Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2019646	05/29/2019
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records, review of the personnel files and interview with the Testing Personnel (TP), the laboratory failed to perform a CA on fourteen out of twenty four TP in the Calendar year 2018. The TP #24 on CMS form 209 confirmed on 5/29/19 at 10:00 am that a CA was not performed on the TP.
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 and interview with Testing Personnel (TP), the laboratory failed to perform and document two level of controls on each day of patient testing for Arterial Blood Gas (ABG) testing performed on the iSTAT analyzer. The findings include: 1. Controls were not run on 7 /4/18, 7/16/18, 7/19/18, 7/20/18, 7/23/18, 7/24/18 and 7/30/18. 2. Approximately fifty

	eight patients were run and reported each day QC was not done. 3. The TP #24 listed on CMS form 209 confirmed on 5/29/19 at 11:00 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 surveyor review of the Quality Control (QC) records and interview with the Technical Consultant (TC), the laboratory failed to verify that the assayed QC materials were within the acceptable ranges before they were put into use for tests performed on the iSTATanalyzer from 1/18/18 to the date of survey. The TP #24 listed on CMS form 209 confirmed on 5/29/19 at 11:00 am that the laboratory did not verify QC material.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC), Calibration Results (CR), and interview with the Technical Consultant (TC) and the Testing Personnel, the laboratory failed to review the effectiveness of corrective actions taken when the laboratory had a positive bias for partial pressure of oxygen (Po2) from January 2018 to the date of survey. The findings include. 1) The laboratory repeated Po2 QC level 1 around seven times per month because of continually high range values. 2) The last two Calibrations ran on the iStat for Po2 levels two out of five calibrators were repeated because of positive bias. 3) PT for events Q1,Q2,Q3 2018, and Q1 2019 Po2 results were above the mean on all specimens. 4) The Technical Consultant stated "There is a consistent positive bias for Po2 on low QC and CR" 5) The TC #2 listed on CMS form 209 confirmed on 5/29/19 that the laboratory failed to review the effectiveness of corrective taken to ensure a positive bias was reduced.

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 Testing Personnel (TP), the laboratory failed to include all the required information on the FR from October 2018 to the date of survey. The finding includes: 1. A review of ten patient FR revealed four out of ten FR did not have the laboratory address. 2. The TP #24 listed on CMS from 209 confirmed on 5/29/19 at 12:00 pm the FR did not have all the required information.