

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0159705	(X3) Date Survey Completed 07/23/2019
Name of Provider or Supplier Caremount Medical Pc	Street Address, City, State 40 Crossways Park Drive, Suite 103, Woodbury, 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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory equipment maintenance records and interview with the laboratory testing person and the laboratory quality assurance administrator, the laboratory failed to follow the laboratory's established equipment maintenance policy and the manufacturer maintenance requirement, which require the laboratory to perform an annual preventative maintenance for the Microscope used for the manual differentials and Reticulocyte count slide reading. FINDINGS: 1. The laboratory equipment maintenance policy and the manufacturer of the Microscope require annual preventive maintenance of the Microscope used for the Manual Differentials and the Reticulocyte Count slide reading. 2. On July 23, 2019 at approximately 11:30 AM the testing person and the quality assurance administrator confirmed surveyor findings that the preventive maintenance of the Microscope was not performed in calendar years 2017 and 2018. 3. Approximately 400 patient slides were read and reported for Manual Differentials and Reticulocyte Count during this time frame.</p>
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:

Based on surveyor review of hematology Quality Control (QC) records and confirmed in an interview with the laboratory testing person and the laboratory quality assurance administrator, the laboratory failed to perform and document at least two levels of QC for manual Reticulocyte Count on each day of patient testing in calendar year 2018 and up to survey date. Approximately 200 patient samples were tested and reported for Reticulocyte Count during the above time frame.