

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0699601	(X3) Date Survey Completed 09/19/2018
Name of Provider or Supplier Atlanticare Pulmonary Apg	Street Address, City, State 741 South 2nd Avenue, Galloway Township, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TS), the laboratory failed to ensure that TP who performed Blood Gas testing participated in the College of American Pathologists PT events in the calendar years 2017 and 2018. The finding includes: 1. A review of all PT event testing revealed that only one out of two TP performed PT events in 2017 and 2018. 2. The TP # 1 listed on the CMS form 209 confirmed on 9/19/18 at 10:30 am that PT events were not rotated between TP.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to perform CA correctly on two of two TP in 2017 and 2018. The findings include: 1. The laboratory did not document what records were reviewed and how CA was assessed. 2. The CA was not assessed for test performance and problem solving skills. 3. The TP # 1 listed in CMS</p>

form 209 stated that CA was performed TP and TP was not qualified to perform CA.
4. The TP # 1 confirmed on 9/19/18 at 11:00 am that CA was not performed correctly.

D5407

PROCEDURE MANUAL

CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Individualized Quality Control Plan (IQCP) and interview with the Testing Personnel (TP) and Laboratory Director (LD), the laboratory failed to have an approved, signed and dated IQCP procedures by the LD and was not complete from 9/29/16 to the date of the survey. The findings include: 1. A review of the IQCP plan revealed that there was no evidence of review, approval or signature of the LD on the Risk Management portion of the IQCP. 2. The IQCP did not include a Quality Control Plan. 3. A Quality Assessment (QA) plan did not include frequency of review of QA. 4. The TP # 1 listed on CMS form 209 confirmed on 9/19/18 at 11:15 am that IQCP plan was not signed by LD.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of the laboratory's Individualized Quality Control Plan (IQCP) and interview with the Testing Personnel (TP) and Laboratory Director, the laboratory failed to have documentation of data used to support their Risk Assessment (RA) for Blood Gas testing before putting in use from 9/29/16 to the date of the survey. The TP # 1 listed on CMS form 209 confirmed on 9/19/18 at 11:00 am that the laboratory did not have data to support their RA.

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 Testing Personnel (TP), the laboratory failed to maintain a record system for Blood Gas tests performed

on the iStat analyzer from 9/29/16 to the date of survey. The TP # 1 listed on CMS form 209 confirmed on 9/19/18 at 10:10 am that the laboratory did not maintain a record system for tests performed.

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 Testing Personnel (TP), the Laboratory Director failed to establish a Competency Assessment (CA) procedure with the required elements from 9/29/16 to the date of the survey. The TP # 1 listed on CMS form 209 confirmed on 9/19/18 at 11:00 am that a CA procedure was not established.