

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2019646	(X3) Date Survey Completed 12/21/2021
Name of Provider or Supplier Columbus Ltach, Llc	Street Address, City, State 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Technical Consultant (TC), the laboratory failed to follow their policy for "Controls" from 1/18/18 to the date of survey. The findings include: 1. The control policy stated "All new shipments of cartridges and Tri-Controls that are received will have testing done by analyzing two (2) levels of Tri-Controls (Level I and Level 3) on the appropriate number of cartridges utilizing a representative sample of each new lot and comparing the results to the expected values published in the Value Assignment Sheets." 2. There was no documented evidence that the above mentioned procedure was followed. 3. The TC confirmed on 12/21/2021 at 1:21 pm the aforementioned policies were not followed.</p>
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>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</p>

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 iSTAT analyzer from 1/18/18 to the date of survey. The TC confirmed on 12/21/21 at 1:00 pm that the laboratory did not verify QC material.

Note: this was cited 5/26/19