

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0139635	(X3) Date Survey Completed 11/20/2018
Name of Provider or Supplier Westchester Medical Group Pllc	Street Address, City, State 3030 Westchester Avenue, Purchase, NY	
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
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency test records and an interview with the laboratory manager, the laboratory failed to perform PT testing in the same manner as patient specimen testing. Findings Include: It was confirmed by the laboratory manager on November 20, 2018, at approximately, 12:10 pm that PT specimens are always performed by one of four testing personnel, whereas, patient specimens are performed by four of four testing personnel.</p>
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of procedures, surveyor observation and an interview with the</p>

	<p>laboratory manager, the laboratory failed to establish and have accessible a safety procedure to protect the laboratory staff from physical, chemical, biochemical, biohazard material and electrical hazards. Findings Include: It was confirmed by the lab manager on November 20, 2018, at approximately 12:10 pm that 1) a water/coffee flask was on the same counter where blood testing is performed on the Coulter AcT Diff II. 2) a nurse was observed eating in the laboratory.</p>
<p>D5413</p>	<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 lack of humidity records and an interview with the Moh's processor, the laboratory failed to follow the manufacturer's instructions to monitor and document the room humidity where testing is performed. Findings Include: It was confirmed by the laboratory manager and the Moh's processor, on November 20, 2018, approximately 11:00 am that the Moh's processor failed to follow the manufacturer's written criteria to monitor and document the humidity of the room where Moh's testing is performed from the date of the last survey, November 10, 2016 through the date of this survey.</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policy/procedure manual, observation and an interview with the laboratory manager, the laboratory director failed to ensure that the laboratory's quality assessment (QA) program was followed. Refer to D2006, D3011 and D5413</p>