Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2164188	12/14/2021
Name of Provider or Supplier	**Street Address, City, State**	
Atlanticare Physician Group, Pa	301 Central Avenue, Suite D, Egg Harbor Twp, NJ	

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 surveyor review of the Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the laboratory failed to sign attestation statements for the 2021 Hematology/Coagulation first PT event with the American Proficiency Institute. The TC confirmed on 12/14/21 at 10:00 am that PT records were not maintained.
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 surveyor review of Competency Assessment (CA) records and interview with the Technical Consultant (TC), the laboratory failed to perform CA for all Testing Personnel (TP) in the calendar year 2020. The finding includes: 1. One out of five TP did not have a CA performed in the calendar year 2020. 2. The TC confirmed on 12/14/21 at 11:15 am that the CA was not performed.
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 surveyor review of the Procedure Manual (PM) and interview with the Technical Consultant (TC) the laboratory failed to have all applicable procedures for laboratory tests from 10/17/19 to the date of the survey. The findings include: 1. The laboratory did not have a procedure for Critical Values 2. The TC confirmed on 12/14 /21 at 11:30 am that the PM did not have all applicable procedures.
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: a. Based on surveyor review of the Temperature Records (TR) and interview with the Technical Consultant (TC), the laboratory failed to accurately document Room Temperatures (RT) where laboratory tests were performed from January 2021 through July 2021. The findings include: 1 There were no temperatures recorded. 2. The TC confirmed on 12/14/21 at 10:00 am that the laboratory failed to accurately record RT.

	b. Based on surveyor review of the TR and interview with the TC, the laboratory failed to monitor and document Refrigerator Temperature (RF) where laboratory testing supplies were stored and tests were performed from January 2020 through July 2021 The findings include: 1. There were no temperatures recorded. 2. The TC confirmed on 12/14/21 at 10:00 am that the laboratory failed to accurately record RF.
D5789	TEST RECORDS CFR(s): 493.1283(b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on surveyor review of Work Records (WR) and interview with the Technical Consultant (TC), the laboratory failed to retain WR for Activated Clotting Tests performed on the i-Stat analyzer from 10/17/19 to the date of survey. The finding includes: 1) A review of five patients WR revealed that five out of five patients did not have a WR. 2) The TC confirmed on 12/16/21 at 11:00 am that records for all patient testing were not retained.
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 surveyor review of Proficiency Testing (PT) records and interview with the Testing Consultant (TC), the Laboratory Director (LD), failed to ensure that all PT results received were reviewed by the appropriate staff to identify any problems that require corrective action for Hematology/ Coagulation performed with the American Proficiency Institute (API) for the first event in the calendar year 2021. The TC confirmed on 12/16/21 at 10:00 am that the PT results were not reviewed.