

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2068454	(X3) Date Survey Completed 02/24/2020
Name of Provider or Supplier Advanced Internal Medicine, Pc	Street Address, City, State 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on lack of proficiency testing (PT) records and confirmed in an interview with the laboratory technical consultant, the laboratory failed to enroll in an approved PT program for the respiratory panel in the calendar year 2019 and up to survey date. FINDINGS: The technical consultant confirmed on February 24, 2020 at approximately 11:00 AM that the laboratory initiated patient testing for virology on the Biofire Film Array analyzer on October 3, 2019 but did not enroll in a PT program in 2019 and the first event of 2020.</p>
D6015	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)</p> <p>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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.</p>

This STANDARD is not met as evidenced by:

Based on a surveyor review of records and an interview with the technical consultant, the laboratory director failed to ensure that the laboratory was enrolled in an approved PT program for the speciality of virology when testing was initiated on October 3, 2019. Refer to D2000.