Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2152556	08/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Georgia Protoncare Center, Inc	615 Peachtree Street, Ne, Atlanta, 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 August 26, 2021. 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:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists (CAP) records and staff interview, the lab failed to rotate Proficiency Test (PT) samples among testing personnel (TP). Findings include: 1. Review of the CAP attestation statements revealed the PT samples were run by the same TP # 5 (CMS 209) for the 2019 event #3, 2020 event #1 & 2. 2. Interview with staff #1 (CMS 209) on 8/26/21 at approximately 11:00 AM, confirmed the PT was not rotated between all TP.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified

	in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on proficiency testing document review and staff interviews, the laboratory failed to maintain satisfactory performance in two of three consecutive events (2020 event #3 and 2021 event #1), resulting in the first unsuccessful occurrence for Chemistry #245 including: creatine # 0405. Findings include: For details refer to D2089
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) document review and staff interviews, the laboratory failed to participate in the College of American Pathology (CAP) proficiency testing events 2020 #3 and 2021 #1. The laboratory failed to participate in two consecutive PT events, which resulted in the 1st unsuccessful occurrence for Routine Chemistry #0245, Creatine analyte #0405. Findings include: 1. Review of the facility CAP PT reports and the CMS Casper 096 report, the laboratory failed the speciality of Chemistry #310, Creatine analyte #0405 for events of 2020 #3 and 2021 #1 with scores of 0% on both events. 2. Interviews with staff #1 (CMS 209) and a nurse supervisor on 8/26/21 at approximately 11:15 AM in office #1106, confirmed non-participation in the aforementioned PT events.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by:

	Based on proficiency testing document review and staff interviews, the laboratory director failed to ensure the lab maintain satisfactory performance in two of three consecutive events (2020 event #3 and 2021 event #1), resulting in the first unsuccessful occurrence for Chemistry #245 analyte creatine # 0405. Findings include: Refer to D6016 & D6018
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on document review of the laboratory's proficiency testing (PT) reports and staff interview, the laboratory director failed to ensure the laboratory maintained satisfactory performance in two of three consecutive events (2020 #3 and 2021 #1), resulting in the first unsuccessful occurrence for Creatine, analyte # 0405. Findings include: 1. Review of the laboratory's College of American Pathologist (CAP) PT) reports disclosed the laboratory failed analyte # 0405, Creatine on event#3 of 2020 with a score of 0% and event #1 of 2021 with a score of 0%. 2. Interview with staff #1 (CMS 209) on 8/26/21 at 11:11 AM in office #1106, confirmed the laboratory failed the aforementioned testing events, resulting in the first unsuccessful performance.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory's Proficiency Testing (PT) records and staff interview, the laboratory director (LD) failed to ensure PT results were reviewed upon receipt from the PT agency. Findings include: 1. Review of College of American Pathologists (CAP) PT records for 2020 events #2 and #3, and 2021 event #1 revealed the LD did not review PT results received from CAP. 2. Interviews with staff #1 (CMS 209) and a nurse supervisor on 8/26/21 at approximately 11:15 AM in office #1106, confirmed the LD failed to review the aforementioned PT events.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to specify, in writing the duties and responsibilities of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of laboratory testing. Findings include: 1. SOP review revealed the LD failed to specify in writing the duties and responsibilities of each person engaged in the performance of all phases of laboratory testing. 2. Interview with Staff #1 (CMS 209) in office# 1106 on 8/26/18 at approximately 11:00 a.m. confirmed the SOP did not contain a duties and responsibilities policy and procedure.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: I. Based on review of testing personnel (TP) documents and staff interview , the technical consultant (TC) failed to perform annual competency on all testing personnel. Findings include: 1. Review of TP competency documents revealed the TC did not evaluate the 2020 annual competency of TP #4, 5, or #7 (CMS 209). (Lack of 2020 competency documents) 2. Interview with staff #1 (CMS 209) on 8/26/21 at 11: 06 AM in office #1106, confirmed the lack of 2020 competency for the aforementioned TP. II. Based on review of competency assessment records and interview with laboratory staff, the Technical Consultant (TC) failed to perform annual competency assessments for testing personnel for the years of 2019 and 2021. Findings include: 1. Review of competency assessment records revealed staff #5 (CMS 209) performed the competency assesments for TP in 2019 and 2021. 2. Review of educational documents revealed TP #5 (CMS 209) did not qualify as TC by education or experience. 3. Interview with staff #1 (CMS209) on 8/26/21 at 11:55 AM in office #1106, confirmed the competencies were not performed by a qualified TC.