Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0483678	04/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Quitman Hospital, Llc	117 North Winnsboro St, Quitman, 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
D0000	The laboratory was surveyed and found to be in-compliance with the conditions of participation found in the CLIA regulations at 42 CFR 493 and recertification is recommended.
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 laboratory policies and procedures, surveyor observation, and interview with facility personnel, the laboratory failed to follow established procedure for performing urinalysis sediment examinations. The laboratory reported an estimated 8,098 urinalysis examinations performed annually on the CMS-116 collected the day of the

	survey. The findings included: 1. Review of the laboratory's procedure "Principles of Urinalysis", under "Operating Procedure", states the following:' "11. If the urinalysis chemical strip shows that a microscopic is needed. Place a cap on the urine centrifuges tube and lace in centrifuge for processing. Centrifuge specimen for 5 minutes at 1500-2000 rpm." 2. At 14:19 hours on 4/8/21 in the laboratory, the surveyor observed the laboratory use 1450 rpm (290 RCF) for 2 minutes on the Horizon Plasmafuge-12 for processing urine specimens for urine sediment analysis. The laboratory reported an estimated 8,098 urinalysis examinations performed annually on the CMS-116 collected the day of the survey. 3. In an in interview at 14: 19 hours on 04/08/2021 in the laboratory, the laboratory manager confirmed the setting did not match the laboratory policy and corrected the discrepancy. Key: RPM - revolutions per minute RCF- Relative centrifugal force (RCF) is used to refer to the amount of force applied when using a centrifuge.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observations and interview with facility personnel, the laboratory failed to label 3 of 3 aliquots of Fischer Brand Heme 3 hematology stain with identity, storage requirements, or preparation and expiration dates on April 8, 2021. The findings included: 1. At 13:54 hours on 4/8/2021 in the laboratory, the surveyor observed three unlabeled aliquots next to the sink, in front of the heat block. 2. In an interview at 13:54 hours on 4/8/2021 in the laboratory, the Laboratory Manager confirmed the aliquots were part of a three-step Fischer Brand Heme 3 hematology stain used for performing hematology peripheral blood smear reviews and white blood cell differentials.
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 policies and procedures, laboratory records, and interview with facility staff, the laboratory failed to verify the reportable range and patient normal ranges prior to reporting patient test results since November 20, 2020 (4 of 4 months) for the Mini Cube automated erythrocyte sedimentation rate (ESR) instrument. The findings included: 1. Based on review of the laboratory policy "VALIDATION OF

	NEW INSTRUMENTS", under PRINCIPLE, the procedure states the following: "Accuracy is verified by the calculated Standard Deviation Index (SDI) as reported by the appropriate intra-laboratory quality assurance program, or by testing at least ten (10) samples of known concentration and demonstrating the 95% fall within the range of mean plus/minus 2SD. Precision is verified by the calculated Coefficient of Variation (CV). The reportable ranges are defined by linearity studies. Carryover is determined by processing samples of known high concentration of the analysis directly followed by two specimens of known low concentration of analyte and comparing the two low values. Normal ranges are verified by running normal patients to obtain a 2 SD range." 2. Based on a review of the Mini Cube User Manual (Rev. 1.1 issued on August 2017), on page 15 of 51, the reportable range is defined as 0 to >140 mm/hr for 4 mL tubes and 0 to >60 mm/hr. On page 10 of 51, under ESR Reference Values (Westergren citrated), the manual states the following: "Guidelines for ESR Reference Values for the Westergren ESR method are as follows: Normal 0-20 mm/hr" 3. Based on a review of implementation records from August 2020, the laboratory performed a method comparison study to assess accuracy and monitored the precision of control materials to assess precision. The laboratory began patient testing November 20, 2020. 4. In a random review of 10 patient records (5 males, 5 female), the patient final reports indicated the laboratory normal patient reference range for males was 0-20 mm/hr and 0-30 mm/hr for females. 5. In an interview at 13: 41 hours on 4/8/21 in the office, when the surveyor requested documentation of verifying the reportable range and verifying the normal patient range, the laboratory manager confirmed those assessments had not yet been completed. Key: SD - standard deviation Rev. - Revision mL - Milliliter mm/hr - millimeters per hour
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 laboratory's Individualized Quality Control Plan (IQCP) procedures for the Radiometer ABL 80 blood gas chemistry analyzer and interview with facility personnel, the laboratory failed to identify the frequency for each potential source of error identified in the laboratory's Risk Assessment (RA). 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. The findings included: 1. Review of the Risk Assessment portion of the Individualized Quality Control Plan (IQCP) for the Radiometer ABL 80 blood gas chemistry analyzer test system included potential sources of error and the anticipated impact of each source of error. The Risk Assessment DID NOT include the frequency with which the laboratory defined potential sources of error had occurred or were likely to occur or an evaluation of these errors on overall test quality. As a potential risk, the laboratory identified the use of expired reagents as a potential risk, with the impact identified as erroneous results.

	The lab did not define how often (frequency) the risk was likely to occur. 2. In an interview at 14:15 hours on 4/8/21 in the office, the Laboratory Manager stated that the laboratory monitored potential sources of error through quality assurance activities but had not defined the frequency and impact of each source of error as part of the IQCP risk assessment.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of chemistry analyzer control instructions-for-use, quality control records, and interview with facility personnel, the laboratory failed to verify or establish the acceptable statistical parameters for 3 of 3 levels of quality control on 3 of 3 assays reviewed. The findings included: 1. Based on review of the Bio-Rad Liquid Assayed Multiqual instructions for use (Ref 694, 695, 696, 2020-02), under Assignment of Values, the instructions for use state the following: "The mean values and corresponding plus/minus 3 standard deviation (SD) ranges in the Assignment of Values Data Charts were derived from replicate analysis and are specific for this lot of product." And; "Laboratory established ranges may vary from those listed during the life of this control. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications." 2. Based on surveyor observations of the quality control values used to set expected means and acceptability criteria, the laboratory had expected standard deviation values set at different values than those provided by the manufacturer. Assay - Bilirubin - Direct Bio-Rad Level 1 - Lot 45861 Expected Mean - 0.225 Plus/minus 3SD range - 0.0113 - 0.337 Expected SD - 0.037 For the same assay, the laboratory had the following quality control expectations: Expected mean: 0.211 Plus/minus 3SD range - -0.209 - 0.631 Expected SD - 0.14 The laboratory's expected standard deviation is ~3.78 times greater than the Bio-Rad expected SD and the acceptability range includes values that are negative (-0.209). These ranges are not able to detect immediate error. Assay - Chloride Bio-Rad Level 3 - 45863 Expected Mean - 121 Plus/minus 3SD range - 114-128 Expected SD - 2.33 For the same assay, the laboratory had the following quality control expectations: Expected mean: 125.07 Plus/minus 3SD range - 110.07-140.07 Expected SD - 5.0 The laboratory's expected standard deviation is ~2.17 times greater than the Bio-Rad expected SD. Assay - Bilirubin - Total Bio-Rad Level 1 - Lot 45863 Expected Mean - 7.0 Plus/minus 3SD range - 6.46 - 7.53 Expected SD - 0.178 For the same assay, the laboratory had the following quality control expectations: Expected mean: 7.028 Plus/minus 3SD range - 5.828- 8.229 Expected SD - 0.4 The laboratory's expected standard deviation is ~2.24

	times greater than the Bio-Rad expected SD. 3. In an interview at 10:42 on 4/9/2021 in the office, the Laboratory Manager stated the expected ranges were supposed to be from historic performance data for each of the assays listed above. Based on a review of the Unity Laboratory Comparison Report, the laboratory stated ranges did not originate from historic data. Assay - Bilirubin - Direct Bio-Rad Level 1 - Lot 45861 Expected SD - 0.037 For the same assay, the laboratory had the following quality control expectations: Expected SD - 0.14 From the Unity Laboratory Comparison Report, based on 228 points submitted, the calculated SD was 0.026, and peer group was calculated to be 0.027. Assay - Chloride Bio-Rad Level 3 - 45863 Expected SD - 2.33 For the same assay, the laboratory had the following quality control expectations: Expected SD - 5.0 From the Unity Laboratory Comparison Report, based on 237 points submitted, the calculated SD was 1.15, and peer group was calculated to be 1.52. Assay - Bilirubin - Total Bio-Rad Level 1 - Lot 45863 Expected SD - 0.178 For the same assay, the laboratory had the following quality control expectations: Expected SD - 0.4 From the Unity Laboratory Comparison Report, based on 227 points submitted, the calculated SD was 0.1, and peer group was calculated to be 0.198. Key SD - standard deviation
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with facility personnel, the laboratory failed to perform gram stain quality control at least each week of use for one patient tested in January 2021 (one of two weeks reviewed). The findings included: 1. Based on review of patient testing records, a gram stain was performed on Sample 23739187 on 1/17/2021. The log titled "Gram Stain Log" had a place to document both positive and negative controls. No controls were documented in January 2021. 2. At 14:07 hours on 4/8/21 in the laboratory, the surveyor observed the gram stain control slides had expired on 8/27/2020. 3. In an interview at 14:07 hours on 4/8/21 in the office, the Laboratory Manager stated the testing personnel who performed the gram stain on 1/17/2021 should have documented the positive and negative controls on the "Gram Stain Log".