Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0483678	05/19/2022
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	Based on a proficiency testing desk review survey performed on May 19, 2022, the laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D2016 - 42 C.F.R. 493.803 Condition: Successful participation D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director, moderate complexity
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, and American Proficiency Institute (API) proficiency testing records from 2021 and 2022, the laboratory failed

	to achieve satisfactory performance (80% or greater) for the specialty of Bacteriology in two out of two consecutive events, resulting in unsuccessful performance. Refer to D2028.
D2028	BACTERIOLOGY CFR(s): 493.823(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, and American Proficiency Institute (API) proficiency testing records from 2021, and confirmed in interview, the laboratory failed to achieve satisfactory performance (80% or greater) for the specialty of Bacteriology in two out of two consecutive events. The findings include: 1. A review of the CASPER report 155 lists a score of "60%" for the API Microbiology 3rd Event, and a score of "70%" for the API Microbiology 1st Event for the specialty of Bacteriology. 2. A proficiency desk review of the API proficiency testing records from 2021 confirmed that the laboratory received unsatisfactory scores for the specialty of Bacteriology for 3rd event 2021 and 1st event 2022.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, patient test records from 2021 and 2022, and confirmed in interview, the facility failed to follow its policy to identify and investigate blood transfusions for four of ten patients reviewed. A) vitals B) hypotension Findings included: 1. Review of the laboratory policy Blood and Blood Products Administration-LS-MKT (policy 31337.2) under Administration revealed "patients will be continuously assessed at the bedside for signs and symptoms of transfusion reactions during the first 15 minutes of transfusion. Life threatening reactions can occur after the infusion of only a small volume of blood. Vital signs will be taken and recorded on the blood product ID tag and in EMR." A) Vitals 2. Random review of the transfusion records from 2021 and 2022 for the following patients revealed no documentation of the vital signs for three of ten records reviewed per the laboratory policy. Patient 336534 - 2/14/2021 Unit W035222126010 transfusion started at 1236 hours; no vitals for pre-transfusion Patient 226355 - 4/6/2022 Unit W035222167574 transfusion started at 1849 hours no respiratory or temperature at 15 minutes after start of transfusion (1912 hours) Patient 335768 - 1/25/2022 Unit W035221419962 no pre transfusion vitals; no post transfusion blood pressure and temperature B) hypotension 3. Review of the laboratory policy Transfusion Reaction Investigation under Hemolytic and Febrile Reactions revealed "acute hemolytic reactions are the most severe adverse effects of transfusion known. Febrile, non-

	hemolytic reactions due to antibodies against HLA or white blood cell related antigens are commonly seen and range in severity from very mild to very severe. Both type of reactions may present similar initial symptoms, including...hypotension" 4. Random review of the transfusion records from 2021 and 2022 revealed one of ten transfusion records of low blood pressure (hypotension) with a diastolic change of greater than 30 mmHg without documentation of the nurse and/or physician accounting for the change for one of ten patients reviewed. Patient 313973 - 2/21/2022 Unit W035222121860 transfusion started at 1534 hours; no vitals for post-transfusion Blood pressure pre transfusion was 119/81 mmHg Blood pressure at 15 minutes (1549) was 125/43 5. An interview with the Med/Surg Director on 5/18/22 at 1114 hours in the conference room confirmed the above findings. She acknowledged that blood pressure is not a criteria or indication of transfusion reaction that she normally screens for.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on a review of reagent instructions for use, turnaround time records, and confirmed in interview, the laboratory failed to have a quality assessment mechanism in place to monitor, assess, and correct issues associated with lactic acid collection and processing for 35 out of 35 patients that exceeded the manufactures requirements for specimen collection and handling reviewed in November 2021 and March 2022. The findings include: 1. Review of the "Siemens Flex Reagent Cartridge Lactic Acid" instructions for use, section "Specimen Collection and Handling" stated: "Blood is best collected without stasis in a container of sodium fluoride/potassium oxalate, followed by immediate chilling of the specimen and separation of the cells within 15 minutes." 2. Review of turnaround time records for November 2021 and March 2022 for lactic acid has the following 35 patients with a documented collect to received time that exceeded the 15-minute requirement for the separation of plasma from cells. November 2021: 21 patients Date - Specimen ID - Collect to Receive time 11/1/2021 - 21TQ-305C0007 - 30m 11/2/2021 - 21TQ-306C0005 - 129m 11/4/2021 - 21TQ-308C0087 - 18m 11/7/2021 - 21TQ-3110016 - 38m 11/7/2021 - 21TQ-311C0029 - 23m 11/8/2021 - 21TQ-312C0085 - 194m 11/9/2021 - 21TQ-313C0080 - 25m 11/13 /2021 - 21TQ-317C0016 - 30m 11/14/2021 - 21TQ-318C0025 - 30m 11/14/2021 - 21TQ-318C0026 - 69m 11/16/2021 - 21TQ-320C0101 - 40m 11/17/2021 - 21TQ-321C0016 - 17m 11/17/2021 - 21TQ-321C0057 - 17m 11/20/2021 - 21TQ-324C0045 - 22m 11/21/2021 - 21TQ-325C0001 - 16m 11/21/2021 - 21TQ-325C0005 - 38m 11 /22/2021 - 21TQ-326C0004 - 33m 11/22/2021 - 21TQ-326C0101 - 122m 11/23/2021 - 21TQ-327C0006 - 18m 11/23/2021 - 21TQ-327C0014 - 45m 11/27/2021 - 21TQ-331C0044 - 39m March 2022: 14 patients Date - Specimen ID - Collect to Receive Time 3/6/2022 - 22TQ-065C0053 - 17m 3/7/2022 - 22TQ-066C0056 - 28m 3/12/2022 - 22TQ-071C0019 - 26m 3/12/2022 - 22TQ-071C0023 - 21m 3/12/2022 - 22TQ-071C0028 - 17m 3/16/2022 - 22TQ-075C0061 - 15m 3/16/2022 - 22TQ-075C0083 - 45m 3/20/2022 - 22TQ-079C0033 - 141m 3/21/2022 - 22TQ-080C0005 - 166m 3/22 /2022 - 22TQ-081C0009 - 20m 3/23/2022 - 22TQ-082C0103 - 19m 3/23/2022 - 22TQ-082C0106 - 15m 3/24/2022 - 22TQ-083C0052 - 53m 3/30/2022 - 22TQ-089C0079 - 20m 3. Surveyor queried the general supervisor (GS) on 5/19/2022 at 10:

	30 hours, for more information on how the laboratory handled the extended turnaround time for lactic acids. The GS explained that the laboratory occasionally receives lactic acid specimens from hospital staff without orders, to which they centrifuge and separate the plasma from the cells for refrigerated storage within the 15 minutes specified, until an order is placed. And that the elapsed time of collection to receive times listed above were inaccurate. Surveyor queried for documentation of such practices and none was provided. 4. In an interview on 5/19/2022 at 10:40 hours, in the conference room, the GS confirmed that the laboratory did not have a pre-analytical quality assessment in place to verify the specimen handling and processing for lactic acid specimens that exceed the manufacturer's requirements for reliable test results.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of manufacturer's instructions, laboratory documents, calibration records, and confirmed in interview, the laboratory failed to follow manufacturer instructions to perform a calibration after changing the source lamp on the Siemens Dimension EXL chemistry analyzer for five of five light-dependent methods reviewed after 2 source lamp changes in December 2021 to April 2022. The findings include: 1. Review of the Siemens Dimension EXL chemistry analyzer operator's guide, chapter 6 "Calibration and Quality Control", subsection "When to Calibrate or Verify Photometric and LOCI Methods" stated: "Calibrate C3, C4, CCRP, CRBM, CRP, GENT, HA1C, HB1C, IGA, IGG, LIDO, MALB, NAPA, PALB, PHNO, PROC, PTN, RCRP, THEO, TOBR, TRNF, VALP, and VANC whenever the source lamp is replaced because these methods are light-dependent." 2. Review of the "Listing of Tests Performed in the Facility" completed by the laboratory general supervisor (GS) had the following light-dependent methods listed as part of the laboratories test menu: HgB A1C (HA1C) Microalbumin (MALB) Phenytoin (PHNO) Theophylline (THEO) Vancomycin (VANC) 3. Review of the Miscellaneous log sheet for the Siemens Dimension EXL Chemistry analyzer had the following dates where the photometer (source lamp) was changed with no time stamp: 4/30/2022: Changed Photometer 12/23 /2021: Changed the source lamp Surveyor queried the GS, on 5/18/2022 at 14:10 hours, for the calibration records that the light-dependent methods HA1C, MALB, PHNO, THEO, VANC were calibrated after the photometer (source lamp) was changed, and none was provided. 4. In an interview on 5/18/2022 at 14:20 hours, in the conference room, the GS confirmed that the laboratory did not calibrate all light-dependent methods after the above change of the Dimension EXL chemistry analyzer photometer.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following

	for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, manufacturer's instructions, laboratory and patient test records from 2022, and confirmed in interview, the laboratory failed to document two acceptable levels of controls for CSF (cerebrospinal fluid) body fluid cell count for two of two days reviewed. Findings included: 1. Review of the laboratory policy CSF Cell Counts (Hemacytometer) (Policy #HEM-012) revealed no acceptance criteria for the quality control. 2. Review of the laboratory records from 2022 revealed the laboratory used the Streck Cell-Chex Body Fluid Cell Count control for the CSF body fluid cell count tests. 3. Review of the package insert for the Streck Cell-Chex Body Fluid Cell Count Control (350537-7, 2019-06) revealed the following the acceptable ranges for RBC (red blood cell) and WBC (white blood cell) Level 1: Lot 13190412 RBC: 4-14 RBCs/uL WBC: 6-16 WBCs/uL Level 2: Lot 13190413 RBC: 80-130 RBCs/uL WBC: 81-131 WBCs/uL 4. Review of the CSF Worksheet from January to May 2022 revealed the following two of two days with unacceptable results for one or both levels of quality control with no corrective action. 4/19/2022 Level 1: Lot 13190412 1.11 RBCs/uL acceptable range 4-14 RBCs/uL 1.11 WBCs/uL acceptable range 6-16 WBCs/uL Level 2: Lot 13190413 10 RBCs/uL acceptable range 80-130 RBCs/uL 12.2 WBCs/uL acceptable range 81-131 WBCs/uL 5/15/2022 Level 2: Lot 13190413 48.3 RBCs/uL acceptable range 80-130 RBCs/uL 50 WBCs /uL acceptable range 81-131 WBCs/uL 5. Review of the patient test records of the above dates revealed the laboratory performed the following two patient testing. 4/19 /2022 Patient ID 279390 5/15/2022 Patient ID 281339 6. An interview with the laboratory manager on 5/18/2022 at 1100 hours in the conference room confirmed the above findings.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on surveyor observations, review of records, and interview with facility personnel, the laboratory failed to compare the relationship between two of two MedTox Scan analyzers at least twice annually for 2021. The findings included: 1. Based on surveyor observations at 16:06 hours on 5/18/2022, the laboratory utilized two MedTox Scan analyzers for toxicology testing: Serial Number: 1919M2179 and Serial Number 2419M1499 2. At 16:04 hours on 5/18/2022, the surveyor requested documentation of comparing the relationship between the results of the two analyzers. 3. In an interview at 16:04 hours on 5/18/2022, the laboratory manager stated the laboratory had not evaluated the relationship between the two analyzers at least twice annually in 2021.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)

	(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory and patient test records from March 2022 to May 2022, and confirmed in interview, the laboratory failed to document corrective actions when the DxH hematology analyzer were performing outside of established performance specifications for three of twenty days reviewed. Findings included: 1. Review of the DxH operator's manual under Individual Troubleshooting revealed the following procedures: "Clearing a Flow Cell Aperture Follow this procedure only when the flow cell is fully clogged or low events are observed. The indications of a full clog included...flow cell DC voltage exceeded the expected range...The Clear Flow Cell aperture cycle flushes the flow cell multiple times with Cleaner followed by a deep clean." 2. Review of the DxH event log from March 2022 to May 2022 revealed the following error messages for the following three days with no corresponding corrective action per the manufacturer's instructions. 3/28/2022 Event ID=835 Message: Flow cell DC voltage exceeded the expected range. Possible full clog. 4/12/2022 Event ID=835 Message: Flow cell DC voltage exceeded the expected range. Possible full clog. 4/13/2022 Event ID=835 Message: Flow cell DC voltage exceeded the expected range. Possible full clog. 3. Review of the CMS116 revealed the laboratory performed 105780 tests annually. 4. An interview with the laboratory manager on 5/19/2022 at 1040 hours in the laboratory confirmed the above findings.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, patient test reports, and confirmed in interview, the laboratory failed to assess all patient test results obtained since the last acceptable test run for QC instances that failed to meet the laboratory's established criteria that could not be resolved through repeat testing for six of six QC failures reviewed in November 2021, January 2022, and April 2022. The findings include: 1. Review of QC records for November 2021, January 2022, and April 2022 have the following six QC instances that failed to meet the laboratory's established acceptance

	criteria that could not be resolved with repeat testing: November 2021: 1 Failure Date, Time - Analyte - Corrective Action 11/9/2021, 0340am - Lactic Acid - "New lot of Lactic Acid" A sampling of patients ran since the last acceptable QC includes: Date - Sample ID - Analyte 11/8/2021 - 275224 - Lactic Acid January 2022: 2 Failures Date, Time - Analyte - Corrective Action 1/14/2022, 0835pm - Troponin - Recalibrate 1/29 /2022, 1227am - Glucose - Troubleshoot with Service A sampling of patients ran since the last acceptable QC includes: Date - Sample ID - Analyte 1/13/2022 - 300568 - Troponin 1/13/2022 - 281049 - Troponin 1/13/2022 - 384821 - Troponin 1/28/2022 - 335696 - Glucose 1/28/2022 - 249544 - Glucose April 2022: 3 Failures Date, Time - Analyte - Corrective Action 4/26/2022, 0100am - Cholesterol and LDL - Recalibrate 4 /22/2022, 2204pm - Vitamin B 12 - Recalibrate Vit 4/23/2022. 1730pm - Total Bilirubin (T Billi) - Troubleshooting with service A sampling of patients ran since the last acceptable QC includes: Date - Sample ID - Analyte 4/21/2022 - 241042 - Vitamin B12 4/22/2022 - 338597 - T Bili 2. Surveyor queried the general supervisor (GS) on 5/18/2022 at 1550 hours, in the conference room, for documentation that the laboratory assessed all patients to the last acceptable run for the above QC failures and none was provided. 3. In an interview on 5/18/2022 at 1600 hours, the GS confirmed that the laboratory did not assess all patient test results obtained since the last acceptable test run for QC instances that failed to meet the laboratory's established criteria that could not be resolved through repeat testing.
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 desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Proficiency Institute (API) proficiency testing records, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program for specialty of Bacteriology for two fo two events in 2021 and 2022. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Proficiency Institute (API) proficiency testing records, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program for the specialty of Bacteriology for two of two events in 2021 and 2022. Refer to D2028.