

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0888263	(X3) Date Survey Completed 01/07/2020
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 January 07, 2020. 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:
D6076	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of Blood Bank maintenance and Quality Controls (QC) records, procedure manual (SOP) and an interview with the laboratory coordinator, the laboratory director failed to provide overall Quality Assurance (QA) management and direction of the laboratory as required. Findings include: Refer to D6093, D6094</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>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 coordinator, the laboratory director failed to provide overall Quality Assurance (QA) management and direction of the</p>

laboratory as required. Findings include: 1.) A review of Blood Bank Quality Control (QC) records revealed that Blood Bank (QC) was not reviewed in 2018 and 2019 by the Technical Supervisor (TS) or laboratory director. 2.) An interview with the laboratory coordinator at approximately 01:55 pm on 01/07/2020 in the 2nd floor conference room confirmed Blood Bank (QC) was not reviewed by the Technical Supervisor (TS) or laboratory director for two years as part of overall (QA) in 2018 and 2019.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the 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 Blood Bank Quality Controls (QC) records, procedure manual (SOP) and an interview with the laboratory coordinator, the laboratory director failed to provide overall Quality Assurance management and direction of the laboratory as required. Findings include: 1.) Blood Bank maintenance records review revealed the followings: freezer, refrigerator and incubator temperature logs were not reviewed for accuracy by the Technical Supervisor (TS) or laboratory director from September 2018 to December 2018. 2.) An interview with the laboratory coordinator at approximately 01:45 pm on 01/07/2020 in the 2nd floor conference room, confirmed the aforementioned Blood bank temperature logs were not reviewed by the (TS) or laboratory director as part of overall Quality Assurance (QA) from September to December 2018.