Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0506831	03/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Parkview Hospital	901 S Sweetwater Street, Wheeler, 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: Based on observations, review of the laboratory's policies and procedures, manufacturer's instructions for use, quality control records and interview of facility personnel, the laboratory failed to define the procedure for establishing means and acceptable ranges when initiating a new lot of chemistry quality control material for use for 3 of 3 randomly reviewed analytes tested on the Vitros 250 chemistry analyzer. The findings included: 1. Observations made during the tour the facility found that the laboratory currently used the Thermo scientific MAS ChemTRAK control materials levels 1, 2 and 3 to verify the quality of results obtained for

chemistry procedures tested on the Vitros 250 chemistry analyzer. 2. Review of the laboratory's written policy titled Laboratory Quality Management Procedure Plan found on page 3 under the heading Procedure Quality Control - "Quality Control (QC; sometimes called process control) is the analysis of materials of known composition or reactivity in conjunction with patient samples testing to verify the performance of a test. QC materials are "pseudo-samples" designed to detect problems in instrument, reagent, software, or analyst performance. QC is predominantly a measure of precision (reproducibility) and confirms that a test system has maintained proper calibration. For some analytes, the control material is a manufactured, purchased control product supplied in either a lypholized or liquid form; the concentration has been both gravimetrically and analytically determined prior to distribution of the product. These materials must be evaluated in house to determine the laboratory mean, standard deviation, and coefficient of variation before placing into service. This data is collected while running in parallel with the control product currently in use. The management of quality control occurs on a real-time basis and as a continuous tool in evaluating the reliability of test data. Technologists, supervisors, and laboratory Directors all contribute to this. Review procesess on a daily, weekly, or monthly basis. The frequency of control analysis, and the preparation, reconstitution, storage conditions, and stability of specimens and reagents are described in individual procedures for each type of test. The tolerance limits for controls are established by individual sections. Values which fall outside these ranges must be evaluated according to the internal control roles used in individual sections. Violation of the QC rules results in review by the supervisor and a work director and may result in rejection of the analytical run. The run must be inspected to determine the cause for error. After solving the problem that caused the QC exception, the entire run may need to be repeated, along with QC evaluation. Quality control, QC records are maintained for a minimum period of three years (five years for transfusion medicine)." 3. Review of the manufacturer's instructions for use found: MAS Chem TRAK - under the heading Control Ranges - "the published control ranges are based upon a combination of replicant assays of representative samples by participating laboratory's, instrument/reagent manufacturers and direct correlation with other analytical systems in accordance with established protocol. Instrument values provided are specific to this lot of control only and are intended to assist the laboratory in establishing its own means and ranges. All values have been assigned with instruments and reagents available at the time of assay and expected values may vary with different reagents and or methodologies. Laboratory established means should fall within the assigned ranges. Although subsequent instrument, reagent or calibration modifications may invalidate assigned values. Peer comparison data and latest QC lot specific updates are available online through LabLink xlQuality Assurance Program at www.maslablink.com. Refer to the technical assistance section for contact information." Review of the MAS Chem TRAK - assay sheet found the mean and range of means for the Vitros chemistry systems listed for the following analytes: Glucose - level 1 mean = 60.1 mg/dL with a range of means 48.1 to 72.2 mg /dL Level 2 mean = 193 mg/dL with a range of means defined as 154 to 231 mg/dL. Level 3 mean = 312 mg/dL, with a range of means defined as 249 to 374 mg/dL Potassium - level 1 mean = 2.81 mEq/L with a range of means defined as 2.25 to 3.37 mEq/L level 2 mean = 4.56 mEq/L with a range of means defined as 3.65 to 5.47 mEq /L level 3 mean = 6.32 mEq/L with a range of means defined as 5.06 to 7.58 mEq/L Sodium - level 1 mean = 158 mEq/L with a range of means defined as 127 to 190 mEq /L level 2 mean = 142 mEq/L with a range of means defined as 114 to 171 mEq /L level 3 mean = 128 mEq/L with a range of means defined as 102 to 153 mEq/L 4. Review of the laboratory established means and limits for lot 2002 expiration 2020-02-28 found the following mean and acceptable criteria established by the laboratory:

	Glucose - level 1 mean = 60.9 mg/dL with a defined acceptable range of 54.5 to 67.3 mg/dL using a one standard deviation of 3.2 Level 2 mean = 192.6 mg/dL with a defined acceptable range of 162.6 to 222.6 mg/dL using a one standard deviation of 15. Level 3 mean = 312.7 mg/dL, with a defined acceptable range of 276.7 to 348.7 mg/dL using a one standard deviation of 18 Potassium - level 1 mean = 2.79 mEq/L with a defined acceptable range 2.632 2.95 mEq/L using a one standard deviation of 0.08 level 2 mean = 4.52 mEq/L with a defined acceptable range of 3.72 to 5.32 mEq /L using a one standard deviation of 0.40 level 3 mean = 6.27 mEq/L with a defined acceptable range of 5.07 to 7.47 mEq/L using a one standard deviation of 0.60 Sodium - level 1 mean = 158.2 mEq/L with a defined acceptable range of 147.322 169.08 mEq/L using a one standard deviation of 5.44 level 2 mean = 142.9 mEq/L with a defined acceptable range of 131.182 154.62 mEq /L using a one standard deviation of 5.86 level 3 mean = 129.1 mEq/L with a defined acceptable range of 110.7 to 147.5 mEq/L using a one standard deviation of 9.2 2. Interview of technical consultant 3 listed on the CMS report 209 conducted on March 5, 2019 at 11:43 AM found that the laboratory established means based on 20 point study. At the end of the 20 point study the laboratory calculated the mean value for the analyte and calculated a one standard deviation value by subtracting the lowest value in the range of means from the mean value listed on the assay sheet, and dividing by three. Interview of technical consultant 2 listed on the CMS report 209 conducted on March 5, 2019 at 11: 50 AM by telephone found that he used a static 0.055 factor for calibrating a two standard deviation range of acceptability for all analytes. The Technical Consultant explained the Calculated mean was multiplied by the 0.055 value and the resulting number was used as a plus/minus 2SD range.
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 calibration records for 2017 and 2018, quality control records and staff interview, the laboratory failed to perform calibration verification of the analytes Uric Acid and Triglycerides, tested on the Vitros 250

	chemistry analyzer at least once every six months in 2017. The findings included: 1. Review of 2017 calibration procedures found documentation of calibration verification activities for Uric Acid and Triglycerides as follows: Triglycerides calibrated November 26, 2017 using Lot/Gen 7591-0737 previously calibrated on March 23, 2017 using Lot/Gen 4690-0734 . Uric acid calibrated August 31, 2017 using Lot/Gen 7928-0528 . Previously calibrated on January 1, 2017 using Lot/Gen 4319-0529 Calibration verification records were requested but not provided. 2. Review of quality control records found that the laboratory tested three levels of quality control once each day of patient testing for triglycerides and uric acid. 3. Interview of technical consultants three listed on the CMS report 209 Laboratory Personnel Report conducted on March 6, 2019 at 12:12 PM confirmed that no additional records for calibration verification were available for review. He stated that because the laboratory tested three levels of control once each day he thought the requirements were met.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Individualized Quality Control Plans (IQCP) for the Hemochron coagulations analyzer and the Triage chemistry analyzer, and interview with facility personnel, the laboratory failed to identify frequency and impact for each risk and failed to identify risks in 2 of 5 categories for the Triage Cardiac Panel. The findings included: 1. Risk assessment is the identification and evaluation of potentials failures and sources of errors in a testing process. Risk assessments for IQCP must include, at a minimum, an evaluation of the following five components: *Specimen *Test System *Reagent *Environment *Testing Personnel The scope of the risk assessments must encompass the entire testing process - preanalytic, analytic, and post-analytic phases - and include, at a minimum, the evaluation of the five risk assessment components listed above for each test for which the laboratory wishes to employ IQCP. Conducting the Risk Assessment To conduct a risk assessment, the laboratory must identify the sources of potential failures and errors for a testing process, and evaluate the frequency and impact of those failures and sources of error on test quality. In-house data, established by the laboratory in its own environment and by its own personnel, must be utilized to demonstrated that the stability of the test system as it is used in that laboratory supports the number and frequency of the QC documented in the QCP. 2. Based on review of the Risk Assessment for the Triage Cardiac Panel, under the column of Possible Sources of Error, the laboratory documented "n/a" for both Environment and Testing Personnel. 3. Based on review of the Risk Assessment for the Hemochron coagulation analyzer, the laboratory failed to identify the frequency and impact on test quality for each risk. Example: For the category of Specimen, the laboratory identified "Clotted or Partially clotted blood" as a potential risk. The laboratory did not document the frequency of receiving clotted or

	partially clotted specimens for analysis on the Hemochron. The laboratory failed to identify the impact of test quality if a specimen that was clotted or partially clotted was analyzed. 4. In an interview at 14:42 hours on 3/6/2019 in the laboratory, the Laboratory Manager confirmed the laboratory did not document the frequency and impact for each risk and failed to identify risks in 2 of 5 categories for the Triage Cardiac Panel.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Observations, review of policies and procedures, patient test records and interview of facility personnel found that the quality assessment program failed to identify and correct problems in the analytic systems. The quality assessment program failed to identify and correct that quality control establishment criteria was not defined in the quality control policy. (See D5403) The quality assessment program failed to identify that calibration verification procedures were not performed for Uric Acid and Triglyceride were not calibrated at least once every six months on the Vitro's 250 chemistry analyzer. (See D5439) The quality assessment program failed to identify the Individualized Quality Control Plans (IQCP) for the Hemochron coagulations analyzer and the Triage chemistry analyzer did not include the frequency and impact for each risk and failed to identify risks in 2 of 5 categories for the Triage Cardiac Panel. (See D5445)