

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2189325	(X3) Date Survey Completed 09/18/2024
Name of Provider or Supplier Titan Health Partners, Llc	Street Address, City, State 201 Route 17 N, Rutherford, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records, Procedure Manual (PM) and interview with the Laboratory Manager (LM) the laboratory failed to ensure that all Testing Personnel (TP) who performed Hematology testing participated in all PT events from the American Proficiency Institute (API) in all events of 2023 and the first and second event of 2024. The findings include: 1. The PM states " Each lab tech will rotate quarterly to perform the proficiency tests." 2. Only one TP performed the 1st and 2nd Hematology PT events of 2024. 3. Only one TP performed the 1st, 2nd and 3rd Hematology PT events in 2023 4. The LM confirmed on 9/18/24 at 11:45 am that the laboratory failed to rotate all TP to participate in all Hematology PT events in 2023 and 2024.</p>
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test</p>

system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Proficiency Testing (PT) records and interview with the Laboratory Manager (LM) the laboratory lacked work records for the 1st Hematology event of 2024 by American Proficiency Institute (API). The finding includes: 1. Surveyor review of PT records on 9/18/24 revealed a lack of work records for the 1st Hematology PT event of 2024. 2. The LM confirmed on 9/18/24 at 11:35 am that work records were not available for the 1st Hematology PT event of 2024.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

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.

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 9/1/22 to 9/18/24. The findings include: 1. There was no documented evidence that the Laboratory Information System (LIS) was verified to perform acceptably before routine patient testing. 2. The LM confirmed on 9/18/24 at 11:30 am that the laboratory failed to ensure that all PS records were adequate.