Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2198228	08/26/2025
Name of Provider or Supplier	**Street Address, City, State**	
Greenberg Medical Services Pc	160 Crossways Park Drive, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on review of Standard Operating Procedures (SOPs), lack of Quality Assessment (QA) policies, lack of Quality Control (QC) documentation as well as interview with the Office Manager (OM), the laboratory failed to retain QC records documenting all analytic system activities. FINDINGS: 1. There was no documentation of twice year verification for calendar year 2024. 2. The current, approved SOPs did not include instructions for retaining such records for minimum two years. 3. The OM confirmed the findings on August 26, 2025, at approximately 11:00 A.M.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of SOPs, lack of QA policies, as well as interview with the OM, the laboratory failed to establish written policies and procedures for an ongoing

	mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory system. FINDINGS: 1. There was no documentation of annual QA performance and review from 2023 through the survey date. 2. The current, approved SOPs did not include instructions for performing an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions and all locations/sites where on-site laboratory testing was performed. 3. The OM confirmed the findings on August 26, 2025, at approximately 11:00 A.M. Repeated deficiency from survey on December 02, 2022.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observations, review of current, approved SOPs, as well as interview with the OM, the laboratory failed to remove from inventory expired reagents in the patient specimen processing laboratory. FINDINGS: 1. The surveyor's observations in the specimen processing laboratory confirmed on August 26, 2025, at approximately 10:30 A.M. the following reagents were not removed from inventory. a. Neg - 50, lot 2585T, expiration: April 2023, one bottle. b. Optic Mount, lot 107965, expiration: October 31, 2022, one bottle. c. Hematoxylin, lot 2219920, expiration: July 28, 2024, one 1 bottle. d. Scott's Tap Water Substitute, lot 2403936, expiration: February 19, 2025, three bottles. 2. The current, approved SOPs did not include instructions for removal of reagents, solutions, control materials, calibration materials, and other supplies from inventory when they have exceeded their expiration date. 3. OM informed the surveyor that the respective reagents were not utilized for patient specimen processing. 4. OM confirmed the findings on August 26, 2025, at approximately 10:30 A.M.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the SOPs and manufacturer's specifications, lack of maintenance records, as well as interview with the OM, the laboratory failed to perform and document equipment maintenance and function checks with at least the frequency specified by the manufacturer. FINDINGS: 1. There was no documentation of cryostat, microscope, and fume hood preventive maintenance records since the indicated expiration of March 17, 2023. 2. The current, approved SOPs did not include instructions for performing and maintaining records for such activity. 3. The OM confirmed the findings on August 26, 2025, at approximately 10:30 A.M.
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 SOPs, lack of QA policies, as well as interview with the OM, the Laboratory Director (LD) failed to draft, approve quality assessment programs to assure the quality of laboratory services provided and to identify failures in quality as they occur. FINDINGS: 1. The current, approved SOPs did not include QA policies for performing an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions and all locations/sites where on-site laboratory testing was performed. 2. The OM confirmed the findings on August 26, 2025, at approximately 11:00 A.M.