

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0677527	(X3) Date Survey Completed 06/18/2021
Name of Provider or Supplier Comanche County Medical Center Company	Street Address, City, State 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
D0000	<p>An entrance conference was held with the laboratory representatives. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, American Proficiency Institute (API) proficiency testing (PT) records (2020 Events 1,2, 3 and 2021 Event 1) and staff interview, Blood Gas testing persons failed to attest to the routine integration of proficiency samples into the patient workload for 4 of 4 events in 2020 and 2021. Findings included: 1. Review of laboratory records revealed the laboratory tested blood gas samples for the following analytes on the Siemens RapidPoint 500 blood gas analyzer (Serial Number 46068): pCO₂ (Blood Gas), pH (Blood Gas), and pO₂</p>

(Blood Gas) 2. Review of API proficiency testing records revealed the following statement: "Attestation Statement SIGNATURES REQUIRED- Testing personnel and the laboratory director must physically sign an attestation statement for all PT results and retain the signed statement (or a copy) for a minimum of 2 years. Either the attestation statement below or a printed copy of the form provided online can be used for this purpose." 3. Review of PT records from 2020 and 2021 revealed the individual performing testing on the PT samples failed to sign the attestation forms for the following events: 2020 Chemistry Core 1st Event Individuals performing pCO₂ (Blood Gas), pH (Blood Gas), pO₂(Blood Gas), BG-01 through BG-05 sample sets failed to sign the attestation form. 2020 Chemistry Core 2nd Event Individuals performing pCO₂ (Blood Gas), pH (Blood Gas), pO₂(Blood Gas), BG-06 through BG-10 sample sets failed to sign the attestation form. 2020 Chemistry Core 2nd Event Individuals performing pCO₂ (Blood Gas), pH (Blood Gas), pO₂(Blood Gas), BG-11 through BG-15 sample sets failed to sign the attestation form. 2021 Chemistry Core 1st Event Individuals performing pCO₂ (Blood Gas), pH (Blood Gas), pO₂(Blood Gas), BG-01 through BG-05 sample sets failed to sign the attestation form. 4. During an interview on 06/16/2021 at 11:42am in the conference room, the Technical Consultant confirmed the laboratory failed to attest to the routine integration of blood gas proficiency samples into the patient workload. Word Key: pCO₂= Partial pressure of carbon dioxide pO₂= Partial pressure of oxygen

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies, submitted Centers for Medicare and Medicaid Services (CMS) 209 form, personnel records, and staff interview, it was revealed the laboratory failed to have documentation of a policy to assess competency, based on the position responsibilities, for 1 of 1 Technical Consultants (TC-1), 1 of 1 Technical Supervisors (TS-2), and 1 of 1 General Supervisors (GS-1). Findings included: 1. A review of the laboratory's policies revealed the laboratory failed to have documentation of a policy of when and how a competency assessment was to be performed on the Technical Consultant, the Technical Supervisor, and the General Supervisor. 2. Review of the submitted Centers for Medicare and Medicaid Services (CMS) 209 form listed one Technical Consultant, one Technical Supervisor for high complexity Bacteriology, Immunology, Chemistry and Hematology testing, and one General Supervisor (GS-1). 3. Review of personnel records for TC-1, TS-2, and GS-1 revealed there was no documented annual competency assessment for the duties performed as a technical consultant, technical supervisor and general supervisor. 4. During an interview on 06/16/2021 at 11:42am in the conference room, the Technical Consultant confirmed the above findings.

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 review of Sysmex CA-660 coagulation analyzer manufacturer's instructions, reference interval study for PT (prothrombin time) and staff interview, the laboratory failed to follow manufacturer's instructions for establishing the reference interval (patient normal range) for PT reagent (Innovin) upon installation of the Sysmex CA-660 coagulation analyzer. Findings included: 1. The Sysmex CA-660 coagulation analyzer manufacturer's instructions (Installation Package Rev 2.1), stated the following: "V. Reference Interval: Verification of Reference IntervalRequirements: Donors must be from a healthy population (no known pathological condition; no pre-surgical or hospitalized patients; Donors should not take any medications, including aspirin; Donors should span the adult range ...Testing should be performed over a period of several days and by different people, if possible, to allow for day to day variation; Samples should be drawn each testing day, following the established laboratory protocol for collection, storage, and processing; The test results from the donors should be analyzed statistically ..." NOTE: This form references CLSI document EP28-A3C: Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory: Approved Guideline, Third Addition, October 2010. 2. Review of records for Sysmex CA-660 coagulation analyzer (Serial Number 26453) revealed it was installed 03/2021. The current MNPT (mean normal prothrombin time) was based on the PT reagent, Innovin, Lot #549771 with 30 George King plasma samples (Batch Number 1166, 15 females and 15 males). The laboratory failed to establish the mean of the normal patient range with the normal individuals as required by the manufacturer which refers to a CLSI document (EP28-A3C). The laboratory did not include donors from their own population with documentation for ensuring individuals were normal. 3. During an interview on 06/16/2021 at 04:12pm in the conference room, the technical consultant confirmed the laboratory did not establish a normal patient range with normal individuals from their own population,

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on review of Siemens RapidPoint 500 blood gas analyzer product specifications (40-17-10378-01-76 01-2018), laboratory environmental records (01/2021 through 04/2021), and confirmed in interview, the laboratory failed to ensure barometric pressure measurements were within operating specifications for the RapidPoint 500 blood gas analyzer (Serial Number 46068) for 120 of 120 days. Findings included: 1. Review of the Siemens RapidPoint 500 blood gas analyzer product specifications revealed the following: "Barometric Pressure: 523-800 mmHg" 2. Review of the laboratory environmental logs (01/2021 through 04/2021) titled "Respiratory Department Laboratory Environment Siemens Rapidpoint 500" revealed

the laboratory specified an acceptable barometric pressure range of 523-800 mmHg. 3. Further review of the laboratory environmental logs (01/2021 through 04/2021) titled "Respiratory Department Laboratory Environment Siemens Rapidpoint 500" revealed 120 of 120 days of documented barometric pressure measurements not within the acceptable range of 523 - 800 mmHg. A random review of environmental records revealed the following barometric pressure readings: 01/01/2021; Barometric pressure = 29.5 01/04/2021: Barometric pressure = 29.8 01/12/2021; Barometric pressure = 30.1 01/18/2021: Barometric pressure = 29.8 01/26/2021; Barometric pressure = 29.5 01/31/2021: Barometric pressure = 29.9 02/01/2021; Barometric pressure = 30 02/05/2021: Barometric pressure = 29.6 02/14/2021; Barometric pressure = 29.9 02/20/2021: Barometric pressure = 30.1 02/26/2021; Barometric pressure = 29.7 02/28/2021: Barometric pressure = 29.6 03/01/2021; Barometric pressure = 29.7 03/04/2021: Barometric pressure = 29.8 03/12/2021; Barometric pressure = 28.4 03/18/2021: Barometric pressure = 29.8 03/26/2021; Barometric pressure = 29.8 03/31/2021: Barometric pressure = 29.7 04/02/2021; Barometric pressure = 30.1 04/05/2021: Barometric pressure = 30.0 04/14/2021; Barometric pressure = 29.6 04/20/2021: Barometric pressure = 29.7 04/26/2021; Barometric pressure = 29.5 04/28/2021: Barometric pressure = 29.5 The laboratory failed to ensure barometric pressure measurements were within acceptable operating specifications for the Siemens Rapidpoint 500 blood gas analyzer. 4. In an interview on 06/17/2021 at 10:15am in the blood gas room, after review of the environmental records, the technical consultant confirmed the above findings. Word Key: mmHg=millimeters of Mercury

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on review of the CMS-209 form, laboratory policies, personnel records, and staff interview, the technical consultant failed to evaluate and document annual competency in 2021 for 5 of 5 Testing Persons (TP-10, TP-11, TP-12, TP-13 and TP-14) who perform moderate complexity testing RapidPoint 500 blood gas analyzer (Serial Number 46068). Findings included: 1. Review of CMS 209 form revealed 5 testing persons who performed moderate complexity testing on the RapidPoint 500 blood gas analyzer (Serial Number 46068). 2. The laboratory policy titled, "Employee Competency Evaluation" (signed by the laboratory director 06/01/2021) stated, "New hires shall, after training, be evaluated for competency at a six month interval during their first year and then annually thereafter using the training/competency form ...The competency form utilizes the following methods for determining competency: (D) Physical demonstration of skills and knowledge; (PT) Proficiency testing with successful results/review; (V) Verbal demonstration of skills and knowledge; (T) Training in progress; (QC/PR) Review of Quality Control and/or patient records; (NA) Not applicable. This employee is not responsible for this duty or procedure." 3. Review of personnel records from 2021 revealed a form titled, "Siemens RapidPoint 500 Competency". This form listed the procedure to change cartridges on the Rapidpoint 500 blood gas analyzer and the procedure to print out paperwork. The Technical Consultant had not performed and documented competency assessment for TP-10, TP-11, TP-12, TP-13 and TP-14 to include: a) Direct observation of routine

patient test performance, including patient preparation, specimen handling, processing and testing. b) Monitoring the recording and reporting of patient test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens or external proficiency testing samples. f) Assessment of problem-solving skills. 4. In an interview on 06/16 /2021 at 1:55pm in the conference room, the technical consultant confirmed the above findings.

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 the laboratory's submitted Centers for Medicare and Medicaid (CMS -209) form, review of laboratory policy, review of the laboratory's personnel records, and in interview with staff, the technical consultant failed to perform testing personnel competency assessments at least twice the first year of patient testing for 2 of 14 testing persons listed on Form CMS-209. Findings included: 1. Review of the CMS 209 form (signed by the laboratory director on 06/08/2021) revealed 5 Testing Persons (TP #10 - TP#14) performing moderate complexity testing on the RapidPoint 500 blood gas analyzer (Serial Number 46068). 2. The laboratory policy titled, "Employee Competency Evaluation" (signed by the laboratory director 06/01/2021) stated, "To ensure employee continued competency on methods and procedures all laboratory personnel will be evaluated at least annually. New employees shall be evaluated twice during their first year and then annually thereafter. For new test methods or procedures all employees shall be evaluated for competency on the new methodology or procedure twice during the first year of use and then annually thereafterNew hires shall, after training, be evaluated for competency at a six month interval during their first year and then annually thereafter using the training /competency form." 3. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of personnel competency assessments at least twice the first year of patient testing for the following 2 of 14 testing personnel (as listed on Form CMS-209) who performed moderate complexity testing on the RapidPoint 500 blood gas analyzer. a. Testing person #12; Date of Hire 10/08/2020 No documentation of personnel competency assessments after 6 months in the first year of patient testing for RapidPoint 500 blood gas analyzer. b. Testing person #13; Date of Hire 03/13/2020 No documentation of personnel competency assessments at least twice the first year of patient testing for the RapidPoint 500 blood gas analyzer. 4. During an interview on 06/16/2021 at 1:55pm in the conference room, the technical consultant was asked to provide documentation of personnel competency assessments at least twice the first year of patient testing for the RapidPoint 500 blood gas analyzer for TP#12 and TP#13. No documentation was provided. This confirmed the above findings.

D6066

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's submitted Centers for Medicare and Medicaid (CMS -209) form, review of laboratory policy, review of the laboratory's personnel records, and in interview with staff, it was revealed the laboratory failed to have documentation of training for the following 2 of 14 testing persons to qualify them to perform moderate complexity testing on the RapidPoint 500 blood gas analyzer. 1. Review of the CMS 209 form (signed by the laboratory director on 06/08/2021) revealed 5 Testing Persons (TP #10 - TP#14) performing moderate complexity testing on the RapidPoint 500 blood gas analyzer (Serial Number 46068). 2. The laboratory policy titled, "Employee Competency Evaluation" (signed by the laboratory director 06/01/2021) stated, "New hires shall, after training, be evaluated for competency at a six month interval during their first year and then annually thereafter using the training /competency form." 3. A review of the laboratory's personnel records revealed the laboratory failed to have documentation training for the following 2 of 14 testing personnel (as listed on Form CMS-209) who performed moderate complexity testing on the RapidPoint 500 blood gas analyzer. a. Testing person #12; Date of Hire 10/08 /2020 No documentation of training for RapidPoint 500 blood gas analyzer. b. Testing person #13; Date of Hire 03/13/2020 No documentation of training for the RapidPoint 500 blood gas analyzer. 4. During an interview on 06/16/2021 at 1:55pm in the conference room, the technical consultant was asked to provide documentation of training for the RapidPoint 500 blood gas analyzer for TP#12 and TP#13. No documentation was provided. This confirmed the above findings.