

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D2127860	<b>(X3) Date Survey Completed</b>  05/02/2019
<b>Name of Provider or Supplier</b>  Westchester Medical Group Pllc	<b>Street Address, City, State</b>  1084 North Broadway, Yonkers, NY	
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>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on a review of storage refrigerator temperature records and an interview with the laboratory managers, the laboratory's storage refrigerator temperature was not within acceptable and remediation was not performed. Findings Include: 1) Controls and calibrator for the AcT Diff II are stored in the storage refrigerator located in the phlebotomy area. 2) The manufacturer package insert states that controls and calibrator are to be stored at a temperature range of 2 - 8 C. 3) It was confirmed with the laboratory managers on May 2, 2019, at approximately 12:45 pm that the refrigerator temperatures were out of acceptable range for the following days and remediation was not performed: April 18, 19, 2018 - 1C May 11, 2018 - 0C May 23, 27, 2018 - 15C June 5, 7, 8, 9, 23, and 25, 2018 - 9C June 9, 11, 12, 13, 14, 16, 20, and 21, 2018 - 10C June 18, 2018 - 13C June 19, 2018 - (-2C) June 30, 2018 - 0C July 9, 2018 - 9C July 31, 2018 - 0C August 27, 2018 - 10C January 19, 2019 - 0C January 26, 2019 - 1C February 8, 2019 - 1C March 22, 30, 2019 - 1C March 30, 31, 2019 - 1C April 19, 26, 2019 - 1C</p>