Boulevard, Suite 105, Great Neck, 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
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 the 2021 and 2022 American Proficiency Institute (API) PT records, virology and bacteriology test result documents and an interview with the technical consultant, the laboratory failed to retain copies of the sign attestation forms by the laboratory director and the testing personnel. Finding: 1. The laboratory director and the testing personnel failed to sign and date the API PT attestation forms for all third event of 2021 and third event of 2022 2. The technical consultant confirmed on an interview on 1/19/2023 about 11:00am.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a

	laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on the review of PT records from the American Proficiency Institute (API) PT program and an interview with the technical consultant, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the specialty virology and bacteriology. The following scores were assigned: Bacteriology 0% 1st and 2nd event of 2022. Virology 0% 1st and 2nd event of 2022.
D2028	BACTERIOLOGY CFR(s): 493.823(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on the review of PT desk review of the CMS PT data reports and PT records from the API PT program, the laboratory failed to participate successfully in proficiency testing for the Bacteriology. The following scores were assigned: 2022 first event 0% 2022 second event 0% This is considered unsuccessful PT performance.
D2064	VIROLOGY CFR(s): 493.831(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on the review of PT desk review of the CMS PT data reports and PT records from the API PT program, the laboratory failed to participate successfully in proficiency testing for the virology. The following scores were assigned: 2022 first event 0% 2022 second event 0% This is considered unsuccessful PT performance.
D3011	FACILITIES CFR(s): 493.1101(d)

	Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation of foods and utensils in the laboratory cabinet the laboratory and food refrigerator in the laboratory, the laboratory failed to follow the laboratory's safety and universal procedures. Finding: 1. The laboratory's safety and universal procedures states, "that no food, beverages, smoking is permitted in the laboratory." 2. The surveyor observed foods and utensils in laboratory cabinets. 3. The laboratory had food refrigerator with multiple food inside under the analyzer. 4. Confirmed on an interview with technical consultant on 1/19/2023 about 11:15am.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's training and competency evaluation policy, the laboratory failed to perform annual competency for technical consultant on calendar year 2021. Findings: 1. 2021 annual competency of technical consultant documentation not available for review. 2. Confirmed on an interview with technical consultant on 1/19/2023 about 10:30am.
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 the review of the laboratory's Quality Assessment (QA) polices/procedures, 2020 through survey date QA records and confirmed in an interview with the technical consultant, the laboratory failed to follow the laboratory's written QA policy to identify and correct the issues below. Findings: 1. Failed to perform proficiency testing (PT) materials within time frame for 2020 third event, 2021 first and second event, 2022 first and second event. 2. Failed to report PT results for 2020 third event, 2021 first and second event, 2022 first and second event. 3. Failed to monitor and document freezer, refrigerator, and lab room temperature, and humidity between 10/13 /2021-13/31/2021. 4. Failed to identify and correct freezer temperature out of range 5 /17/2021-10/12/2021. 5. Failed to perform annual QA review 2021. 6. Failed to perform annual competency 2021 of technical consultant 7. Failed to print laboratory name and demographics on laboratory report. 8. Food in laboratory cabinet, food refrigerator under the analyzer in laboratory. 9. No second identifier in lab report 10. The centrifuge preventative maintenance not performed in calendar year 2022.

D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on the review of patient test report, under guidelines 493.1242(a)(3), the laboratory failed to report proper two identification. Confirmed on an interview with technical consultant. Finding: 1. The laboratory patient test report included only the patient's full name without a second unique identifier. 2. Confirmed on an interview with technical consultant on 1/19/2023 about 11:45am.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on the review of the laboratory's temperature records and confirmed in an interview with the laboratory technical consultant, the laboratory failed to document the refrigerator and freezer temperatures, humidity as required by the laboratory's log for the proper storage of Quality Control (QC) and reagent materials. Finding: 1. Freezer temperature out of range 5/17/2021-10/12/2021. 2. Temperature log of freezer, refrigerator, lab room temperature and humidity not available between 10/13 /2021-12/31/2021. 3. Confirmed on an interview with technical consultant on 1/19 /2023 about 10:30am.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) 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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by:

	Based on observation of the Quest reference centrifuge located in the laboratory used to spin sample tubes and the labeled titled, "Centrifuge Performance Test" on the centrifuge, the laboratory failed to maintain the annual maintenance for the Quest reference centrifuge for calendar year 2022. Confirmed on an interview with technical consultant on 1/19/2023 about 11am.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on the review of patient test report, the laboratory failed to take corrective action to correlate patient information between specimen and report with two identifiers. Confirmed on an interview with technical consultant about 12:00pm.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the review of freezer temperature log, the laboratory failed to identify and perform corrective action of freezer temperature out of range between 5/17/2021 through 10/12/2021. Confirmed on an interview with technical consultant on 1/19/2023 about 11am.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by:

	Based on random review of the BioFire analyzers printed patient test reports, Electronic Medical Record (EMR) patient reports, and an interview with the laboratory technical consultant, the patient reports reviewed failed to include the following Findings: 1. Two identifiers, patient's name, identification number and or accession number. 2. Name and address of testing location. 3. Confirmed on an interview with technical consultant on 1/19/2023 about 11:30am.
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 the surveyor's findings and an interview with the practice manager, the laboratory director failed to provide overall management of the laboratory. Finding: 1. Failed to perform proficiency testing (PT) materials within time frame for 2020 third event, 2021 first and second event, 2022 first and second event. (D6016) 2. Failed to report PT results for 2020 third event, 2021 first and second event, 2022 first and second event. (D2016) 3. Failed to monitor and document freezer, refrigerator, and lab room temperature, and humidity between 10/13/2021-13/31/2021. (D5413) 4. Failed to identify and correct freezer temperature out of range 5/17/2021-10/12/2021. (D5781) 5. Failed to perform annual QA review 2021. (D6021) 6. Failed to perform annual competency 2021 if technical consultant. (D6029) 7. Failed to print laboratory name and demographics on laboratory report. (D5805) 8. Food in laboratory cabinet, food refrigerator under the analyzer in laboratory. (6011) 9. No second identifier in lab report. (D5779, D5805) 10. The centrifuge preventative maintenance not performed in calendar year 2022. (D5433)
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) 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. (c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed. This STANDARD is not met as evidenced by: Based on the request to speck with laboratory director regarding proficiency testing of 2020 through 2020 on 1/19/2023 about 12pm, the laboratory director was not available.
D6011	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) 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)(2) and 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 the observation of food and food refrigerator with food inside in the laboratory, the laboratory director failed to provide safe environment for employees from chemical, physical and biohazard harm. Confirmed on an interview with technical consultant on 1/19/2023 about 11:45am.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on the review of API proficiency testing records for calendar year 2020 through 2022, the laboratory failed to test samples as required under subpart H. Finding: 1. 2020 third event not tested. 2. 2021 first and second event not tested. 3. 2022 first and second event not tested. 4. Confirmed on an interview with technical consultant 1/19 /2023 about 10:45am.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on the review of API PT summary reports and an interview with the laboratory supervisor, the laboratory director failed to review the scored proficiency testing reports received from API to evaluate the laboratory's performance for following events of virology and bacteriology: 2021 third event 2022 first and second event.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on the review of the laboratory's API PT records, the laboratory director failed to ensure that corrective action was performed and documented for the laboratory's unsatisfactory PT performance for the first and second event of 2022 for virology and bacteriology. Confirmed on an interview with technical consultant on 1/19/2023 about 10:45am.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the competency records for calendar year 2021, it was determined that the laboratory director failed follow the establish competency for 2021 to perform training/competency for technical consultant.