Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2189325	(X3) Date Survey Completed 08/02/2022
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Lab Quality Assurance Supervisor (LQAS), the laboratory failed to retain all QC records for tests performed on the Sysmex XP-450 analyzer from July 2020 to the date of survey. The finding includes: 1. The LQAS was unable to reveal current control values entered in the analyzer. 2. The LQAS confirmed on 8/2/2022 at 11:00 am that all QC records could not be accessed.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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. This STANDARD is not met as evidenced by: A) Based on surveyor review of the Procedure Manual (PM), Operators Manual (OM) and interview with the Lab Quality Assurance Supervisor (LQAS), the laboratory failed to follow all procedures written for Hematology tests performed in on the Sysmex XN-450 analyzer from July 2020 to the date of the survey. The findings include: 1. The procedure "VI. Printing Logs" "B. Monthly: QC" , "E. Monthly log

	sheets tab", "F. QC insert & Lot to Lot tab" were not performed. 2. The LQAS confirmed on 8/2/22 at 10:30 am that the laboratory did not follow the PM. B) Based on surveyor review of the Procedure Manual (PM), Quality Assurance Plan (QAP) and interview with the LQAS, the laboratory failed to have a procedure to verify the Laboratory Information System (LIS) for Hematology tests performed in on the Sysmex XN-450 analyzer from July 2020 to the date of the survey. The LQAS confirmed on 8/2/22 at 10:30 am that the laboratory that the QAP did not have a procedure to verify the LIS.
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 Complete Blood Cell (CBC) and automated differential Performance Specification (PS) records and interview with the Lab Quality Assurance Supervisor (LQAS), the laboratory failed to ensure that all PS records were adequate for all analytes run on the Sysmex XN-450 Analyzer from July 2020 to the date of survey. The findings include: 1. There was no source cited for Normal Patient Range. 2. There was no documented evidence that the Laboratory Information System (LIS) was verified. 3. The LQAS confirmed on 8/2/22 at 11:30 am that the laboratory failed to ensure that all PS records were adequate.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

	This STANDARD is not met as evidenced by: Based on surveyor review of the Sysmex Certificate of Calibrations (COC) and interview with the Lab Quality Assurance Supervisor (LQAS), the laboratory failed to perform calibration verification every 6 months on the Sysmex XN-450 analyzer used for Hematology testing. The findings include: 1. There was no documentation of the number, type and concentration of the materials used for performing Calibration Verification (CV). 2. The COC did not provide lot numbers of calibration material used for CV. 3. The LQAS confirmed on 8/2/22 at 10:00 am that the laboratory failed to perform CV every 6 months.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records and interview with the Lab Quality Assurance Supervisor (LQAS), the laboratory failed to verify commercial QC material with each new lot and/or shipment of QC used for Hematology tests performed on Sysmex XN-450 analyzer from July 2020 to the date of survey. The finding includes: 1. There was no documented evidence that QC was verified before being put into use. 2. The LQAS confirmed on 8/2/22 at 10:20 am that the QC material was not verified before putting in use.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records, Procedure Manual (PM) and interview with the Lab Quality Assurance Supervisor (LQAS), the Laboratory Director (LD) failed to ensure that the QC program was maintained for

	laboratory services provided from July 2020 to the date of the survey. The findings include: 1. There was no documented evidence that the QC program defined in the PM was followed. Cross refer D5401 3. The LQAS confirmed on 8/2/22 at 11:30 am the LD did not ensure the QC plan was maintained. .
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on surveyor review of the Personnel Files (PF) and interview with the Lab Quality Assurance Supervisor (LQAS), the Laboratory Director (LD) failed to have appropriate education documentation for all Testing Personnel (TP) performing laboratory testing on the date of survey. The findings include: 1. The laboratory did not have education records for one out of two TP listed on the CMS form 209. 2. The LQAS confirmed on 8/2/22 at 11:40 am the above record was not on file.