Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2019646	01/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Columbus Ltach, Llc	495 N 13th Street, Newark, 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 Proficiency Testing (PT) records and interview with the General Supervisor (GS) the laboratory failed to maintain copies of all PT records for Blood Gas testing performed with the American Proficiency Institute (API) in 2017. The finding includes: 1. A review of PT revealed the laboratory didn't maintain work records for events 2 and 3 in 2017. 2. The GS #2 listed on CMS form 209 confirmed on 1/18/18 at 11:05 am that all PT records were not maintained.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

	This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records, Procedure Manual and interview with the General Supervisor (GS), the laboratory failed to retain the Manufacturer's Package Inserts (MPI) for Blood Gas cartridges and QC material used on the Abbott iSTAT analyzer from May 2017 to the date of survey. The GS #2 listed on CMS form 209 confirmed on 1/18/18 at 10:00 am that the MPI were not retained.
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 (PM) and interview with the General Supervisor (GS), the laboratory failed to have a written procedure for lot to lot Quality Control (QC) verification for all tests performed on the Abbott iSTAT analyzer from May 2017 to the date of survey. The GS #2 listed on CMS form 209 confirmed on 1/18/18 at 11:00 am that the procedure mentioned above was not in the PM.
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 General Supervisor (GS), the laboratory failed to verify accuracy, precision and reportable range on Blood Gas tests performed on the Abbott iSTAT analyzer before reporting patient test results from May 2017 to the date of survey. The GS #2 on the CMS form 209 confirmed on 1/18/18 at 11:50 am PS were done.
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 Report (FR) and interview with the General Supervisor (GS), the laboratory failed to include the name and address of the laboratory where Blood Gas testing was performed from May 2017 to the date of the survey. The GS #2 on CMS form 209 confirmed on 1/18/18 at 11:50 am the laboratory location 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 General Supervisor (GS), the laboratory failed to include the Normal Reference Intervals (NRI) for Blood Gas tests performed on the Abbott iSTAT analyzer from May 2017 to the date of survey. The GS #2 listed on CMS form 209 confirmed on 1/18/18 at 11:55 am that the laboratory failed to include the NRI on the FR.
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 surveyor review of the Quality Control (QC) records and interview with the General Supervisor (GS), the Laboratory Director failed to ensure that a QC program was established for laboratory services provided from May 2017 to the date of the survey. The GS #2 listed on CMS form 209 confirmed on 1/18/18 at 11:20 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 the lack of a Quality Assessment (QA) program and interview with the General Supervisor (GS), the Laboratory Director failed to ensure that a QA program was established from May 2017 to the date of survey. The GS #2 listed on CMS form 209 confirmed on 1/18/18 at 11:25 am that the laboratory did not have a QA program.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on surveyor review of Personnel Files (PF) and interview with the General Supervisor (GS), the Laboratory Director failed to have education records for 27 out of 27 Testing Personnel from May 2017 to the date of the survey. The GS #2 listed on CMS form 209 confirmed on 1/18/18 at 9:40 am that there were no education records.
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 General Supervisor (GS), the Laboratory Director failed to establish a Competency Assessment (CA) procedure with the required elements for Testing Personnel from May 2017 to the date of the survey. The GS #2 listed on CMS form 209 confirmed on 1/18/18 at 10:10 am that a CA procedure was not established.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the General Supervisor (GS), the Laboratory Director failed to ensure that an approved procedure manual was available for Blood Gas testing from May 2017 to the date of the survey. The GS #2 listed on CMS form 209 confirmed on 1/18/18 at 9:45 am that an approved PM was not available.
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 surveyor review of the Personnel Files (PF) and interview with the General Supervisor (GS), the Laboratory Director (LD) did not specify in writing the duties and responsibilities of Testing Personnel (TP) engaged in the performance of preanalytic, analytic and post analytic phases of Abbot iSTAT Blood Gas tests from May 2017 to the date of survey. The GS #2 listed on CMS form 209 confirmed on 1 /18/18 at 10:20 am that the LD did not specify the duties and responsibilities of TP.