Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0155533	08/02/2023
Name of Provider or Supplier	**Street Address, City, State**	
Woodmere Medical Associates	15 Irving Place, Woodmere, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on the review of the American Proficiency Institute (API) Proficiency Test (PT) records, the laboratory failed to rotate throat culture 2022 event 1, 2, 3 proficiency testing between testing person #1 and #2. Confirmed the finding on an interview with the testing person #1 and #2 on 8/2/2023 about 12:30pm.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on the review of competency evaluation documentation, the laboratory failed to perform annual competency for calendar year 2022. Confirmed on an interview with technical consultant on 8/2/2023 about 12pm.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) 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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Control (QC) records, the laboratory failed to perform a verification of current lot number to new lot number of the hematology analyzer Pentra 60 C+. FINDINGS: 1. The new QC lot to lot validation documentations of hematology analyzer were not available upon request during the survey since the hematology analyzer implementation date to survey date. 2. The testing person #1 and testing person #2 confirmed during interview on 8/2/2023 about 1pm, the new lot to lot validation of QC material for hematology analyzer was not performed.