

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0677527	(X3) Date Survey Completed 12/04/2024
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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, American Proficiency Institute (API) proficiency testing (PT) records, review of the laboratory's CMS-209 form, and confirmed in interview, the laboratory failed to ensure qualified personnel participated in proficiency testing for one of three events in 2023 and one of two events in 2024 (cross refer to D6046). Findings include: 1. Review of the laboratory's policy titled "SUBJECT: PROFICIENCY TESTING" determined: "Testing Proficiency Samples Samples are to be tested by personnel who normally perform laboratory testing." 2. Review of API PT records revealed the following PT samples were tested for blood gas: 2023: a. Date/Time: 01/11/2023 09:36 Sample: BLX-01 b. Date/Time: 01/11/2023 09:39 Sample: BLX-02 c. Date/Time: 01/11/2023 09:42 Sample: BLX-03 d. Date/Time: 01/11/2023 09:46 Sample: BLX-04 e. Date/Time: 01/11/2023 09:49 Sample: BLX-05 2024: a. Date/Time: 05/27/2023 08:43 Sample: BG-06 b. Date /Time: 05/27/2023 08:46 Sample: BG-07 c. Date/Time: 05/27/2023 08:49 Sample: BG-08 d. Date/Time: 05/27/2023 08:52 Sample: BG-09 e. Date/Time: 05/27/2023 08:55 Sample: BG-10 3. Review of the laboratory's CMS-209 form determined the operator performing the proficiency testing samples was not listed as a testing person. 4. Testing Person-16 (TP-16), as listed on the CMS-209 form confirmed the findings during an interview conducted on 12/03/2024 at 1150 hours in the conference room.</p>

D2009

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(1)

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.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, review of American Proficiency Institute (API) proficiency testing (PT) attestation forms, and confirmed in interview, the laboratory failed to attest the routine integration of PT samples for six of nine events in 2024.

Findings include: 1. Review of the laboratory's policy titled "SUBJECT:

PROFICIENCY TESTING" determined: "Testing Proficiency Samples Print

attestation statement. This must be signed by all personnel participating in the survey

and by either the medical director or designated representative." 2. Review of PT

attestation forms determined the following attestation forms were not signed by the

laboratory director or designated representative in 2024: a. Hematology / Coagulation

1st Event b. Hematology / Coagulation 2nd Event c. Immunology /

Immunohematology 2nd Event d. Microbiology 2nd Event e. Chemistry Core 2nd

Event f. Chemistry Core Verification 2nd Event 3. The Technical Consultant (TC-1),

as listed on the CMS-209 form confirmed the findings during an interview on 12/03

/2024 at 1140 hours in the conference room. Key: CMS - Centers for Medicare and

Medicaid Services

D5807

TEST REPORT

CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

I. Based on review of patient final reports, and confirmed in interview, the laboratory failed to provide normal reference ranges on patient final reports for four of four Wet

Prep tests performed in 2024. Findings included: 1. Review of Wet Prep patient final

reports in 2024, revealed the laboratory failed to provide normal patient reference

ranges on the four of four patient final reports in 2024. Patients reviewed: (See Patient

Alias List) 1. Patient 1 2. Patient 2 3. Patient 3 4. Patient 4 The laboratory was asked

to provide documentation of normal patient reference ranges for Wet Prep testing

provided to physicians, and none were provided. 2. In an interview with the Technical

Consultant (TC-1) on 12/04/2024, at 12:25 PM, TC-1 confirmed the laboratory failed

to provide normal reference ranges on patient final reports for four of four Wet Prep

tests performed in 2024. This confirmed the above findings. 49553 II. Based on

review of manufacturer's instruction for use (IFU), review of patient final reports, and

confirmed in interview, the laboratory failed to provide normal reference ranges on

patient final reports for MRSA Screen tests for five of five patients in 2024 (random

review). Findings include: 1. Review of the manufacturer's IFU titled "remel Spectra

(Trademark) MRSA," IFU 1821, Revised April 16, 2013 determined:

"INTERPRETATION OF THE TEST After 24 hours incubation, MRSA will appear

as small to medium denim blue colonies against a white background Other

organisms (non-MRSA) will exhibit marked inhibition or produce white colonies. If

after 24 hours no denim blue colonies are observed, the specimen is considered negative and plates should be discarded." 2. Review of MRSA Screen patient final reports determined the laboratory failed to provide normal patient reference ranges for five of five patient final reports in 2024 (random review): Patients reviewed: (See Patient Alias List) 1. Patient 1 2. Patient 2 3. Patient 3 4. Patient 4 5. Patient 5 The laboratory was asked to provide documentation of normal patient reference ranges for MRSA Screen tests provided to physicians, and none were provided. 3. The Technical Consultant (TC-1) confirmed the findings during an interview conducted on 12/04 /2024 at 0930 hours in the conference room. Key: MRSA - methicillin-resistant Staphylococcus aureus

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 American Proficiency Institute (API) proficiency testing (PT) records, review of the laboratory's CMS-209 form, and confirmed in interview, the technical consultant failed to evaluate the competency of personnel performing PT for blood gas for one of three events in 2023 and one of two events in 2024. Refer to D2007.

D6049

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

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:
Based on review of moderate complexity testing person competency assessment, and confirmed in interview, the technical consultant failed to include the review of proficiency testing in competency assessments for four of four moderate complexity testing persons in 2024. Findings included: 1. Review of competency assessments for moderate complexity blood gas testing on the RapidPoint 500 Blood gas system, revealed the technical consultant failed to include documentation of proficiency testing review in the competency assessment for the following four of four testing persons: Testing Person 16 (TP16): Competency performed on 01/05/2024 Testing Person 17 (TP17): Competency performed on 01/05/2024 Testing Person 18 (TP18): Competency performed on 02/21/2024 Testing Person 19 (TP19): Competency performed on 03/07/2024 The laboratory was asked to provide documentation of proficiency testing review as part of the competency assessment for the above testing persons. No documentation was provided. 2. In an interview with Technical Consultant 2 (TC-2) in the conference room on 12/03/2024 at 3:20 PM, TC-2 confirmed the technical consultant failed to include the review of proficiency testing in competency assessments for four of four moderate complexity testing persons in 2024. This confirmed the above findings.

D6052

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(vi)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

This STANDARD is not met as evidenced by:

Based on review of moderate complexity testing person competency assessment, and confirmed in interview, the technical consultant failed to include the assessment of problem-solving skills in competency assessments for four of four moderate complexity testing persons in 2024. Findings included: 1. Review of competency assessments for moderate complexity blood gas testing on the RapidPoint 500 Blood gas system, revealed the technical consultant failed to include problem solving skills in the competency assessment for the following four of four testing persons: Testing Person 16 (TP16): Competency performed on 01/05/2024 Testing Person 17 (TP17): Competency performed on 01/05/2024 Testing Person 18 (TP18): Competency performed on 02/21/2024 Testing Person 19 (TP19): Competency performed on 03/07/2024 The laboratory was asked to provide documentation of problem-solving skills as part of the competency assessment for the above testing persons. No documentation was provided. 2. In an interview with Technical Consultant 2 (TC-2) in the conference room on 12/03/2024 at 3:21 PM, TC-2 confirmed the technical consultant failed to include the assessment of problem-solving skills in competency assessments for four of four moderate complexity testing persons in 2024. This confirmed the above findings.