

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0888263	(X3) Date Survey Completed 06/29/2022
Name of Provider or Supplier Town Park Cmc Laboratory	Street Address, City, State 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 June 29, 2022. 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:
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on observation during the lab tour and staff interview, the laboratory failed to ensure reagents, tubes, and test kits were stored in proper conditions by monitoring the environmental specifications by the manufacturers. Findings include: 1. Observation during the laboratory tour on 6/29/2022 at approximately 10:20 a.m. revealed the room temperature or humidity of the storage room were not monitored to ensure proper storage conditions. 2. Interview with the laboratory technical supervisor (CMS 209) in the laboratory on 6/29/2022 at approximately 10:20 a.m. confirmed the room temperature or humidity of the storage room were not monitored to ensure proper storage conditions.</p>
D6086	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)</p>

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:

Based on review of the Sysmex XN 10 installation data and staff interview, the laboratory director (LD) failed to approve the method comparison, carryover study, and reportable range verification performed on November 4, 2020. Findings include: 1. Review of the Sysmex XN 10 installation data including the method comparison, carryover verification, and reportable range verification revealed the LD did not approve the data before the XN 10 was used to report patient results. 2. Interview with the technical supervisor (CMS 209) on 6/29/22 at approximately 1:30 p.m in his office, verified the LD failed to approve the aforementioned installation data.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control 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 Blood Bank Quality Controls (QC) records, procedure manual (SOP) and an interview with the laboratory technical supervisor, the laboratory director failed to provide overall Quality Assurance (QA) management and direction of the laboratory as required. Findings include: 1. Review of Blood Bank Quality Control (QC) records revealed the Blood Bank (QC) was not reviewed for July, August, September, November, or December 2021 by the Technical Supervisor (TS) or by the Laboratory Director. 2. Interview with the laboratory Technical Supervisor, at approximately 1:30 pm, on 6/29/2022 in the TS office, confirmed Blood Bank (QC) was not reviewed by the Technical Supervisor (TS) or Laboratory Director for the aforementioned dates.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on review of testing personnel documents and staff interview, the Technical Supervisor (TS) failed to perform annual competency on all testing personnel. Findings include: 1. Review of testing personnel training and competency documents revealed the TS failed to perform competency evaluations on 7 of 8 testing personnel (CMS 209) for the year of 2020. Documents were not available to review on staff # 1, 2, 3, 4, 5, 7, and 9 (CMS 209) for 2020. 2. Review of testing personnel training and competency documents revealed the TS failed to perform competency evaluations on

2 of 8 testing personnel (CMS 209) for the year of 2021. Documents were not available to review on staff # 3 and 7 (CMS 209) for 2021. 3. Interview with the TS (CMS 209) in his office on 6/29/22 at 1245 p.m confirmed the aforementioned statements.