Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2152586	04/30/2025
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Medical Of Grand Central Pc	1200 Gravesend Neck Road, Suite Lc, Brooklyn, 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
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Quality Control (QC) records, monthly QC data, Standard Operating Procedures (SOPs), as well as interview with the Technical Consultant (TC), the laboratory failed to ensure QC control material results met the laboratory's acceptability criteria before reporting patient test results. FINDINGS: 1. QC results were unacceptable for Progesterone, Follicle Stimulating Hormone, Luteinizing Hormone, Prolactin, Prostate Specific Antigen, Thyroid Stimulating Hormone, Vitamin D, Folate, and Free Thyroxine analytes. 2. There was no documentation of repeated QC performance prior to patient specimen testing and results reporting. 3. This is contrary to instructions indicated in the current, approved SOPs that "no specimens are to be tested or reported when controls and instrument calibration are unacceptable." 4. Approximately 121 patients were tested with unacceptable QC results for the respective analytes. 5. The TC confirmed the findings on April 30, 2025, at 12:00 P.M.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable

	patient test results. This STANDARD is not met as evidenced by: Based on review of QC records, monthly QC data, current, approved SOPs, as well as interview with the TC, the laboratory failed to perform and document corrective action for unacceptable QC results which failed to meet the laboratory's established criteria for acceptability to ensure reporting of accurate and reliable patient results. Refer to D5481.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of QC records, monthly QC data, current, approved SOPs, as well as interview with the TC, the Laboratory Director (LD) failed to ensure that the established quality control and quality assessment program identified failures in quality as they occurred. Refer to D5481 and D5783.