Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2115187	09/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Prana Healthcare	200 Forsythe Street, Fayetteville, 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
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 the absence of records and interview with TP(testing personnel) 9/12/18, the laboratory failed to enroll in proficiency testing for blood gas (pH, pO2, pCO2), creatinine, glucose, sodium, potassium, lactate, and hematocrit testing. Based on the absence of records, the laboratory failed to enroll in proficiency testing for the following analytes tested on the epoc Blood Analysis System: blood gas (pH, pO2, pCO2); calcium; creatinine; glucose; sodium; potassium; lactate; hematocrit. During interview at approximately 11:20 a.m., TP #1 confirmed that the laboratory was not enrolled in proficiency testing.
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 review of 2016, 2017, and 2018 epoc blood gas quality control records and interview with TP (testing personnel) 9/12/18, the laboratory failed to retain all quality control records for at least two years. Review of quality control records for the epoc blood analysis system revealed the laboratory did not have the VAD (Value Assignment Datasheet) available for the following quality control lot numbers: 1. Eurotrol GAS-ISE Metabolites Level 1 lot #179-1-B546 (Sensor Configuration 27.1 and 28.4); 2. Eurotrol GAS-ISE Metabolites Level 3 lot #179-3-B547 (Sensor Configuration 27.1 and 28.4). During interview at approximately 1:10 p.m., TP #1 stated this lot number was used before she was hired, so she was unsure where the VADs might be if they were not with the other records.
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 review of the laboratory's policies and procedures and interview with TP (testing personnel) 9/12/18, the laboratory's procedure manual was not complete and current for the testing performed. Findings: 1. The laboratory did not have a written procedure describing the process for reporting patient arterial blood gas test results. During interview at approximately 9:35 a.m., TP #1 stated that patient test results are scanned into the patient chart. 2. The IQCP (Individualized Quality Control Plan) in the laboratory's manual stated "External Quality Controls High and Low External controls are tested with each new lot number, shipment and/or every 30 days, whichever comes first." The laboratory did not have a quality control policy that included the quality control material used and the corrective action to take if control results are unacceptable.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures 9/12/18, the procedures had not been approved by the laboratory director before use. Review of the laboratory's procedures revealed the laboratory director had not signed and dated the following to indicate review and approval for use by the laboratory: 1. "epoc Blood Analysis System Procedure Manual" provided by the manufacturer; 2. "Arterial Blood Gas Protocol" and other policies and procedures in the laboratory's manual.
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 review of manufacturers' instructions, review of temperature logs, and interview with TP (testing personnel) 9/12/18, the laboratory failed to monitor and document room temperature and humidity as specified by the manufacturer for operation of the epoc Blood Analysis system and storage of supplies and failed to consistently monitor refrigerator temperature to ensure proper storage of quality control material. Findings: 1. Room temperature and humidity The "epoc Blood Analysis Procedure Manual" states on page 6 "SUPPLIES AND STORAGE REQUIREMENTS epoc Test Cards epoc Test Cards should be stored at room temperature (15-30 degrees C) ... Never use Test Cards shipped outside the specified temperature limits (2-30 degrees C). ... Quality control fluids ... Follow the Manufacturer's storage and handling instructions. If ampoules are taken from cool storage, equilibrate the ampoules to Room Temperature (20-25 degrees C). ... epoc Reader The Reader can be operated between 15 degrees C - 30 degrees C. ... The Reader must be used in relative humidity of less than 85% at 30 degrees C, non condensing. ..." The "Eurotrol epoc GAS-ISE Metabolites - Level 1" product insert states "... Storage ... Eurotrol epoc GAS-ISE Metabolites - Level 1 is stable for 1 week when stored unopened at room temperature. ... Procedure 1. ... Bring the ampules to room temperature (22 degrees C, 71.6 degrees F) prior to use. ... Limitations ... 4. The pO2 values of Eurotrol epoc GAS-ISE Metabolites - Level 1 vary inversely with temperature changes. To obtain a high degree of correlation with the values in the table, the ampules should be equilibrated as close to 22 degrees C (71.6 degrees F) as possible. ..." There were no records available to indicate that room temperature and humidity had ever been monitored by the laboratory. TP #1 confirmed during interview at approximately 12:30 p.m. that the laboratory does not monitor room temperature and humidity. 2. Refrigerator temperature The "Eurotrol epoc GAS-ISE Metabolites - Level 1" product insert states "... Storage Eurotrol epoc GAS-ISE Metabolites - Level 1 can be used until the expiry date as indicated on the labels on the ampules and outer box, if stored unopened at a temperature of 2-8 degrees C (35-46 degrees F). ..." Review of 2017 and 2018 refrigerator temperature logs revealed: a. There were no refrigerator temperatures documented for September 2017, March 2018, May 2018, June 2018, and July 2018. b. Refrigerator temperature logs for

	August 2017, October 2017, November 2017, December 2017, January 2018, February 2018, and April 2018 were incomplete. For example, refrigerator temperature was documented only 11 of 31 days in December 2017. Temperature readings documented were below manufacturer's acceptable limits on all 11 days with no corrective action documented (see D5785).
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of 2017 and 2018 epoc blood gas records and interview with TP (testing personnel) 9/12/18, the laboratory failed to discard calibration verification material that exceeded its expiration date. Review of epoc blood gas records revealed the laboratory performed calibration verification on 3/20/17, 8/11/17, and 9/10/18. For the calibration verification performed 8/11/17, the laboratory used calibration verification material that expired 7/31/17. During interview at approximately 1:05 p. m., TP #1 stated she was unable to locate any other calibration verification records.
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 review of manufacturer's instructions and the absence of records, the laboratory failed to perform and document the manufacturer's specified verification of reader performance twice a year during 2017 and 2018. The "epoc Blood Analysis System Procedure Manual" states on page 15 "... Verification of Reader Performance ... The epoc Reader contains a thermal control subsystem consisting of two (2) heater blocks each with an embedded factory calibrated precision chip-based temperature sensor. There is one (1) calibrated thermistor located elsewhere within the Reader. When measurements are performed at a controlled temperature, a heater block contacts the Test Card's sensor region and maintains temperature of the sensors and fluids that come into contact with the sensors at the required temperature: 37 degrees +/- 0.15 degrees C. Thermal QA should be performed twice a year for each Reader. For best results, perform Thermal QA on a Reader after it has been resting in a location with no airflow (e.g. box or cabinet) and no change in temperature for at least two (2) hours. Thermal QA records may be saved, sent to EDM, and printed. " There were no records available to document that the manufacturer's specified "Thermal QA" was performed during 2017 or 2018.
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 the laboratory's policies and procedures, review of the laboratory's IQCP (Individualized Quality Control Plan), and review of 2017 and 2018 epoc blood gas records 9/12/18, the laboratory failed to perform and document calibration verification at least once every six months from 3/20/17 - 9/10/18. The "epoc Blood Analysis System Procedure Manual" provided by the manufacturer states on page 15 "... Optional Quality Control: Calibration Verification Follow the calibration verification procedure to verify accuracy of test results over an extended measurement range of a test. Performance of this procedure at defined intervals may be required by regulatory or accreditation bodies. ..." Review of the laboratory's IQCP revealed the plan specified the performance of calibration verification "Every Six Months". Review of epoc blood gas records revealed the laboratory performed calibration verification on 3/20/17, 8/11/17, and 9/10/18. There was no documentation of calibration verification performed between 8/11/17 and 9/10/18. In addition, the laboratory used expired calibration verification material for the calibration verification performed 8/11/17 (see D5417).
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions and review of 2017 and 2018 temperature logs 9/12/18, the laboratory failed to ensure corrective action was taken and documented for refrigerator temperatures outside acceptable limits for storage of quality control material. The "Eurotrol epoc GAS-ISE Metabolites - Level 1" product insert states "... Storage Eurotrol epoc GAS-ISE Metabolites - Level 1 can be used until the expiry date as indicated on the labels on the ampules and outer box, if stored unopened at a temperature of 2-8 degrees C (35-46 degrees F). ..." Review of 2017

	and 2018 temperature logs revealed multiple days when the refrigerator temperature recorded was outside the acceptable limits of 2-8 degrees Celsius (35-46 degrees Fahrenheit). Examples: a. In August 2017, all temperatures were recorded in the "Min /Max Temp" section, but only one temperature was documented on 14 of the 17 days, and 13 of 17 temperatures recorded were below the acceptable limit with no corrective action documented. b. In October 2017, 13 of 13 temperatures recorded were below the acceptable limit with no corrective action documented. c. In February 2018, 6 of 6 temperatures recorded were below the acceptable limit with no corrective action documented.
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 review of a random patient test report (patient #06081958) and interview with TP (testing personnel) 9/12/18, the laboratory's test reports did not include all required information. Review of a random patient test report (patient #06081958) revealed the test report did not include the name and address of the laboratory. During interview at approximately 2:10 p.m. TP #1 stated they were unaware it was required.
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 review of a random patient test report (patient #06081958) and interview with TP (testing personnel) 9/12/18, the laboratory's test reports did not include all required information. Review of a random patient test report (patient #06081958) revealed the test report included reference ranges for analytes with abnormal results (low or high), but did not include the reference range for each test performed. During interview at approximately 2:10 p.m. TP #1 stated they were unaware it was required.
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 review of 2017 and 2018 laboratory records, the laboratory director failed to provide overall management and direction for the laboratory. Findings: 1. The laboratory director failed to ensure the verification of performance specifications for the epoc Blood Analysis System prior to the initiation of patient testing (see D6013); 2. The laboratory director failed to ensure the laboratory was enrolled in an HHS-approved proficiency testing program for the testing performed (see D6015); 3. The laboratory director failed to ensure the establishment and maintenance of a quality control program (see D6020); 4. The laboratory director failed to ensure the establishment of an effective quality assessment program to identify and correct problems and prevent their recurrence (see D6021); 5. The laboratory director failed to ensure testing personnel were trained prior to testing patient specimens (see D6029).
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 the absence of records and interview with TP (testing personnel) and the laboratory director 9/12/18, the laboratory director failed to ensure validation of the epoc Blood Analysis System prior to the initiation of patient testing. There were no installation records available for review during the survey. There was no documentation available to indicate that the performance specifications including accuracy, precision, and reportable range of the epoc Blood Analysis System were verified prior to the initiation of patient testing. During interview at approximately 1: 20 p.m., TP #1 stated that the analyzer was installed before she was hired. She stated she was unable to locate any of the records showing that the performance specifications were verified before patient testing began. During the exit interview at approximately 2:45 p.m., the laboratory director stated that the verification was performed by the manufacturer's representative who set up the analyzer, but he was unsure where the records might be.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

	This STANDARD is not met as evidenced by: Based on the deficiency cited at D2000 and the absence of records 9/12/18, the laboratory director failed to ensure the laboratory was enrolled in an HHS-approved proficiency testing program for the testing performed. Based on the absence of records, the laboratory failed to enroll in proficiency testing for the following analytes tested on the epoc Blood Analysis System: blood gas (pH, pO2, pCO2); calcium; creatinine; glucose; sodium; potassium; lactate; hematocrit.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of the laboratory's policies and procedures, and review of 2017 and 2018 laboratory records 9/12/18, the laboratory director failed to ensure that a quality control program was established to assure the quality of laboratory services provided. Findings: 1. The laboratory failed to retain all quality control records for at least two years (see D3031). 2. The laboratory's quality control procedure was not complete and current and had not been approved by the laboratory director (see D5403, D5407). 3. The laboratory failed to monitor and document room and refrigerator temperature and humidity as required to ensure proper analyzer operation and ensure proper storage of quality control material and supplies and failed to document corrective action as needed (see D5413, D5785). 4. The laboratory used expired calibration verification material (see D5417). 5. The laboratory failed to perform and document Thermal QA twice a year for the epoc Blood Analysis System Reader (see D5429). 6. The laboratory failed to perform and document calibration verification at least once every six months for the epoc Blood Analysis System (see D5439). 7. The laboratory failed to document that the performance specifications of the epoc Blood Analysis System including accuracy, precision, and reportable range were verified prior to the initiation of patient testing (see D6013). 8. The laboratory failed to ensure the IQCP (Individualized Quality Control Plan) was reviewed on an annual basis by the laboratory director and modified as required (see D6021).
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 the absence of records, review of the laboratory's IQCP (Individualized Quality Control Plan), and interview with the laboratory director and TP (testing personnel) 9/12/18, the laboratory director failed to ensure the establishment and maintenance of an effective quality assessment program designed to identify and correct problems and prevent their recurrence. Findings: 1. The laboratory did not have a quality assessment procedure available for review, and there were no records available to indicate that the laboratory had a quality assessment program in place to identify and correct problems identified during the survey in the following areas: a. proficiency testing (see D2000); b. quality control and calibration (see D3031, D5417, D5439, D6020); c. procedures (see D5403); d. test systems (see D5413, D5785); e. maintenance and function checks (see D5429); f. test reports (see D5805, D5807); g. personnel training (see D6029). 2. Review of the laboratory's IQCP for the epoc blood gas analyzer revealed the following "Quality Assessment of IQCP: Ongoing Monitoring of IQCP will include: Review of personnel training records for completion of required training and competency assessments. Monthly review of external quality controls. Daily review of patient results for reporting errors and Clinician complaints. Evaluating errors related to preanalytical, analytical and postanalytical phases of the testing process. This will also include review of manufacturer bulletins, recalls or alerts, and any Improvement Opportunity Forms generated. Evaluation of QC failures, PT failures and patient reporting errors will be examined and addressed. If ongoing failures are identified in one or more components of the quality control plan the laboratory will examine the cause and revise the IQCP as needed. Review and approval of the quality control plan by the laboratory director at least annually." There was no documentation that the laboratory director reviewed quality control records, calibration verification records, personnel records, or the quality control plan since it was implemented 3/1/17, and there was no documentation that the plan had been revised.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel records, review of email records, and interview with TP (testing personnel) 9/12/18, the laboratory director failed to ensure that prior to testing patient specimens, 2 of 2 TP received appropriate training and could perform all testing operations reliably to provide and report accurate test results. Review of personnel records revealed there were no training records available for TP #1 (hired in July 2018) or TP #2 (hired in June 2018). The only training records available were for former testing personnel no longer employed by the laboratory. Review of email records provided by TP #1 revealed the laboratory had contacted the manufacturer's representative in July and August 2018 to request on-site training and assistance with installing a software upgrade for the epoc analyzer. Review of email records revealed the manufacturer's representative failed to schedule a time for on-site training. During

	interview at approximately 1:30 p.m., TP #1 confirmed there were no training records available for review. She stated that the manufacturer's representative who did the original training was not available because the company had been bought by another company. She stated the new representative would not provide on-site training, so the two testing personnel had to train themselves.