Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0689665	06/06/2018
Name of Provider or Supplier	**Street Address, City, State**	
Long Island Pulmonary Associates Pc	520 Franklin Ave Suite 153, Garden City, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on the surveyor's review of Quality Control (QC) records and an interview with the technical consultant, the laboratory failed to follow the manufacturer's instructions for performing external positive and negative controls for the Siemens Multistix 10SG Urinalysis Reagent Strips from March 2017 until date of survey and for the Bio-Fire Respiratory Panel since February 2018 to date of survey. The laboratory also did not have procedures or package inserts available for review for all waived testing performed. FINDINGS: 1. At approximately 11:00 AM on June 6, 2018, the technical consultant confirmed that the Siemens Multistix 10 SG Reagent Strips requires that external positive and negative controls are tested with each new vial of reagent strips. Documentation for the required external control testing was not available since March 2017 to date of survey. Approximately 100 patients have been tested in that time frame. 2. At approximately 11:10 AM on June 6, 2018, the technical consultant confirmed that the Bio-Fire Respiratory panel requires external QC to be run with each new test kit. Two kits had been opened since February 2018 and QC was not run. Approximately 75 patients were tested. 3. The technical consultant confirmed that the current package inserts for all the waived tests were not available at time of survey.
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 a review of the laboratory procedure manual and the quality assurance documentation and an interview with the technical consultant, the laboratory is not following their monthly schedule for quality monitoring. Findings: At approximately 1:30 PM on June 6, 2018, the surveyor determined that the laboratory did not follow their procedure for the following items: 1. In January the laboratory did not perform the variance between analyzers performing the same testing. This laboratory does not have multiple analyzers performing the same test and no notation was made regarding this item. 2. In February, the laboratory did not perform the requisition, patient ID and labeling review. 3. In April, the laboratory did not perform Proficiency review and test tracking.
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 surveyor review of the laboratory's temperature records and confirmed in an interview with the technical consultant and the testing person, the laboratory failed to store BioRad Liquichek controls at the proper temperature in the freezer as required by the manufacturer. FINDINGS: The Bio-Rad Liquichek controls are required to be stored at -20 to -70 degrees Celsius. During calendar year 2018 the freezer temperature was above -20 degrees Celsius for approximately 75 days.
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 the surveyor's review of the laboratory's calibration verification records and an interview with the laboratory technical consultant and the testing person, the laboratory failed to perform calibration verification at least once every six months for chemistry, general immunology and endocrinology testing on the Beckman AU480 analyzer since March 2017. FINDINGS: At approximately 1:00 PM on June 6, 2018, the technical consultant confirmed the laboratory had not performed calibration verification on the Beckman AU-480 for all analytes with less than three calibrators. Approximately 500 patients were tested during this time period.
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 a review of laboratory QC records and an interview with the technical consultant, the laboratory failed to perform lot to lot verification of Streck hematology assayed controls. Findings: At approximately 12:00 PM on June 6, 2018, the technical consultant confirmed that the laboratory had not verified assayed hematology QC prior to laboratory implementation.
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 a review of the laboratory records and confirmed by interview with the technical consultant, the laboratory director failed to ensure that the QC program for hematology, chemistry, endocrinology and immunology testing was maintained to assure quality of laboratory services. Refer to: D1001, D5439, D5469
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 review of the laboratory quality assessment records (QA), and interview with the technical consultant, the laboratory director failed to follow the laboratory's QA procedures. Findings Include: At approximately 2:15 PM on June 6, 2018, the technical consultant confirmed that although monthly QA reviews were performed , the reviews did not follow the schedule laid out in the QA procedure. Refer to D5413 and D5401.