

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2052546	(X3) Date Survey Completed 03/09/2021
Name of Provider or Supplier Patient First-Lancaster	Street Address, City, State 1625 Oregon Pike, Lancaster, PA	
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: Based on review of the Abbott istat analyzer validation records and interview with Technical consultants (TC) #2 and #3, the laboratory failed to establish criteria for acceptable performance specifications the Abbott istat Chem 8+ Cartridges Validation used to routine chemistry specimens from February 21, 2020 to March 9, 2021. Findings Include: 1. On the day of survey, 03/09/2021, review of the Istat System Validation records revealed, the validation performed on 02/21/2020 did not include criteria for acceptable precision and accuracy. 2. From 02/21/2020 to 03/09/2021, 654 patients were analyzed on the Abbot istat. 3. TC #2 and TC #3 confirmed the finding above on 03/09/2020 around 11:10 a.m.</p>