

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0124328	(X3) Date Survey Completed 03/15/2023
Name of Provider or Supplier Titan Health Partners Llc	Street Address, City, State 3 Progress St, Edison, 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
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Consultant (TC) the laboratory failed to review and evaluate results when they received an unacceptable score in Hematology/Coagulation tests performed with the American Proficiency Institute (API), for 3rd event 2022. The findings include: 1. The laboratory received grades 20% for Erythrocyte Count, 40% for Hematocrite, 60% for Hemoglobin. 2. The TC confirmed on 3/17/23 at 10:45 pm that the laboratory did not document an evaluation of unacceptable PT results.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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: a) Based on surveyor review of the Procedure Manual (PM), and interview with the Technical Consultant (TC), the laboratory failed to follow their procedure for "Monthly Ending Quality Control Review" for Complete Blood Counts (CBC) performed on the ABX Micros 60 analyzers from the calendar year 2022 to the date of survey. The findings include: 1) The PM stated "The end of the month QC report with Levey-Jennings graphs should be printed out, reviewed by testing personnel to</p>

identify and deviation from the mean of the controls". "At the en of the month, the IQAP (interlaboratory Quality Assurance Program) data will be reviewed. 2) There was no documented evidence that the aforementioned procedure was performed. 3) The TC confirmed on 3/15/23 at 11:30 am that the laboratory did not follow the above mentioned procedure. b) Based on surveyor review of the Procedure Manual (PM), and interview with the TC, the laboratory failed to to follow their procedure for "Quality Control Corrective Action" for Complete Blood Counts (CBC) performed on the ABX Micros 60 analyzers from the calendar year 2022 to the date of survey. The findings include: 1) The PM stated "After the second failed QC run, the Quality Control Corrective Action form will be completed". 2) There was no documented evidence that the aforementioned procedure was performed. 3) The TC confirmed on 3 /15/23 at 11:30 am that the laboratory did not follow the above mentioned procedure.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:
Based on surveyor review of Calibration (C) records, Manufactures Instructions (MI) and interview with the Techincal Consultant (TC), the laboratory failed to follow MI for "Calibration Procedure" for Hematology Tests performed on the ABX Micros 60 analyzer in the calendar years 2022 and 2021. The findings include: 1. A review of C records revealed that the laboratory failed to correctly perform and document "Reproducibility". The MI states "Run reproducibility preferably using fresh normal patient 10 times. This checks the stability of the instrument. Calculate the Coefficient of verification (CV%) to confirm that the following parameters are not greater than the following: WBC = 2.5%, RBC = 2.0%, HGB = 1.5%, HCT = 2.0%, PLT = 5.0%". 2. The TC confirmed on 3/15/23 at 1:00 pm that the laboratory failed to follow the MI.