Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2157969	08/01/2019
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	An initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on August 01, 2019. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director, the laboratory failed to enroll in a CMS approved Proficiency Testing (PT) Program for Chemistry as required by Clinical Laboratory Improvement Amendments. The findings include: 1.) A review of Proficiency Testing (PT) records revealed that patient testing on the Abbott I-Stat 1 began in November of 2018 and the laboratory should have enrolled in Proficiency Testing by the 1st quarter of 2019 for Chemistry I-Stat BMP but failed to do so. 2.) An interview with the laboratory director at approximately 11:50 a.m on August 1, 2019 in the break room confirmed the clinic is not yet enrolled in proficiency testing (PT) for Chemistry as of 08/1/2019.
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 document review and an interview with the Laboratory director, it was determined that the laboratory failed to check Relative Humidity (RH), Room Temperature (RT) and Refrigerator temperatures daily as recommended by manufacturer of the Abbott I-Stat 1 Chemistry Analyzer. Findings include: 1.) Document review revealed that there was a lack of documentation for the required daily refrigerator, room temperature, and Relative Humidity (RH) checks, as reccomended by the manufacturer, from November 2018 through August of 2019, during patient testing. 2.) An interview with the Laboratory director at approximately 11:55 am, on August 1, 2019, in the conference room confirmed that daily temperatures and (RH) were not documented during patient testing from November 2018 to August 2019.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on the I-Stat 1 calibrations document review and interview with the laboratory director, the laboratory failed to perform instrument calibrations every six months, as required. Findings include: 1. I-Stat 1 calibrations document review revealed the laboratory failed to perform instrument calibrations between November 2018 and August 2019. 2. An interview with the laboratory director on August 01, 2019 in the conference room at approximately 12:00 p.m. confirmed the Chemistry analyzer calibrations were not performed during the aforementioned gaps in 2018 and 2019.

D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of the laboratory's maintenance and Quality Assurance(QA) records and an interview with the laboratory director, the Technical Consultant (TC) who is also the laboratory director failed to ensure that Monthly (QA) reports and maintenance logs between November 2018 and August 2019 were reviewed and signed. Findings include: 1. Maintenance and Quality Assurance report review revealed QA logs were not completed, reviewed, or signed from November 2018 thru August 2019 by the Technical Consultant(TC) , who also serves as the laboratory director. 2. An interview with the laboratory director on August 01, 2019, at approximately 12:20 pm, in the conference room confirmed that maintenance logs and QA reports were not completed, reviewed, or signed by the (TC), who is also the laboratory director.