

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  07D0856441	<b>(X3) Date Survey Completed</b>  04/25/2019
<b>Name of Provider or Supplier</b>  Western Connecticut Medical Group	<b>Street Address, City, State</b>  95 Locust Ave, Danbury, CT	
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>D2010</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to test proficiency testing (PT) samples the same number of times that it routinely tests patient samples. Findings include: 1. Record review on 4/25/19 of the laboratory's PT records from American Proficiency Institute (API) revealed the following complete blood count (CBC) samples were tested twice by two testing personnel (TP) before submission to API for evaluation. a. 2017 Event 1: Tested by TP# 1 &amp; 2 b. 2017 Event 2: Tested by TP# 3 &amp; 4 c. 2017 Event 3: Tested by TP# 5 &amp; 6 d. 2018 Event 1: Tested by TP# 4 &amp; 7 e. 2018 Event 2: Tested by TP# 8 &amp; 9 f. 2018 Event 3: Tested by TP# 3 &amp; 2 g. 2019 Event 1: Tested by TP# 10 &amp; 11 2. Record review on 4/25/19 of laboratory's CBC procedure manual revealed patient samples are routinely tested once. 3. Staff interview with the technical consultant on 4/25/19 at 10:15 AM confirmed the above findings. 4. The laboratory performs 18,650 CBC's annually.</p>
<b>D6051</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)(v)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure all testing</p>

personnel (TP) have tested unknown samples to demonstrate competency in performing laboratory tests in the specialty of hematology. Findings Include: 1. Record review of the American Proficiency Institute's (API) complete blood count (CBC) attestation sheets on 4/25/19 revealed 8 of 14 TP did not examine proficiency testing material to accurately assess their skills in 2017 and 2018. 2. Record review of employee competency records on 4/25/19 revealed 8 of 14 TP did not examine previously analyzed specimens, internal blind testing samples or external proficiency testing samples to accurately assess their skills in 2017 and 2018. 3. Staff interview with the technical consultant on 4/25/19 at 11:00 AM confirmed the above findings.