Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2164188	10/17/2019
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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 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. This CONDITION is not met as evidenced by: Based on the lack of Proficiency Testing (PT) records and interview with the Practice Administrator (PA), the laboratory failed to enroll in an approved PT program for Prothrombin Time and International Normalized Ratio (PTT/INR) test from March 2019 to the date of survey. The PA confirmed on 10/17/2019 at 1:00 pm the laboratory was not enrolled in PT testing for PTT/INR.
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 surveyor review of the Procedure Manual and interview with the Practice

	Administrator (AP), the laboratory failed to establish a written procedure for Biannual Assessment (BA) for Celite Activated Clotting Time (cACT) test from March 2019 to the date of survey. The AP confirmed on 10/17/19 at 10:50 am that a BA procedure was not established for cACT.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual, and interview with the Practice Administrator (PA), the laboratory failed to follow the "Verify Newly Received Cartridges and Control" procedure. From 3/5/19 to the date of survey. The Finding includes; 1. The PM stated to "Verify that the transit temperatures were satisfactory using the four window temperature indicator strip included in the shipping container" but there was no evidence the temperature was verified. 2. The PA confirmed on 10/17 /19 at 1:00 pm that the laboratory did not follow the "Verify Newly Received Cartridges and Control Materials" procedure.
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 lack of Temperature Logs and interview with the Practice Administrator (PA), the laboratory failed to monitor and document room Temperature where the i-Stat analyzers were stored for Hematology tests from 3/5/19 to the date of survey. The PA confirmed on 10/17/19 at 10:20 am that the laboratory did not document temperature of the aforementioned room.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on lack of Performance Specifications (PS) records and interview with the Practice Administrator (PA), the laboratory failed to verify PS for Prothrombin Time and International Normalized Ratio tests performed on the i-Stat analyzer from 3/5/19 to the date of survey. The PA confirmed on 10/17/19 at 10:45 am that the PS were not performed.
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 lack of Calibration Verification (CV) records and interview with the Practice Administrator (PA), the laboratory failed to perform and document CV procedures at least once every six months for Hematology Tests performed on the i-Stat analyzer from 3/5/19 to the date of the surveyor. The AP confirmed on 10/17/19 at 12:10 pm CV was not performed every six months.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the lack of Quality Control (QC) records and interview with Practice Administrator (PA), the laboratory failed to perform and document two levels of

	controls on each day of patient testing for Prothrombin Time and International Normalized Ratio testing performed on the i-Stat analyzer in from 3/5/19 to the date of survey. The findings include: 1. There was no documented evidence two levels of QC were run from 3/5/19 to the date of survey. 2. The PA stated the laboratory "was running one level of control". 3. The laboraotry had only one level of control. 4. Total ten patients were run and reported. 5. The PA confirmed on 10/17/19 at 10:30 am that two levels of QC were not performed every day of patient testing.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the lack of Quality Control (QC) records and interview with the Practice Administrator (PA), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment of Hematology tests performed on the i-Stat analyzer from 3/5/19 to the date of survey. The PA confirmed on 10/17/19 at 10:15 am that the assayed values of QC material were not verified before putting in use.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on surveyor review of the Laboratory Records and interview with the Practice Administrator (PA), the laboratory failed to perform and document comparison studies for the two i-Stat analyzers twice per year from March 2019 to the date of the survey. The PA confirmed on 5/21/19 at 12:20 pm that the laboratory did not do comparison studies.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the

	following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on lack of an Accession Log (AL) and interview with the Practice Administrator (PA), the laboratory failed to maintain an Accession Log (AL) for Prothrombin Time and International Normalized Ratio test from 3/5/19 to the date of survey. The PA confirmed on 10/17/18 at 11:15 am that the laboratory did not maintain an AL for the above mentioned test.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Practice Adminstrator (PA), the laboratory failed to establish a written procedure to verify new Quality Control (QC) material before use for Prothrombin Time, International Normalized Ratio and Celite Activated Clotting Time tests performed on the i-Stat analyzer from 3/5/19 to the date of survey. The PA confirmed on 10/17/19 at 1:00 pm that the laboratory did not have a procedure to verify new QC.
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 an surveyors review of the laboratory's records, procedures and interview with the Practice Manager (PA), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory to ensure that laboratory testing is performed satisfactorily and in compliance with the CLIA regulations from 3/5/19 to the date of the survey. 1. The LD failed to enroll in Proficiency Testing. Cross Refer to D2000. 2. The LD failed to ensure a Performance Specification were adequate. Cross Refer to D6013. 3. The LD failed to ensure a Quality Control program was maintained. Cross Refer to D6020. 4. The LD failed to establish a Quality Assurance plan. Cross Refer to D6021 5. The LD failed to establish a Competency Assessment procedure with the applicable elements. Cross Refer to D6030. 6. The LD failed to specify the duties and responsibilities of Testing Personnel. Cross Refer to D6032 7. The LD failed to establish the capability of testing personnel to identify problems that may adversely affect test performance. Cross Refer to D6074.

D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: a) Based on surveyor review of the Performance Specification (PS) records and interview with the Practice Administrator (PA), the Laboratory Director (LD) failed to ensure that PS procedures performed for Celite Activated Clotting Time test performed on the i-Stat analyzer were adequate from 3/5/19 to the date of survey. The findings include: 1. There was no criteria for accuracy or precision. 2. There was no evidence that linearity was performed. 3. There was no evidence that the LD approved the PS. 4. The PA confirmed on 10/18/19 at 11:15 am that PS records were not adequate.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the lack of the Quality Control (QC) records, and interview with the Practice Administrator (PA), the Laboratory Director failed to ensure that a QC program was established for Prothrombin Time, International Normalized Ratio and Celite Activated Clotting Time tests from 3/5/19 to the date of the survey. The PA confirmed on 10/17/19 at 10:40 am the LD did not ensure a QC plan was established.
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 a lack of a Quality Assurance (QA) plan and interview with the Practice

	Administrator (PA), the Laboratory Director failed to establish a QA plan from 3/5/19 to the date of the survey. The PA confirmed 10/17/19 at 12:00 pm that a QA plan had not been established.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Practice Adminstrator (PA), the Laboratory Director failed to establish a Competency Assessment (CA) procedure with the required elements for Hematology tests from 3/5 /19 to the date of the survey. The PA confirmed on 10/17/19 at 10:40 am that a CA procedure was not established.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on the lack of the Personnel Records (PR) and interview with the Practice Adminstrator (PA), the Laboratory Director (LD) failed to specify in detail the duties and responsibilities for four out of four TP engaged in the performance of Hematology testing from 3/5/19 to the date of survey. The PA confirmed on 10/17/19 at 11:15 am that the LD did not specify the duties and responsibilities of TP.
D6074	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5) Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test

	results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director. This STANDARD is not met as evidenced by: Based on the lack of Quality Control (QC) records and interview with the Practice Administrator (PA), the Testing Personal failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the i-Stat analyzer from 3/5/19 to the date of survey. The PA confirmed on 10/17/19 at 1:00 pm that trends and shifts were not reviewed.