Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2152556	08/28/2019
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	An initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on August 28, 2019. 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:
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 the laboratory records, the standard operators procedure manual (SOP), and staff interview, the laboratory failed to establish and follow written policies and procedures for an ongoing review to assess all facets of the laboratory's technical and non-technical functions (QA). Findings include: 1. Review of the SOP and lab records provided revealed the lab did not have a QA plan to follow. 2. Interview with staff #1 and Staff #11 (CMS 209 form) on 8/28/19 in office #2 on the main lobby level at 11:30 AM, confirmed the lab did not have a QA plan.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: Based on review of the standard operators procedural manual (SOP) and staff interview, the lab failed to include written procedures for all tests or procedures required. Findings include: 1. Review of the SOP revealed the lab did not have procedures for: duties and responsibilities for all lab positions, safety, critical values, inoperable test system, corrective actions, or proficiency testing (PT). 2. Interviews with staff #1 and staff #11 (CMS 209 form) on 8/28/19 in office #2 on the main lobby level at 11:30 AM, confirmed the SOP did not have the aforementioned procedures.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the standard operators procedural manual (SOP) and staff interview, the lab director (LD) failed to approve, sign, and date the SOP before use. Findings include: 1. Review of the SOP revealed the LD did not approve, sign, and date the SOP before use. 2. Interviews with staff #1 and staff #11 (CMS 209 form) on 8/28/19 in the office #2 on the main lobby level at 11:30 AM, confirmed the SOP was not signed, dated, or approved by the LD.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on review of temperature log sheets, operators manual, and staff interview, the laboratory failed to monitor the room temperature (RT) and relative humidity (RH) as required. Findings include: 1. Review of temperature logs sheets revealed the RT and RH were not being monitored. 2. Review of the Novabiostat Sensor's operators guide revealed it was required to monitor RT and RH for proper operation. 3. Interview with staff #11 (CMS 209 form) on 8/28/19 in the lab at 10 AM, confirmed the RT and RH were not monitored.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 record review and interview with testing personnel (TP), the lab failed to document maintenance on the Novabiostat Sensor analyzer per the procedure manual. Findings include: 1. Record review revealed the lab did not document maintenance on the Novabiostat Sensor analyzer. 2. Interview with TP #11 (CMS 209 form) on 8/28 /19 in office #2 on the main lobby level at 11:30 AM, confirmed the maintenance was not documented.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on lab report review and staff interviews, the laboratory failed to include all the required information on the in-house laboratory test reports. Findings include: 1. Review of patient test report revealed the report did not contain the name and address of the laboratory location where the test was performed. 2. Interview with TP #11 (CMS 209 form) on 8/28/19 in office #2 on the main lobby level at 11:28 AM, confirmed the required information was not on the report.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) document review and staff interviews, the lab director (LD) failed to ensure the lab was enrolled in a PT program. Findings include: 1. Review of College of American Pathology (CAP) PT reports revealed the LD did not enroll the lab in PT until 2019 testing event #2. 2. . Interviews with staff #1 and staff #11 (CMS 209 form) on 8/28/19 in office #2 on the main lobby level at approximately 11:30 AM, confirmed the LD did not enroll the lab in 2019 PT testing event #1.
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 proficiency testing (PT) document review and staff interviews, the lab director (LD) failed to review and sign the PT result reports received from the vendor. Findings include: 1. Review of College of American Pathology (CAP) PT reports revealed the LD did not review the results received for 2019 testing event #2. 2. . Interviews with staff #1 and staff #11 (CMS 209 form) on 8/28/19 in office #2 on the main lobby level at approximately 1:00 PM, confirmed the LD did not review the PT results.