Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0124550	05/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Preventive Healthcare Assoc/	102 James Street Suite 202, Edison, NJ	

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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor review of the Manufactures Package Insert (MPI) and interview with the Laboratory Director (LD), the laboratory failed to follow the MPI for the Bio-Rad Liquichek Immunoassay Premium Controls lot# 27310 from 12/22/17 to the date of the survey. The finding includes: 1. A review of the MPI stated "data not available at the time of printing. Please inquire" for analytes that have a delta sign for quantitative values, but the laboratory failed to obtain Vitamin D control values from the manufacturer. 2. The laboratory used the previous lot control values for Vitamin D. 3. 89 patients where run and reported for vitamin D. 2. The LD confirmed on 5/18 /18 at 10:30 am that the MPI was not followed.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by:

	Based on surveyor observation of the Quality Control (QC) material and interview with the Laboratory Director (LD), the laboratory failed to put new expiration dates on routine chemistry and endocrinology at the time of survey. The findings include. 1) The expiration date of control material shortens once opened. 2) The laboratory did not put new expiration dates on Bio-Rad Liquichek Immunoassay Premium Control Lot# 27310 in use. 3) The LD confirmed on 5/18/18 at 11:01 am the laboratory failed to put new expiration dates on the control material
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Laboratory Director (LD), the laboratory failed to verify that the assayed QC materials were within the acceptable ranges before they were put into use for analytes performed on the Access 2 analyzer from 12/22/17 to the date of survey. The LD confirmed on 5/18/18 at 12:00 pm that the laboratory did not verify QC materials for analytes performed on Access 2 analyzer.
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 surveyor review of the Test Report (TR) and interview with the Laboratory Director (LD) the laboratory failed to have all the required information on the TR from December 2017 to the date of survey. The findings include: 1. Thyroid Stimulating Hormone did not have a reference range. 2. The "Test Report Date" was

	not indicated. 3. The TR had one patient identifier. 4. There was no explanation of "Dilution 1" on the TR 3. The LD confirmed on 5/18/18 at 12:35 pm that the TR did not have all the required information.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report and interview with the Laboratory Director (LD), the laboratory failed to identify the source of the Reference Intervals (RI) used for routine chemistry and endocrinology tests from December 2017 to the date of survey. The LD confirmed on 5/18/18 at 12:20 pm that the source of the RI was not known.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Laboratory Director (LD), the laboratory failed to have a procedure to verify manually entered results into electronic medical records for accuracy from December 2017 to the date of survey. The LD confirmed on 5/18/18 at 10:15 am that the laboratory did not have the procedure mention above.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Laboratory Director (LD), the LD failed to ensure that PS procedures performed on the Access 2 analyzer were adequate from December 2017 to the date of survey. The findings include: 1. The LD did not review and sign the PS records. 2. Precision results were marked as yes where the option was Pass/Fail /Uncertain. 3. Accuracy and normal range study was not performed. 4. No range study

	was performed. 4. The LD confirmed on 5/18/18 at 11:15 am that PS records were not adequate.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Laboratory Director (LD), the LD failed to have an approved procedure manual available for routine chemistry and endocrinology testing at the time of the survey. The LD confirmed 5/18/18 at 10:15 am an approved PM was not available.