Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D2239259	06/27/2024
Name of Provider or Supplier	**Street Address, City, State**	
Quitman Community Hospital	340 Getwell St, Marks, MS	

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
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 Hematology records (to include analyzer quality control (QC) printouts and Insight Historical Data Comparison QC reports) and interview with the laboratory manager, the laboratory failed to retain daily Hematology QC results for complete blood count (CBC) performed on the Sysmex XN 450 Hematology analyzer for twelve of twenty-two months. Findings Include: 1. Review of the Sysmex XN 450 Hematology QC records to include the Peer Group Comparison and Historical Data Comparison, from 8/31/2022 through 6/19/2024, confirmed the daily QC performed on the Sysmex XN 450 was not retained from the actual analyzer nor was the daily QC retained in the Insight QC documentation returned to the laboratory from the Sysmex Company for twelve of twenty two-months. 2. Interview with the laboratory manager on 6/26/24 at 2:00 p.m. revealed the Sysmex daily QC analyzer printouts were not retained and included in the QC data returned from Sysmex in the Historical Data Comparison or the Peer Group Comparison.
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: A. Based on review of the Epoc Blood Gas System Standard Operating Procedure, lack of documentation and interview with testing personnel (TP) #6 /Respiratory dept, the laboratory failed to perform calibration verification on the Epoc Blood Gas System for pH, pCO2 and pO2 for three of four six-month periods. Findings include: 1. Review of the Epoc Blood Gas records revealed only one documentation of calibration verification/linearity performed on the Epoc Blood Gas system for blood gases (pH, pCO2, pO2) on 8/10/2022. 2. The Epoc System Standard Operating Procedure states to "Follow the calibration verification procedure to verify accuracy of test results over an extended measurement range of a test. While commercial calibration verification sets contain five levels, verification of the measurement range can be accomplished using lowest, highest and mid-levels." 3. TP #6/Respiratory confirmed in an interview on 6/27/24 at 11:00 a.m. there was only one calibration verification performed and documented. THIS IS A REPEAT DEFICIENCY B. Based on review of Dimension EXL Chemistry analyzer records to include quality control, maintenance and calibration records, and interview with the laboratory manager, the laboratory failed to perform calibration verification on the Siemens Dimension EXL Chemistry analyzer for Sodium (Na), Potassium (K), and Chloride (Cl) for three of four six-month periods. Findings include: 1. Review of Siemens Dimension EXL calibration verification records revealed that a calibration verification was not performed on Sodium (Na), Potassium (K), and Chloride (Cl) for three of four six-month periods. The last calibration verification performed was on 5/24/2022. These chemistry tests have only 1 calibration point and therefore require calibration verification to be performed every 6 months including at least a minimal (zero) value, a mid-point, and a maximum value to verify the laboratory's reportable range. 2. Interview with the laboratory manager on 6/27/2024 at 4:00pm confirmed that Na, K, and Cl calibration verifications due in November of 2022, May of 2023 and November of 2023 were not performed by the laboratory staff.
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 Epoc Blood Gas records, patient Blood Gas log, lack of documentation of an Individualized Quality Control Plan (IQCP), and interview with respiratory testing personnel (TP) #6, the blood gas testing staff failed to include at least two levels of control material each day of patient testing for eleven of eleven months. Findings include: 1. Review of Epoc quality control (QC) records from 7/29 /2022 through 6/29/2024 revealed no QC was performed for eleven of eleven months, on days patients were tested and blood gas results reported. The last day QC was performed was on 8/10/2022. 2. Review of blood gas patient test records from 8/2 /2022 through 7/13/2023 revealed eighteen patient blood gas results were reported during this time with no documentation of performance of two levels of QC (Eurotrol level 1 and Eurotrol level 3) each day of patient testing. 3. There was no documentation of establishment of an IQCP, if two levels of control are not included each day of patient testing. 4. Interview with TP #6/Respiratory testing personnel confirmed no IQCP was written for blood gas testing on the Epoc Blood Gas System and QC had not been performed.
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 review of the laboratory proficiency testing records, Centers for Medicare and Medicaid Services (CMS) database proficiency testing CASPER report and confirmation with the laboratory manager, the laboratory director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing (PT) program for Hematology, Chemistry, Toxicology and Blood Gases for one of six proficiency testing events. Findings include: 1. Review of the CMS database proficiency testing CASPER report revealed no scores or participation for Hematology, Chemistry, Toxicology or Blood Gas for the 1st event of 2023. The laboratory did not enroll and participate in one of six proficiency events. 2. Review of the laboratory proficiency records from 7/29/2022 through 6/27/2024, revealed no evidence of proficiency testing enrollment or participation for the 1st proficiency testing event of 2023. 3. The laboratory manager confirmed in an interview on 6/26/2024 at 2:00 p.m. that the laboratory director did not ensure the laboratory was enrolled in proficiency testing for Hematology, Chemistry, Toxicology and Blood Gases in time to participate in the 1st proficiency testing event of 2023.
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 laboratory testing personnel (TP) records, the Centers for Medicare and Medicaid Services (CMS) 209 form and interview with the laboratory manager, the laboratory director had not ensured that two of six testing personnel as listed on the CMS 209 personnel form had received the appropriate documented training prior to performing and reporting all testing in the laboratory to include Hematology, Chemistry and Toxicology. Findings Include: 1. Review of laboratory personnel records and lack of training documentation revealed two of six TP had no documentation of initial training prior to performing patient testing. 2. Interview with the laboratory manager on 6/27/2024 at 3:00 p.m. confirmed that TP #2 (hire date 10 /20/23) and TP #4 (hire date 10/23/23) lacked documentation of initial training.
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing records, Centers for Medicare and Medicaid Services (CMS)proficiency testing CASPER report and interview with the laboratory manager, the technical consultant failed to ensure the laboratory enrolled and participated in an HHS approved proficiency testing (PT) program for Hematology, Chemistry, Toxicology and Blood Gas. Findings include: 1. Review of the laboratory proficiency records for 2022, 2023 and 2024 and the CMS database report revealed no proficiency testing was reported for Hematology, Chemistry, Toxicology and Blood Gases for 1st event of 2023. The laboratory did not participate in one of six proficiency events since the last survey. 2. Review of the laboratory proficiency records for 2022, 2023 and 2024 and the CMS database report revealed the Respiratory Department did not participate in the 1st, 2nd or 3rd events of 2023 or the 1st and 2nd event of 2024. Patient blood gases were being run on the EPOC blood gas analyzer during the time of the 1st and 2nd events of 2023, until 7/13/2023. The laboratory manager and the respiratory TP confirmed the Epoc Blood Gases System was inoperable from 7/13/2023 until 6/27/2024. 3. The laboratory manager confirmed in an interview on 6/26/2024 at 12:00 p.m. that the laboratory did not participate in the 1st proficiency event of 2023 for Hematology, Chemistry, Toxicology and Blood Gases.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

	This STANDARD is not met as evidenced by: Based on review of laboratory testing personnel (TP) records, Centers for Medicare and Medicaid Services (CMS) 209 personnel form and interview with the laboratory manager, the technical consultant (TC) failed to evaluate and document the performance of two of six testing personnel at least semiannually during the first year of moderate complexity testing. Findings include: 1. Review of the laboratory personnel records since the last survey on 7/29/2022 revealed no semiannual evaluation available for the performance of two of six testing personnel. a. TP #2 date of hire-10/20/2023, semiannual evaluation due-4/24 b. TP #4 date of hire-10/23/2023, semiannual evaluation due-4/24 2. The laboratory manager confirmed in an interview on 6/27/2024 at 3:00 p.m., there was no personnel file containing the semiannual evaluation/competency on the testing personnel #2 and #4.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of laboratory testing personnel (TP) records including the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, and interview with the laboratory manager, the technical consultant failed to evaluate the performance for three of six testing personnel as listed on the CMS 209 form, at least annually. Findings include: 1. The surveyor reviewed personnel records from 7/29/2022 through 6/27/2024 including competency evaluations and the CMS 209 personnel form. 2. There was no annual competency/evaluation for: a. TP#1- competency /evaluation for 2022 and 2023 b. TP#3- competency /evaluation for 2024 c. TP#6- competency /evaluation for 2022 and 2023 3. The laboratory manager confirmed in an interview on 6/27/2024 at 3:30 p.m. that no annual competency evaluation had been documented as performed by the TC for three of six testing personnel.