

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1066047	(X3) Date Survey Completed 07/29/2025
Name of Provider or Supplier Titan Health Partners Llc	Street Address, City, State 1200 Us Highway 22 East, Bridgewater, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Patient Test Reports (PTR) and interview with the Testing Personnel (TP), the laboratory failed to follow the Micros 60 Flags and Codes procedure from 6/16/25 to 7/29/25. The findings include: 1. Surveyor review of five PTR revealed that accession number 58119 had \$ flags on results from the analyzer. 2. The PM stated for results with the "\$" flag to " Invert tube and rerun. If flag does not appear, report result. Otherwise send out to reference lab. 3. There was no documented evidence the laboratory reran the sample or sent it to a reference lab. 4. The TP confirmed on 7/29/25 at 10:55 am, laboratory did not follow the procedure for Micros 60 Flags and Codes.</p>
D5779	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(a)</p> <p>(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to follow</p>

the Corrective Action (CA) policy for Quality Control Corrective Action Form for Hematology tests performed from 4/1/25 to 4/30/25. The finding includes: 1. The PM stated "After the second failed QC run, the Quality Control Corrective Action form will be completed (attached). This is to ensure appropriate interventions are documented for failed QC." 2. QC lot # 5041 Low QC failed on runs #59 and #60. The QC passed on run #61. 3. The laboratory did not complete the Quality Control Corrective Action form for the failed QC run. 4. The TP confirmed on 7/29/25 at 10:45 am, the laboratory failed to follow the laboratory's CA policy.