Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2157969	07/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Preventclinic, Inc,	6000 Lake Forrest Drive, Nw, Suite 540, Sandy Springs, 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 July 28, 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:
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on the review of American Proficiency Institute (API) Proficiency Testing (PT) records and interviews with the laboratory director and TP # 2 (CMS 209), the laboratory director failed to review and attest that PT samples were tested in the same manner as patient specimens in 2020 and 2021. Findings include: 1. Review of (API) PT records revealed the laboratory failed to provide or retain signed attestation forms by the laboratory director for all events in 2020 and 2021. 2. An interview with staff (TP# 2 CMS 209) on 07/28/2021 at approximately 1:00 pm in the break room confirmed signed (API) PT Attestation documents for 2020 and 2021 were unavailable at the time of survey.
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 review of the laboratory procedure manual (SOP), quality assurance (QA) policy and interviews with staff and laboratory director, the laboratory failed to have an adequate (QA) policy to assess, evaluate, monitor and correct problems in the laboratory as required by CLIA. The findings include: 1. Review of QA records revealed that the laboratory's current QA policy does not indicate the necessary steps to be taken to identify and correct problems. Corrective actions and QA activities were not documented in the laboratory to reflect all phases of the QA policy (Pre analytic, Analytic and Post Analytic phases) in 2020 and 2021. 2. An interview with the laboratory director and TP #2 (CMS 209) on 07/28/ 2021 at approximately 1:1 PM in the break room confirmed that the laboratory was not documenting QA activites in 2020 and 2021.
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 laboratory procedure manual (SOP) and staff interviews, the laboratory director (LD) failed to create a Standard Operating Procedure (SOP) specific to Brain Natriuretic Peptide (BNP) testing on the Abbott I-Stat Chemistry analyzer. Findings include: 1.) Review of current SOP approved on 11/22/2018 on the I-Stat analyzer by the laboratory director, does not have a concrete Step by step testing of BNP. 2.) No normal ranges and panic values were found in the (SOP). 3.) Interviews with TP#2 (CMS 209) and the lab director at approximately 1:00 PM on 07 /28/2021 in the break room confirmed the above findings.
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 the laboratory tour and staff interview, the laboratory failed to have professional maintenance on the centrifuge as required. Findings include: 1. Observation during the laboratory tour revealed that the Horizon 642E Drucker Diagnostics centrifuge was NOT calibrated annually as required. The last calibration was performed on 02/21/2019. 2. An interview with testing personnel #2 (CMS 209) on 07/28/2021 in the breakroom at approximately 10:00 AM, confirmed the lack of the aforementioned professional maintenance on the centrifuge.

D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Quality Control (QC) document review, staff and laboratory director interviews, the laboratory failed to perform and document QC on each day of patient testing for Brain Natriuretic Peptide (BNP) on the Abbott I-Stat 1 Chemistry Analyzer in 2020 and 2021. Findings include: 1. Based on review of QC documents, liquid controls were NOT performed during patient testing on a daily basis 2020 and 2021. 2. There was NO Individualized Quality Control Plan (IQCP) established by the laboratory. 3. During an interview TP#2 (CMS-209) on 07/28/2021 at approximately 12:00 PM in the break room, it was confirmed liquid controls were not performed on a daily basis during patient testing in 2020 and 2021.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on Quality Assurance(QA) manual review and interview with the staff, the Lab Director(LD) failed to review all QA documents on a monthly basis as required by Clinical Laboratory Improvement Amendments (CLIA). Findings include: 1. Quality Assurance (QA) documents review revealed the laboratory director did not review quality assurance documents including all maintenance and temperature and Humidity logs as required in 2020 and 2021. 2. An interview with the lab director and TP#2 (CMS 209) in the break room on 07/28/2021 at approximately 12:40 PM, confirmed the LD did not review the aformentioned logs 2020 and 2021.