Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2004600	10/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
Premiere Health And Wellness Medical	2609 N Duke Street, Suite 403, Durham, NC	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on procedure manual review, review of manufacturer's instructions (package inserts), and interview with laboratory director 10/02/18, the laboratory's procedure manual was not complete and current for the testing performed. The laboratory performs Amphetamine, Barbiturate, Benzodiazepine, Cocaine, Creatinine, and Methadone urine drug testing on the Diatron Pictus 400 chemistry analyzer. 1. Review of laboratory's calibration procedure and manufacturer's package inserts revealed the laboratory's calibration procedures do not include what type of calibration material is used for each analyte , what levels of calibration material are to be used for each

	analyte, the criteria used to determine if calibration is acceptable and the corrective action to take when calibration fails. For example: Laboratory policy "Required Quality Control" states; "Calibration requirements: Urine drug testing (Refer to manufacturer's requirements for each analyte.) With change of reagent lot number, When QC shifts or trends are noted, After major maintenance or service." Package insert for Amphetamine states; "Quality Control and Calibration", "Good laboratory practice suggests the use of control specimens to ensure proper assay performance. Use controls near the cutoff calibrator to validate the calibration. Control results must fall within established ranges, as determined by laboratory procedures and guidelines. If results fall outside of established ranges, assay results are invalid. All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements. Each laboratory should establish its own calibration and control frequency." 2. Review of laboratory's quality control procedure and manufacturer's package inserts revealed the laboratory's quality control procedures do not include what type of quality control material is used for each analyte, what levels of control material (established value) are used for each analyte, and the corrective action to take when quality control results are not within range. For example: Laboratory policy "Required Quality Control" states; "Test controls each day of patient testing. At least two levels must be within acceptable limits prior to patient testing and after calibration. Acceptable limits = established value/result or control mean +/- 2 std dev." Package insert for Amphetamine states; "Quality Control and Calibration", "Good laboratory practice suggests the use of control specimens to ensure proper assay performance. Use controls near the cutoff calibrator to validate the calibration. Control results must fall within established ranges, as determined by laboratory procedures and guidelines. If results fall outside of established ranges, assay results are invalid. All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements. Each laboratory should establish its own calibration and control frequency." 3. Review of laboratory's calibration verification procedure revealed the procedure does not include what type of calibration material is to be used for each analyte, or the levels (values) of the calibration material to be used for calibration verification of each analyte. For example: Laboratory policy " Calibration Verification" states; "Calibration Verification Materials"...There are various materials with known concentrations that can be used for calibration verification... Commercially available calibration materials or linearity sets....Proficiency testing samples with known results.....Control materials with known results.....Since calibration verification is used to check if the test systme is providing accurate results across the reportable range of the test, it is important to use calibration verification materials that include at least.....a low value....a mid-point value....a high value..." Package insert for Amphetamine states; "Quality Control and Calibration", "Good laboratory practice suggests the use of control specimens to ensure proper assay performance. Use controls near the cutoff calibrator to validate the calibration. Control results must fall within established ranges, as determined by laboratory procedures and guidelines. If results fall outside of established ranges, assay results are invalid. All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements. Each laboratory should establish its own calibration and control frequency." 4. Review of laboratory procedure manual and random patient test report (RE07211990) revealed the laboratory performs potential of hydrogen (PH) testing on urine samples. The laboratory procedure manual did not include a procedure for the determination of PH in urine samples.
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 review of laboratory policies and procedures, review of calibration records, review of calibration verification records, and laboratory director (LD) interview 10/02 /18, the laboratory failed to perform and document calibration verification at least once every six months during 2017 and 2018. The laboratory performs Amphetamine, Barbiturate, Benzodiazepine, Cocaine, Methadone and Urine Creatinine testing on the Diatron Pictus 400 chemistry analyzer. Review of laboratory policy "Calibration Verification" revealed "the lab must perform calibration as specified in the manufacturer's instructions.....the lab must also perform calibration verification at least every six months, using at least three levels of materials that are within the reportable range of the test." Review of 2017 and 2018 calibration records revealed the laboratory performs 2 point calibrations for the testing performed on the Diatron Pictus 400 chemistry analyzer. Review of 2017 and 2018 calibration verification records revealed the laboratory failed to perform a 3 point calibration for the testing performed on the DIatron Pictus 400 chemistry analyzer at least once every six months for 2017 and 2018. Interview with laboratory director at approximately 11:00 a.m. confirmed the laboratory failed to perform and document calibration verification at least once every 6 months during 2017 and 2018. This deficiency was previously cited 08/12/16.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of laboratory calibration records and review of patient test reports 10/02/18, the laboratory director failed to ensure that patient test reports included the pertinent information required for test

	result interpretation. The laboratory performs Amphetamine, Barbiturate, Benzodiazepine, Cocaine and Methadone testing on the Diatron Pictus 400 chemistry analyzer. Review of manufacturer's product inserts and review of laboratory calibration records for Amphetamine, Barbiturate, Benzodiazepine, Cocaine and Methadone testing on the Diatron Pictus 400 chemistry analyzer revealed the laboratory is following manufacturer's instructions for performing qualitative analysis only. Qualitative test analysis cannot be used to result semiquantitative (numerical) values. Qualitative test results can only be reported as either "positive" or "negative" for the analyte tested. For example: 1. Review of product insert for Thermo Scientific DRI Amphetamines Assay revealed "Qualitative Analysis...For qualitative analysis of samples, use the DRI Multi-Drug Urine Calibrator 1 or 2. The Calibrator 1 contains 500 ng/ml d-methamphetamine, which is used as a cutoff reference for distinguishing "positive" from "negative" samples for a 500 ng/ml cutoff. The Calibrator 2 contains 1000 ng/mL d-methamphetamine, which is used as a cutoff reference for distinguishing "positive" from "negative" samples for a 1000 ng/mL cutoff.....Semi-quantitative analysis....For semi-quantitative analysis, use all calibrators.....Semi-quantitative results...A rough estimate of drug concentration in the samples can be obtained by running a standard curve with all calibrators and quantitating samples off the standard curve...Results and Expected Values...Qualitative results...A sample that exhibits a change in absorbance value equal to or grater than the value obtained with the cutoff calibrator is considered positive. A sample that exhibits a change in absorbance value lower than the value obtained with the cutoff calibrator is considered negative." 2. Review of product insert for Thermo Scientific DRI Barbiturate Assay revealed "Qualitative Analysis....For qualitative analysis of samples, use the 200 ng/mL calibrator as a cutoff level. The DRI Multi-Drug Calibrator 2, which contains 200 ng/mL secobarbital, is used as a cutoff reference for distinguishing "positive" from "negative" samples.....Semiquantitative results.....For semiquantitative analysis, use all calibrators...Results and Expected Values... Qualitative results...A sample that exhibits a change in absorbance value equal to or grater than the value obtained with the cutoff calibrator is considered positive. A sample that exhibits a change in absorbance value lower than the value obtained with the cutoff calibrator is considered negative." Review of laboratory calibration records revealed the laboratory is performing qualitative analysis only by performing 2 point calibrations, one below the cutoff level determined for the analytes and one above the cutoff level determined for the analytes. Review of patient test reports, AJ05211996, JA04231986, RE07211990 revealed the laboratory reported numerical values (semiquantitative results) under the "Result" column for the each of the analytes tested and under the "Level" column reported either normal or abnormal. The test report also included reference values for each of the analytes tested.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on the absence of records and technical supervisor (director) interview on 10/2 /18 at 11:00 a.m.. the director failed to document the performance of the individuals responsible for high complexity testing at least semi-annually during the first year the individual tests patients specimens, and annually thereafter. The review of the CMS-

	209 Form, revealed that the director occupied all positions in the laboratory. Thus, the review of the performance evaluations reflected a self evaluation performed by the director.