Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0124328	08/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
Titan Health Partners Llc	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	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Supervisor (TS), the laboratory failed to evaluate results when the laboratory received an unacceptable PT score for Hematology tests performed with the Medical Laboratory Evaluation (MLE) in 2-2018. The finding includes: 1. There was no review or evaluation documented when the laboratory received an unacceptable result for specimen HD-8 Granulocytes Percent in event 2018 MLE - M2. 2. The TS confirmed on 8/23/18 at 10:00 am that the laboratory did not perform and document an evaluation of unacceptable PT performance.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by:

	Based on surveyor review of the Quality Control (QC) records and interview with the Technical Supervisor (TS), the laboratory did not document corrective action taken when Hematology controls were out of range from January to June 2018. The findings include: 1. There was no documented evidence of Corrective Action (CA) taken when Hematology controls were out of range as follows: a. Red Blood Cell Count (RBC) - High and Low Control Lot MX409 on 1/10/18 b. Mean Corpuscular Volume (MCV) - Low, Normal & High Control Lot MX411 on 5/17/18 c. Hemoglobin (HGB) - Low & High Control Lot MX411 on 6/4/18 and 6/21/18 d. Mean Corpuscular Hemoglobin Concentration (MCH) - Normal and Low Control Lot MX411 on 6/13/18 2. Approximately 80-100 patient samples were run per day. 3. The TS confirmed on 8/23 /18 at 10:45 am that corrective action was not taken on out of range controls.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR), Critical Values (CV) found in the procedure manual and interview with the Technical Supervisor (TS), the laboratory failed to correct problems in the postanalytic system when the test results were flagged as a Panic Value (PV) and the result did not agree with established CV from 8 /30/16 to the date of the survey. The finding includes: 1. The FR revealed that abnormal Granulocytes, Lymphocytes and Monocytes Percent and Number were reported out as a PV but the laboratory did not define a CV for the above parameters. 2. The TS confirmed on 8/23/18 at 11:10 am that PV flagging was incorrect on the TR.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on lack of a Quality Assessment (QA) policy and interview with the Technical Supervisor (TS), the Laboratory Director failed to ensure that a QA program was established from 8/30/16 to the date of survey. The TS confirmed on 8/23/18 at 11:50 am that the laboratory did not have a QA program.
D6074	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5) Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test

	results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Technical Supervisor (TS), the Testing Personnel (TP) failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for Hematology tests performed on the Horiba ABX - Micros 60 from 8/30/16 to the date of the survey. The TS confirmed on 8/23/18 at 10:20 am that trends and shifts were not reviewed.