

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0702454	(X3) Date Survey Completed 10/24/2018
Name of Provider or Supplier Titan Health Partners Llc	Street Address, City, State 629 Cranbury Rd, East Brunswick, 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
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p> <p>This STANDARD is not met as evidenced by: Based on observation of the Specimen Collection Tubes (SCT), Laboratory Information System, Specimen Requisition System (SRS), the AcT Diff analyzer, review of the Final Reports and interview with the Technical Consultant (TC), the laboartory failed to have an accurate collection time from pre-analytic, analytic and post-analytic phases of Hematology testing from March 12, 2018 to the day of survey. The findings include: 1. There was no collection time on the SCT. 2. The SRS had collection time when specimen was entered. 3. On the FR collection time was of the LIS entry when Identification number was generated. 4. None of the above times were accurate as there was no time on SCT. 5. The TC confirmed on 10/24/18 at 12:15 pm that collection time was ot correct through out the testing process.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p>

This STANDARD is not met as evidenced by:
Based on surveyor review of the Final Report (FR), observation of AcT Diff 2 analyzer and interview with the Technical Consultant (TC), the laboratory failed to ensure that the analyzer had accurate time adjusted from March 12, 2018 to the date of survey. The TC confirmed on 10/24/18 at 12:00 pm that the AcT Diff 2 was off by an hour and fifteen minutes on the day of survey and no one noticed it.

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Competency Assessment (CA) records and interview with the Technical Consultant (TC), the laboratory failed to document CA on assessment of test performance through testing unknown samples for one of four testing personnel in 2018. The TC confirmed on 10/24/18 at 11:00 am that CA was not done for the above procedure.