Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1100091	02/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Atlanticare Regional Medical Center - Hammonton	219 White Horse Pike, Hammonton, 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
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 Hematology Procedure Manual (PM) and Final Reports and interview with the Technical Consultant (TC), the laboratory failed to follow Sysmex pocH100i PM, section Reference Ranges (RR) from 3/1/17 to the date of survey. The finding includes: 1. The PM had Male and Female RR but the FR had same range for Male and Female patients. 2. The TC # 1 listed on CMS form 209 confirmed on 2/14/19 at 2:30 pm that the laboartory did not follow PM.
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 surveyor review of the Quality Control (QC) records, Individual Quality Control Plan (IQCP) and interview with Technical Consultant TC), the laboratory failed to perform and document controls each day of patient testing for Troponin, B-

	Type Natriuretic Peptide and International Normalized Ratio tests performed on the iSTAT analyzer from 3/1/17 to the date of survey. The findings include: 1. The laboratory ran liquid QC once a month. 2. The TC stated that the laboratory developed IQCP but the Quality Control Plan was not established. 3. The TC did not know how many patient samples were run. 4. The TC # 1 listed on CMS form 209 confirmed on 2 /14/19 at 2:00 pm that QC was not done on each day of patient testing.
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 surveyor review of the Procedure Manual (PM), Hematology work records and interview with the Technical Consultant (TC), the laboratory failed to perform corrective action when the Comparision of pocH 100i analyzers failed on 12/5/18. The findings include: 1. The PM stated "Difference between two instruments should not exceed the following limits": a. Hemoglobin limit was +/- 1.5% but the laboratory had 6.5% difference. 2. The TC # 2 signed off on 12/5/18 but it was not noticed. 3. The TC # 1 listed on CMS form 209 confirmed on 2/14/19 at 2:10 pm that corrective action was not performed.
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 Technical consultant (TC), the laboratory failed to maintain a record system for Chemistry and Hematology tests performed on the iStat and pocH 100i analyzers respectively from 3/1/17 to the date of survey. The TC # 1 listed on CMS form 209 confirmed on 2.14/19 at 2:10 Pm that the laboratory did not maintain a record system for all tests perfomed.
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 surveyor review of the Final Reports (FR) and interview with the Technical Consultant (TC), the laboratory failed to ensure that the Test Report Date (TRD) was indicated on the FR for Chemistry and Hematology tests performed on the iSTAT and pocH 110i analyzers respectively from 3/1/17 to the date of survey. The TC # 1 listed on CMS form 209 confirmed on 2/14/19 at 1:55 pm that the TRD was not on the FR.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the Technical Consultant (TC), the laboratory failed to identify the source of the Reference Intervals (RI) used for Hematolgy tests from 3/1/17 to the date of survey. The TC #1 listed on CMS form 209 confirmed on 2/14/19 at 2:00 pm that the source of the RI was unknown.