Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0506605	05/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Parmer Medical Center	1307 Cleveland Avenue, Friona, TX	

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: Review of policies and procedures, quality control records and interview facility personnel found that the laboratory failed to include the procedure for establishing acceptable ranges for quality control materials in their own policy titled Quality Control Schedule. The findings included: 1. Review of the policy titled Quality Control Schedule found under the heading General and Immuno-Chemistry - "for the Roche C311 in the E411, two levels of control material or performed for each 24-hour period of operation. Both levels of control material must be within performance range in order for patient results to be reported. QC only needs to be run for the tests that are

	ordered by the provider. For example, low volume or tests not routinely done on weekends (i.e. ETOH, TDM's, lipids, A1c, iron, UIBC, etc.) . QC will be run if a test is ordered." 2. Review of quality control records for MAS chemistry controls lots CHA20021A and CHA20023A found the laboratory established new means by analyzing eight replicates of the control material between December 28, 2017 and December 31, 2017, but used the manufacturers expected mean value and a historical standard deviation (SD) from the previous lot of quality control material to establish the acceptable range criteria. Creatinine level I manufacturers mean value= 1.04 laboratory mean =1.07 historical SD= 0.2 level III manufacturers mean value = 6.98 laboratory mean = 7.06 historical SD = 0.110 Glucose level I manufacturers mean value= 58 laboratory mean = 59.88 historical SD= 1.010 level III manufacturers mean value = 360 laboratory mean = 367.63 historical SD = 5.490 Sodium level I manufacturers mean value= 153 laboratory mean = 153.75 historical SD= 1.48 level III manufacturers mean value = 119 laboratory mean = 120.75 historical SD = 1.36 3. Interview of the general supervisor conducted on May 16, 2019 at 2:25 PM confirmed the laboratory established new means by analyzing eight replicates of the control material between December 28, 2017 and December 31, 2017 but used the manufacturers mean value to establish acceptable range criteria. She further confirmed that there was no other procedure for establishing acceptable ranges.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the Opti CCA - TS2 blood gas analyzer operator's manual, analyzer verification studies from 2018, patient analytic records and patient final report records, and interview with the laboratory General Supervisor, the laboratory failed to verify the patient normal ranges for 4 of 4 analytes prior to performing patient testing. The findings included: 1. Based on review of the Opti CCA - TS2 blood gas analyzer operator's manual, on page 9-11, the manual states the following: "9.5.7 Reference Intervals Reference intervals are useful in describing typical results found in a defined population of apparently healthy people. Reference intervals should not, however, be used as absolute indicators of health and disease due to variability among methods, laboratories, locations, and other considerations. Individual laboratories should generate their own set of reference intervals. Guidelines for defining and determining reference intervals are published in the 2000 NCCLS C28-A2 guideline: "How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline - Second Edition". This analyzer is preset to adult reference intervals derived from "Tietz, Burtis C. et al (Eds.), Textbook of Clinical Chemistry and Molecular diagnostics, 4th Ed., (Elsevier Saunders, 2006) pps. 2252-2302". The reset intervals and procedures for adjusting the intervals to those derived for the individual laboratory are described in section 3.2.2.4 of this manual." Based on review of the Opti CCA - TS2 blood gas analyzer operator's manual, on page 3-13, the manual states the following: "3.2.2.4 This menu allows you to set up reference and

	critical measurement limits for all measured parameters. A result that is outside the limits you define here will be flagged with a single up-arrow if above the high reference limit, or a single down-arrow if below the low reference limit. Results above or below the critical limits will be flagged with a double up-/or down-arrow. A message is included on the printout explain each arrow. NOTE: When the patient temperature has been changed, both the corrected and corrected parameters will be checked against the limit values programmed here and flagged accordingly." And; " The instrument is preset to the following reference ranges: pH: 7.200 - 7.600 pCO2: 30.0 - 50.0 mmHg pO2: 70 - 700 mmHg sO2: 90 - 100 percent" 2. Based on review of the laboratory's verification studies, the accuracy, precision, and reportable range were verified for use and approved on November 2, 2018. 3. Based on review of the Opti CCA - TS2 blood gas analyzer patient analytic records, the reference ranges from the operator's manual were printed at the bottom of the analytic record for each patient analysis. Based on the review of the final patient reports from the laboratory information system (LIS), the reference ranges printed on the final patient reports differed from the analytic record/operator's manual. Examples: The following five of five randomly reviewed patient final reports contained reference ranges that differed from the analytic records and Opti CCA - TS2 blood gas analyzer operator's manual: Patient 10002141, tested on 12/31/2018 Patient 10004660, tested on 4/23/2019 Patient 10004956, tested on 5/4/2019 Patient 10005107, tested on 5/11/2019 Patient 10005122, tested on 5/12/2019 The reference ranges printed on the final patient reports were as follows: pH: 7.35 - 7.48 pCO2: 33 - 45 mmHg pO2: 68 - 100 mmHg sO2: 94 - 100 percent" 3. Based on review of the previous blood gas analyzer operator's manual (OPTI-CCA - TS, PD7040) on page "v", the manual states the following: "Reference Interval Laboratory normal ranges for arterial carbon dioxide tension, PCO2, and pH are well documented and widely accepted: pH: 7.35 - 7.45 pCO2: 35 - 40 mmHg Arterial oxygen tension, pO2 is dependent upon the inspired oxygen tension, as well as various physiologic variables, and the administration of oxygen is common in the treatment of patients in need of blood gas analysis. Hypoxemia is defined as an arterial pO2 below an acceptable range while breathing room air, with about 21 percent oxygen, at sea level. Increasing altitudes above sea level will produce lower inspired oxygen tension and therefore, lower arterial pO2 values. Below are listed acceptable arterial oxygen tension at sea level, while breathing room air: Adult and Child Normal - 97 mmHg Acceptable range - greater than 80 mmHg Hypoxemia - less than 80 mmHg Newborn Acceptable range - 40 - 70 mmHg Aged Acceptable range 60 years old - greater than 80 mmHg 70 years old - greater than 70 mmHg 80 years old - greater than 60 mmHg 90 years old - greater than 50 mmHg" 4. In an interview at 11:14 hours on 5/16/2019 in the conference room, the laboratory General Supervisor stated she was unaware of where the patient normal ranges that were printed on the final patient report originated.