

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0954485	(X3) Date Survey Completed 09/11/2018
Name of Provider or Supplier Buffalo Medical Group Pc	Street Address, City, State 3900 North Buffalo Road, Orchard Park, 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
D5413	<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 surveyor's review of the laboratory's temperature records and an interview with the laboratory supervisor, the laboratory failed to follow the laboratory's temperature policy for laboratory testing. FINDINGS: 1. The laboratory's temperature policy requires the refrigerator temperature to be between 4 to 10 degree Celsius. 2. The laboratory supervisor confirmed on September 11, 2018 at approximately 2:30 PM, the surveyor's findings that the laboratory failed to take and document corrective action for the months March & April 2017 and January through May 2018 when the refrigerator temperatures were out of acceptable range for 23 days in 2017 and 68 days in 2018.</p>
D5781	<p>CORRECTIVE ACTIONS 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)</p>

(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.

This STANDARD is not met as evidenced by:

Based on a surveyor's review of laboratory's temperature records and an interview with the laboratory supervisor, the laboratory failed to document corrective action when the refrigerator temperatures were outside the established ranges. Refer to D5413.