

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2041037	(X3) Date Survey Completed 09/12/2018
Name of Provider or Supplier Titan Health Partners Llc	Street Address, City, State One Exchange Place, Jersey City, 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 Testing Personnel (TP), the laboratory failed to evaluate results when they received an unacceptable score in Hematology performed with the American Proficiency Institute (API) in the 1st and 2nd events of 2018. The findings include: 1. There was no review or evaluation documented when the laboratory received an unacceptable grade for White Blood Cell sample COU - 02 in 1-2018 and Monocyte % sample COU - 07 in 2-2018. 2. There was no documented evidence the laboratory investigated the failures. 3. The TP confirmed on 9/12/18 at 10:20 am that the laboratory did not perform and document an evaluation of unacceptable PT results.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Performance Specifications (PS) records and interview</p>

	<p>with the Testing Personnel (TP), the laboratory failed to verify Precision and Reportable Range for all Hematology analytes performed on the Beckman Coulter Unicel DX 600 analyzer before reporting patient test results from January 2018 to the date of survey. The TP confirmed on 9/12/18 at 11:40 am that all PS were not done.</p>
<p>D5807</p>	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the Testing Personnel (TP), the laboratory failed to ensure that the Normal Reference Intervals (NRI) were indicated on the FR for Hematology from July 2018 to the date of survey. The TP confirmed on 9/12/18 at 11:35 am that the NRI were not on the FR.</p>
<p>D5891</p>	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: a. Based on surveyor review of the Final Report (FR), Reference Intervals (RI) found in the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to correct problems in the postanalytic system when the test results were flagged as a abnormal from 9/15/16 to the date of the survey. The findings include: 1. The FR revealed that results were flagged as abnormal (AB) but were within the RI as below: a. Monocyte Number : 0.2 AB - RI 0.1 - 0.6 b. Monocyte Percent: 2.7 AB - RI 1.7 - 9.3 c. Granulocyte Percent: 67.6 AB - RI 42.2 - 75.6 d. Absolute Neutrophil Count: 5.2 Abnormal - RI 1.4 - 6.5 2. The TP confirmed on 9/12/18 at 11:10 am that AB flagging was incorrect on the FR. b. Based on surveyor review of the FR, Units of Measure (UM) found in the PM and interview with the TP, the laboratory failed to correct problems in the postanalytic system when the UM were not accurate on the FR in the calendar year 2018. The findings include: 1. The UM were reported as 10 for: Basophil Number (#), Eosinophil #, Neutrophil #, Lymphocyte #, White Blood Cells (WBC), UWBC, Red Blood Cells and Platelets. 2. The TP confirmed on 9/12/18 at 11:40 am that UM were incorrect on the FR.</p>
<p>D6013</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p> <p>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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance</p>

characteristics of the method;

This STANDARD is not met as evidenced by:

Based on surveyor review of the Performance Specification (PS) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that PS procedures performed on the Beckman Coulter Unicel DXH 600 analyzer were adequate from January 2018 to the date of survey. The findings include: 1. The LD did not review and sign the Method Comparison (MC) results. 2. There was no documented criteria for acceptance of the MC. 3. The LD confirmed on 9/12/18 at 11:15 am that PS records were not adequate.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director failed to establish a Competency Assessment (CA) procedure with the required elements from 9/15/16 to the date of the survey. The TP confirmed on 9/12/18 at 10:00 am that a CA procedure was not established.