

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2178650	(X3) Date Survey Completed 09/10/2021
Name of Provider or Supplier Lab X Health Llc	Street Address, City, State 4 Brighton Road, Clifton, 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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p> <p>a) Based on surveyor review of Performance Specification (PS) records and interview with the General Supervisor (GS), the laboratory failed to ensure that all PS procedures were adequate for all analytes run on the Tosoh AIA-360, Abbott Architect ci4000, i1000, Cell Dyn Emerald, Cell-Dyn Ruby Hematology, and Alcor iSED analyzers from January 2020 to the date of survey. The finding includes: 1. There was no evidence that Reference Intervals (RI) were verified before starting patient testing. 2. The GS confirmed at 10:10 am on 9/10/21 that RI were not verified.</p> <p>b) Based on surveyor review of Procedure Manual (PM), PS records and interview with the GS, the laboratory failed to ensure that precision was adequate for all analytes run on the Abbott Architect i1000 analyzer from January 2020 to the date of survey. The findings includes: 1. Folate II had a verified linearity of 0-20 ng/ml. 2. The precision raw data for Folate II revealed that 10 out of 10 data points were >20 ng/ml outside of the analyzers linear range. 3. There was no documentation that the 95% confidence limit was met as stated in the PM. 3. The GS confirmed at 10:20 am on 9/10/21 that the PS for Folate II precision were not adequate.</p>
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</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 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:

a) Based on surveyor review of Quality Control (QC) records and interview with the General Supervisor (GS), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment of Bacteria and Virology QC used for Bacteria and Virology tests performed on the GeneXpert XVI analyzer from September 2020 to the date of the survey. The findings include: 1. ZeptoMetrix NATrol Chlamydia Trachomatis Controls had no documented evidence that QC verification was performed. 2. ZeptoMetrix NATrol Flu/RSV/SARS-CoV-2 Controls had no documented evidence that QC verification was performed. 3. Xpert FII & FV NOR/MUT Controls had no documented evidence that QC verification was performed. 4. The GS confirmed on 9/10/21 at 11:00 am that assayed QC material was not verified before putting in use. 43129 b) Based on surveyor review of QC records and interview with the GS, the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment of Erythrocyte Sedimentation Rate (ESR) QC used for ESR tests performed on the ALCOR iSED ESR analyzer from February 2020 to the date of the survey. The findings include: 1. ESR Controls had no documented evidence that QC verification was performed. 2. The GS confirmed on 9/9/21 at 10:00 am that assayed QC material was not verified before putting in use.