

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0928351	(X3) Date Survey Completed 05/10/2023
Name of Provider or Supplier Core Laboratory	Street Address, City, State 204 Sigma Drive, Ridc Park, Pittsburgh, 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
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of Comparison study records and interview with the Technical Consultant (TC)#2, the laboratory failed to evaluate the relationship between the 2 of 2 Abbott i-Stat analyzers from 06/16/2021 to date of survey. Findings: 1. At the time of inspection on 05/10/2023 at 9:21 am, review of Comparison study records revealed , the laboratory did not evaluate twice annually the relationship between test results using the different instruments for the 2 of 2 Abbott i-Stat analyzers for the following analytes: PT/INR Ph pCO2 pO2 Chloride Potassium Sodium Ionized Calcium tCO2 Lactate Creatinine Glucose BUN Hemoglobin Hematocrit. 2. The laboratory reported an annual testing volume of 650 for Chemistry and 800 for Hematology. (CMS-116) 3. The TC #2 confirmed the above findings on 05/10/2023 around 3:20pm.</p>