Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0677527	09/24/2020
Name of Provider or Supplier	**Street Address, City, State**	
Comanche County Medical Center Company	10201 Highway 16 North, Comanche, 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
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: No deficiency details available.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: No deficiency details available.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b)

	The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: ********** Revisit conducted 09/23/2020 -- 09/24/2020 This is a NEW finding. Based on review of specimen receipt logs, patient reports, and in interview with staff, the laboratory failed to enter an accurate received and/or collection time for specimens received from outside clients in their Laboratory Information System (LIS) for 5 of 5 patients (random sampling from May - September 2020). Findings included: 1. A review of the laboratory Specimen Receipt Logs from May - September 2020 revealed the following information was documented on the log: "Patient Name and Date of Birth Today's Date and Tests Ordered Time Paperwork Dropped off at Administration Time Specimen(s) Dropped Off at Lab Collection Time and Name of Collector Home Health Number and Fax Number Number to Call a Critical" 2. A random review of test reports from patients listed on the laboratory specimen receipt logs revealed the following: Date 07/15/2020 Patient M000045353 Date/ Time Received documented on Log = 07/15/2020 1120 hours Date/Time Received in LIS = 07/15/2020 1139 hours Date 07/22/2020 Patient M000017368 Date/ Time Received documented on Log = 07/22/2020 1148 hours Date /Time Received in LIS = 07/22/2020 1158 hours Date 08/21/2020 Patient M000000625 Date/ Time Received documented on Log = 08/21/2020 1718 hours Date /Time Collected documented on Log = 08/21/2020 1240 hours Date/Time Received in LIS = 08/21/2020 1738 hours Date/Time Collected in LIS = 08/21/2020 1700 hours Date 09/02/2020 Patient M000000842 Date/ Time Received documented on Log = 09 /02/2020 1555hours Date/Time Collected documented on Log = 09/02/2020 1530 hours Date/Time Received in LIS = 09/02/2020 1856 hours Date/Time Collected in LIS = 09/02/2020 1455 hours Date 09/07/2020 Patient M000008340 Date/ Time Received documented on Log = 09/07/2020 0830 hours Date/Time Received in LIS = 09/07/2020 1010 hours 3. In an interview on 09/24/2020 at 1000 hours in the conference room, the laboratory manager confirmed the above findings. **********
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: ********** Revisit Conducted 09/23/2020 -09/24/2020 This is a NEW finding. Based on review of the laboratory's defined analytical ranges, review of the laboratory's verification studies performed on the Siemens RAPIDPoint 500 (Serial Number 46068) blood gas analyzer, and staff interview, it was revealed the laboratory failed to have documentation of studies to support the analytical ranges currently in use. Findings included: 1. 1. A review of the laboratory's defined analytical ranges revealed the laboratory utilized the following ranges to aid in the assessment of patient test results: Test Hemoglobin; Analytical Range: 2.0 - 25.0 g/dl

	pO2; Analytical Range: 10.0 - 700.0 mmHg pCO2; Analytical Range: 5.0 - 200.0 mmHg pH; Analytical Range: 6.500 - 7.800 2. A review of the laboratory's verification studies performed on the Siemens RAPIDPoint 500 (Serial Number 46068) blood gas analyzer on 01/13/2020 through 01/15/2020 revealed the laboratory was able to prove the following analytical ranges: Test Hemoglobin; Analytical Range: 4.83 - 21.10 g/dl pO2; Analytical Range: 51.07 - 519.53 mmHg pCO2; Analytical Range: 15.60 - 173.40 mmHg pH; Analytical Range: 6.7020 - 7.6987 3. The laboratory was asked to provide documentation of performing studies to support the reportable ranges currently in use. No documentation was provided. 4. In an interview on 09/23/2020 at 1332 hours in the conference room, the respiratory therapy manager confirmed the above findings. **********