

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1048082	(X3) Date Survey Completed 09/24/2024
Name of Provider or Supplier Titan Health Partners Llc	Street Address, City, State 9 Centre Drive, Monroe Township, 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: Based on surveyor review of the Horiba Micros 60 Performance Specification (PS) records and interview with the Laboratory Manager (LM), the laboratory failed to ensure that all PS records were adequate for all analytes run on the Horiba Micros 60 Analyzer from 5/1/22 to 9/24/24. The findings include: 1. There was no documented evidence that the Laboratory Information System (LIS) was verified before routine patient testing. 2. The LM confirmed on 9/24/24 at 10:50 am that the laboratory failed to ensure that all PS records were adequate.</p>