Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1048082	10/29/2019
Name of Provider or Supplier	**Street Address, City, State**	
Titan Health Partners Llc	9 Centre Drive, Monroe Township, 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	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) and interview with the Technical Consultant (TC), the laboratory failed to follow the procedure for reviewing results with flags obtained on the Cell Dyne Emerald analyzer used for Hematology testing from January 2019 to the date of survey. The finding includes: 1. The PM stated to remix and rerun samples with a flagged result but a review of ten patient results with flags revealed the laboratory did not rerun ten out of ten patients. 2. The TC confirmed on 10/29/19 at 11:00 am that the laboratory did not follow the procedure for flag review. b) Based on surveyor review of the Abbott Cell Dyne Emerald Operators Manual, PM and interview with the TC, the laboratory failed to follow the instrument calibration procedure for Hematology tests performed on the Cell-Dyne Emerald analyzer from 9/17/18 to the date of survey. The finding includes: 1. The PM stated calibration must be run every six months but the laboratory calibrated on November 2018 and July 2019. 2. The TC confirmed on 10/29/19 at 11: 10 am that the PM not followed.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3)

	Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor review of Manufactures Package Insert, observation of the Quality Control material, and interview with the Technical Consultant (TC), the laboratory failed to put a new expiration date on Hematology Control material used on the Cell Dyne Emerald on the date of the survey. The TC confirmed on 10/29/19 at 10:20 am the laboratory failed to put a new expiration date on the control material.
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 records and interview with the Technical Consultant (TC), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment of Hematology QC used on the Cell Dyne Emerald analyzer from 9/19/17 to the date of survey. The findings include: 1. There was no documented evidence to show QC was verified in the calendar year 2108. 2. The procedure stated to run QC five times on different days but Lot 9154 expired on 9/20 /19 and QC Lot 9238 was run five times and verified on 9/23/19. 3. There were no instrument printout to show QC Lot 8267 and 8351 were verified. 4. The TC confirmed on 10/29/19 at 11:15 am that all assayed QC material was not verified before putting in use.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (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 Technical Consultant (TC), the laboratory failed to ensure control results were within manufacturers acceptable range each day of patient testing for Hematology Tests performed on the Cell Dyne Emerald analyzer from in May and June 2019. The

	findings include: 1. A review of the QC record for Lot 9070 revealed two of three levels of QC were not within range for parameters below: a. Platelets - Normal and Low QC on 5/30/19 b. Mean Corpuscular Volume (MCV) - Normal and High 6/28/19 c. White Blood Counts (WBC) - Normal and High 6/6/19, 6/10/19, 6/14/19 and 6/17 /19 2. Approximately 30 patients were run on each date listed above. 3. The TC confirmed on 10/29/19 at 11:35 am that patient results were reported when QC results were out.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(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. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual, Quality Control (QC) records and interview with the Technical Consultant (TC) the Testing Personnel, failed to follow the laboratory's Corrective Action (CA) policy and document CA to ensure accurate and reliable patient results were reported from 3/28/19 to 6/28/19. The finding includes: 1. There was no CA documented when QC was out of range and/or run repeatedly as follows: a. Low (L) QC Platelets were out of range: 3/29/19 thru 4/5/19, 4/8/19 thru 4/10/19, 4/12/19, 4/17/19, 4/23/19, 5/2/19, 5/6/19, 5/16/19 (QC was run three times), 5/23/19, 5/28/19, 5/30/19, 5/31/19, 6/5/19 and 6/10/19 (QC was run three times), 6/14/19, 6/17/19 (QC was run six times),6/18/19 thru 6/21/19, and 6/26/19 thru 6/28/19. b. Normal (N) QC was run five times on 4/17/19. Platelets were out of range: 5/30/19 and 6/14/19 (QC was run three times) c. N QC - White Blood Cells (WBC) were out of range 5/7/19 (run four times), 6/6/19, 6/10/19 (run four times), 6 /12/19 thru 6/14/19 (ran three time), 6/17/19 (ran 4 times) d. N QC - Mean Corpuscular Volume (MCV) was out of range 6/25/19 thru 6/28/19 (run four times on 6/25/19 and 6/27/19) e. N QC - % Lymphocytes and Granulocytes 6/17/19 (run four times) f. High (H) QC - MCV was out of range 5/9/19, 5/10/19, 5/14/19 (run three times), 5/14/19, 5/15/19, 6/28/19 (run five times) g. H QC - WBC were out of range 5 /7/19 (run three times), 5/8/19, 5/9/19 (run three times), 5/10/19, 5/14/19 (ran three times), 5/15/19, 6/4/19 (ran four times), 6/5/19, 6/6/19, 6/10/19 (ran four times), 6/14 /19, 6/14/19 (ran seven times) h. H QC - % Lymphocytes 6/28/19 (ran five times). 2. The TC confirmed on 10/29/19 at 11:00 am that controls were repeatedly run as stated above and CA was not documented.
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 Consultant (TC), the Testing Personal failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests

	performed on the Cell Dyne Emerald analyzer from 9/19/17 to the date of the survey. The TC confirmed on 10/29/19 at 10:45 am that trends and shifts were not reviewed.