Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0888263	05/19/2026
Name of Provider or Supplier	**Street Address, City, State**	
Town Park Cmc Laboratory	750 Town Park Lane, Kennesaw, GA	

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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on May 19, 2026. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) document review and staff interview, the laboratory failed to document ALL quality assessment activities on a monthly basis as stated in their QA policy manual from July through December 2024. Findings: 1. A review of the laboratory QA documents revealed the technical supervisor (TS) and laboratory director failed to review and sign monthly quality activity checklists and maintenance logs from July 2024 through December 2024. 2. A review of daily maintenance logs including: Room Temperature(RT), humidity, eye wash, freezer, refrigerator, centrifuge cleaning and DI water check logs were not reviewed and signed by the laboratory director (LD) or TS from July 2024 through December 2024. 3. Interviews with the (TS) on 05/19/2026 at approximately 01:35 PM in the conference room confirmed the above laboratory logs and QA checklists were not reviewed and signed by the TS or LD from July 2024 through December 2024.
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 maintenance records review and staff interviews, the laboratory failed to perform and document ALL equipment maintenance checks for the Abbott IStat 1 chemistry analyzer as required by the instrument manufacturer every six months in 2024. Findings: 1. A review of Abbott IStat 1 electronic simulator maintenance logs revealed that the Thermal probe, CLEW upload and calibration verification was NOT performed in June and December of 2024. 2. An interview with the technical supervisor (TS), at approximately 1:40 PM, in conference review room , confirmed that no documentation of the thermal probe upload and calibration was performed in June and December of 2024.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on documents review and interview with the manager, the laboratory director failed to ensure that all phases of quality testing (preanalytic, analytic and post analytic) guidelines were followed to identify and fix problems in the laboratory from July 2024 - December 2024 as required by Clinical Laboratory Improvement Amendments (CLIA). Findings: 1. (QA) documents review revealed the lab director and the technical supervisor (TS) failed to review and sign ALL monthly maintenace checklists to identify and fix problems in the laboratory from July 2024 - December of 2024. 2. An interview with the technical supervisor(TS) (TP#2 on form CMS 209) in the conference review room on 05/19/2024 at approximately 1:20 PM, confirmed the lab director failed to ensure proper oversight of the laboratory from July 2024 - December 2024.