Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D1023102	10/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Premier Medical Pllc	265 Mason Avenue, Staten Island, NY	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor's review of the procedure manual, random QC & calibration records, validation studies, temperature logs and an interview with the current technical consultant, the laboratory failed to retain QC & calibration records and temperature logs from January 2, 2017 through July 28, 2018. FINDINGS: 1. The current technical consultant confirmed on October 16, 2018 at approximately 11:45 AM the surveyor's findings that the laboratory failed to retain QC & calibration records and temperature logs from January 2, 2017 through July 28, 2018. Approximately 300 patient samples for both chemistry and endocrinology were tested and reported during this time period. a. temperature policy requires that the temperature records be retained for 2 years. 2. The current technical consultant could not locate the backup files for the QC & calibration records for the following analyzers: a. Beckman Coulter AcT Diff II hematology analyzer, Elite Envoy 500 chemistry analyzer and TOSOH AIA-900 endocrinology analyzer 3. The laboratory's information system (LIS) using LABDAQ software was down during this survey and the records were not available for review from January 2, 2017 through July 28, 2018. THIS IS A REPEATED DEFICIENCY FROM THE SURVEY CONDUCTED ON MARCH 15, 2016.
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 surveyor's review of the laboratory's Quality Assessment (QA) policies and procedures and confirmed in an interview with the current technical consultant, at the time of this survey, the laboratory failed to follow their established QA policy and perform a QA review for the 2017 calendar year.
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 surveyor's review of the laboratory's temperature policy, revised temperature sheets and an interview with the current technical consultant, the laboratory failed to follow the manufacturer's instructions for monitoring and maintaining room and refrigerator temperatures from July 28, 2018 through survey date. FINDINGS: 1. The current technical consultant confirmed on October 16, 2018 at approximately 10:30 AM, the surveyor's findings that the laboratory failed to record the five refrigerator's and room temperatures for storing the analyzers reagents, calibrators and substrate materials. a. the staff failed to record the temperatures from July 28, 2018 through survey date. Since the laboratory director had signed the cease testing letter on July 28, 2018, therefore no patient test results were jeopardized during this time period. 2. The following reagents, calibrators and substrate materials were stored in these refrigerators and laboratory area room: Chemistry Envoy 500 Reagents: Albumin (2 boxes); BUN (3 boxes); Uric Acid (1 box); Alkaline Phosphorous (2 boxes); ALT (2 boxes); AST (2 boxes); Calcium (2 boxes); CK (2 boxes); T. Bilirubin (3 boxes); D. Bilirubin (2 boxes); Creatinine (3 boxes); Glucose (2 boxes); HDL Cholesterol (3 boxes); GGT (2 boxes); Iron (2 boxes); Triglyceride (2 boxes); Phosphorus (2 boxes); Calibrators (6 boxes); Vital controls (1 box); wash solution (2 boxes); Cleaner (2 boxes); ISE solution (3 boxes); ISE diluents (3 boxes); Conditioner (3 boxes). Hematology Coulter AcT Diff 4-C controls (1 box) and calibrator (1 box) TOSOH AIA 900 Reagents: Cortisol (1 box); TSH (1 Box); FT4 (1 box); T3 (1 box); substrate II (12 bottles & 2 boxes); calibrators (10 boxes) THIS IS A REPEATED DEFICIENCY FROM THE SURVEY CONDUCTED ON MARCH 15, 2016.
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 surveyor's findings and an interview with the current technical consultant, the laboratory director failed to provide overall management of the laboratory. THIS IS A REPEATED DEFICIENCY FROM THE SURVEY'S CONDUCTED ON MARCH 15, 2016 AND APRIL 22, 2014.
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 lack of QA records and an interview with the current technical consultant, the laboratory director failed to follow the established QA procedures and identify issues, take and document remedial and corrective action for all phases of laboratory testing. Refer to D3031, D5291 and D5413. THIS IS A REPEATED DEFICIENCY FROM THE SURVEY CONDUCTED ON MARCH 15, 2016.