

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2101598	<b>(X3) Date Survey Completed</b>  10/22/2019
<b>Name of Provider or Supplier</b>  Total Healthcare	<b>Street Address, City, State</b>  3504 Hwy 280, Alexander City, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5221</b>	<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 a review of the 2017 - 2019 CAP (College of American Pathologists) Proficiency Testing records and an interview with Technical Consultant #2, the laboratory failed to document corrective action for three of six surveys with results less than 100 % (percent). The findings include: 1. A review of the CAP PT Hematology survey results revealed no documentation of investigation or corrective action for three surveys with results less than 100% as follows: A) 2018 FH1-B and 2019 FH1-A with scores of 80% for Lymphocyte % on each survey B) 2019 FH1-B Hematology with scores of 80% each for Hemoglobin and Mean Corpuscular Volume (MCV); a score of 60% for Mean Platelet Volume (MPV), resulting in a total score of 96% for Hematology. 2. In an interview on 10/22/2019 at 1:50 PM, Technical Consultant #2 confirmed the laboratory had failed to document an investigation, and any corrective actions for the CBC parameters with scores less than 100%. .</p>
<b>D5481</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Sysmex XP 300 Hematology analyzer quality control (QC) records and an interview with Technical Consultant #1, the surveyor determined the</p>

laboratory failed to ensure at least two levels of Hematology QC were within acceptable limits before patient testing began. This was noted on one day of patient CBC (Complete Blood Count) testing in 2019. The findings include: 1. A review of the daily Hematology QC printouts revealed the Low and Normal QC were outside acceptable limits on 8/21/2019. 2. During an interview and review of the QC records on 10/22/2019 at 1:10 PM, Technical Consultant #1 confirmed the above noted findings. The surveyor then asked if any patient CBC's were performed on 8/21/2019; Technical Consultant #1 checked the records and at 1:35 PM stated seventeen patient CBC's had been run and reported. Thus the above noted findings were confirmed. .

**D6041**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(3)

(b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

This STANDARD is not met as evidenced by:  
Based on a review of the CAP (College of American Pathologists) proficiency testing (PT) records and website information, and an interview with Technical Consultant #2, the surveyor determined the Technical Consultant failed to ensure the laboratory was enrolled with an approved proficiency testing program to ensure receipt of all three 2018 PT events for regulated tests in Hematology. The findings include: 1. A review of the CMS CASPER Report 0096D (Proficiency Testing Scores) for this facility's CLIA number revealed no scores were submitted to CMS for CBC (Complete Blood Count) parameters in Event 1-2018. 2. A review of the proficiency testing records revealed CAP was the PT provider in 2017-2019, however there were no results for the 2018-Event 1 Hematology survey (2018 FH1-A). A "Remedial Action Form" dated 2/14/2018 documented "no PT samples received d/t (due to) CAP survey renewal not being submitted; email went to former employee". [A review of the PT Schedule on the CAP website revealed the 2018 FH1-A Hematology survey was shipped to laboratories on 1/22/2018.] 3. During an interview on 10/22/2019 at 1:50 PM, the surveyor reviewed and confirmed the above noted findings with Technical Consultant #2. The surveyor explained each laboratory performing regulated tests must participate in three PT events annually, and must have procedures in place to ensure the annual PT order is submitted in a timely manner. Thus the above noted findings were confirmed. SURVEYOR ID#32558 Licensure and Certification Surveyor