

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  07D2094414	<b>(X3) Date Survey Completed</b>  08/01/2019
<b>Name of Provider or Supplier</b>  Westchester Medical Group Pllc	<b>Street Address, City, State</b>  644 West Putnam Ave, Greenwich, 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>D5781</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to take corrective action when the laboratory freezer temperature was out of range. Findings include: 1. Record review of the laboratory freezer temperature log on 8/1/19 revealed: a. Acceptable freezer temperature range in 2017 and to date in 2019 was -20C or colder. b. Corrective action was not documented for each occurrence outside the above acceptable range. 2. Record review of the Quidel Troponin and D-dimer package inserts on 8/1/19 revealed the storage stability requirements for the quality control storage is -20C or colder. 3. Record review of the laboratory's "Temperature Procedure" on 8/1/19 revealed the following: a. The Freezer temperature range was -15C to -35C, which did not correlate with the manufacture's package insert indicated above. b. On Page 2 of the procedure states "The staff responsible for logging the temperatures...also verifying temperatures falls into the range...readings outside of the range should be documented as well. 4. Staff interview with technical consultant (TC) on 8/1/19 at 1:30 PM confirmed the freezer temperature was out of range on many</p>

	<p>occasions each month for 2017 and to date in 2019. TC also stated that the testing personnel were not aware that temperatures below -20C were outside the acceptable limits. 5. The laboratory performs 260 Troponin and D-dimer tests annually.</p>
<p><b>D6046</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to evaluate the competency of testing personnel (TP) to perform moderate complexity testing annually. Findings include: 1. Record review of the laboratory's TP competency records on 8/1/19 revealed 47 of 51 TP performing moderate complexity testing were not evaluated in the Greenwich location in 2017 and 2018 to assess their competency in all six required competency assessment criteria. 2. Staff interview with technical consultant (TC) on 8/1/19 at 11:00 AM confirmed 47 of 51 TP were not evaluated in all six required competency assessment criteria in the Greenwich location in 2017 and 2018 to perform moderate complexity testing. TC stated, the TP were trained at their other locations and would rotate amongst the locations. 3. Laboratory performs 5,520 moderate complexity tests annually.</p>
<p><b>D6051</b></p>	<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 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) proficiency testing (PT) attestation sheets on 8/1/19 revealed not all TP examined PT material to accurately assess their skills in 2017 and t2018. 2. Record review of employee competency records on 8/1/19 revealed not all TP examined 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 (TC) on 8/1/19 at 1:20 PM confirmed not all TP had examined unknown samples including proficiency testing material to accurately assess their skills in the specialty of hematology in 2017 and 2018. 4. Laboratory performs 5, 250 tests annually. * This is a repeat deficiency</p>
<p><b>D6053</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least</p>

semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to evaluate testing personnel (TP) competency necessary to perform moderate complexity laboratory testing twice during the first year of employment. Findings include: 1. Record review of the new testing personnel competency records on 8/1/19 revealed the laboratory failed to provide documentation of competency assessment twice during the first year of employment for 47 of 51 new TP. 2. Interview with the technical consultant on 8/1/19 at 11:30 AM confirmed 47 of 51 new TP were not assessed twice during the first year of employment. 3. The laboratory performs 5,250 moderate complexity tests annually \* This is a repeat deficiency

**D6136**

**CLINICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1457

The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to have a policy in place to assess the competency of all laboratory personnel. Findings include: 1. Record review of the laboratory's personnel competency records on 8/1/19 revealed the following: a. The laboratory did not have a policy in place to assess the competency of the clinical consultant. b. Competency documentation for the above laboratory personnel was not available. 2. Staff interview with the laboratory technical consultant on 8/1/19 at 11:15 AM confirmed the above findings.