

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2100718	(X3) Date Survey Completed 08/16/2022
Name of Provider or Supplier Patient First - Hamilton	Street Address, City, State 641 Us Highway Route 130, Hamilton, 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
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 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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records and interview with the Clinical Consultant (CC), the laboratory failed to verify commercial QC material with each new lot and/or shipment of QC used for Chemistry tests performed on iSTAT analyzer from 8/14/19 to the date of survey. The finding includes: 1. There was no documented evidence that QC was verified before being put into use. 2. The CC confirmed on 8/16/22 at 1:20 pm that the QC material was not verified before putting in use.</p>