

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 33D2094610	<b>(X3) Date Survey Completed</b> 11/13/2018
<b>Name of Provider or Supplier</b> Optum Medical Care Pc	<b>Street Address, City, State</b> 340 Dogwood Avenue, Franklin Square, 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>D5211</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's Proficiency Testing (PT) reports and interview with the office manager, the laboratory failed to evaluate, perform and document remedial action for the PT scores less than 100% for the following analyte in 2018: FINDINGS: 1. On 11/13/2018 at 11:00 AM the office manager confirmed the surveyor's review of the PT reports finding that the laboratory participated in the College of American Pathologists (CAP) PT program to verify twice annually the accuracy of the urine colony count testing. 2. The office manager confirmed that the laboratory failed to document corrective action for the score of 50% for 2018 second event colony count.</p>
<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:</p>

Based on a surveyor's review of laboratory temperature records and an interview with the office manager, the laboratory failed to follow the manufacturer's instructions for monitoring incubator temperatures for incubating throat cultures and urine culture. Findings Include: 1. The laboratory performs throat and urine cultures. The manufacturer of the throat culture media and the manufacturer of the Uri-Cult Paddles used for testing require that the incubation temperature to be in the range of 35-37 degree Celsius. No records of the incubator temperature for the calendar year 2017. 2. Approximately 1600 specimens were tested and reported for throat culture and approximately 8 specimens were tested and reported for colony count in calendar year 2017.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:  
Based on a surveyor's review of the personnel files and interview with the office manager, the laboratory director, acting as the technical consultant, failed to perform annual competency evaluation for the five of seven testing persons in calendar year 2017.