

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0867894	(X3) Date Survey Completed 01/12/2023
Name of Provider or Supplier Mitchell County Hosp Blood Gas Lab	Street Address, City, State 997 West Ih 20, Colorado City, 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	An onsite survey conducted January 11, 2023 thru January 12, 2023 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
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 policy, proficiency testing records from 2022 and interview with testing personnel, the laboratory failed to ensure the individual testing and the laboratory director attested to the routine integration of the samples into the patient workload for two of three proficiency testing events in 2022. The findings included: 1. Based on the laboratory policy "AccuTest Program", the policy stated the following: "The blood gas lab participates in blind study testing of it blood gas instruments, for the purpose of Quality Control and to meet CLIA requirement The blood gas lab is enrolled in a third-party Quality Assurance Pogrom called AccuTest. The blood gas lab shall follow all procedures in accordance with the standards set by Accutest testing services. The blood gas lab shall maintain all records in accordance to AccuTest testing services. Samples are run 3 times per year: April/June/ October Samples will be stored, handled, analyzed, and submitted according to AccuTest testing services. The Medical Director of the Blood Gas Lab will review and sign all outgoing and incoming results. " 2. Based on review of the AccuTest proficiency testing records, the individual testing and the laboratory director did not attest to the integration of the samples into the patient workload using the laboratory's routine methods for the second and third events of 2022. 3. In an interview at 15:15 hours on 1 /12/2023, Testing Person 1 (as listed on the CMS-209 Laboratory Personnel Report) stated she was not aware of the attestation requirement for proficiency testing.</p>

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:

Based on review of laboratory policy, calibration verification records, blood gas operator's manual, and interview with testing personnel, the laboratory failed to perform calibration verification at least every six months for three of three routine chemistry analytes in 2022. The findings included: 1. Based on review of the laboratory policy "PVP TESTING", the policy stated: "The blood gas lab participates in PVP testing every six months as part of Quality Control standards to meet CLIA requirements. All results have to be reviewed and approved by ABG Laboratory Director PVP material will be analyzed according to product instructions. PVP material will be stored according to product recommendations. PVP material will not be used passed expiration date. Testing results will be submitted to I.L. for Linearity results. I.L. technical support may be contacted for assistance in evaluating results." 2. Based on review of laboratory calibration verification data, the last calibration verification procedures were performed for pH, pCO₂, and pO₂ on 10/04/2021 and evaluated on 10/13/2021, approximately one year and three months prior to the date of survey. 3. Based on review of the GEM Premier 3500 Operator's Manual, on page 11.11, the reportable ranges were listed as: The reportable range of pH is 6.8 to 7.8 The reportable range of pCO₂ is 5 to 115 mmHg The reportable range of pO₂ is 0 to 760 mmHg. 4. In an interview at 12:04 p.m. on 1/12/2023, Testing Person 1 stated the laboratory had failed to order the PVP calibration verification material for 2022. Key: pH: potential hydrogen pCO₂: partial pressure of carbon dioxide pO₂: partial pressure of oxygen PVP: Performance Verification Product ABG: arterial blood gas

D5801

TEST REPORT

CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report

destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on review of blood gas analyzer analytic records, patient final reports, and interview with facility personnel, two of eight patient final reports reviewed between June 2022 and December 2022 contained errors. The findings included: 1. Based on patient records, two patient final reports had different values than those reported on the analytic record from the GEM Premier 3500 blood gas analyzer. Accession Number 10026122 Analytic record from analyzer: SO₂c was 91 percent The patient final report was reported as 93 percent. Accession Number 10026572 Analytic record from analyzer: pH was 7.32 The patient final report was reported as 7.33 2. In an interview at 14:42 hours on 1/12/2023, Testing Person 1 stated the laboratory did not have an electronic interface for transmission of results from the analyzer to the patient records and each result must be manually entered into the patient record and confirmed the patient records above contained transcription errors. Key: pH: potential hydrogen SO₂c: oxygen saturation

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 laboratory policy, proficiency testing records from 2022 and interview with testing personnel, the Laboratory Director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing program for one of three events in 2022. The findings included: 1. Based on the laboratory policy "AccuTest Program", the policy stated the following: "The blood gas lab participates in blind study testing of its blood gas instruments, for the purpose of Quality Control and to meet CLIA requirement The blood gas lab is enrolled in a third-party Quality Assurance Program called AccuTest. The blood gas lab shall follow all procedures in accordance with the standards set by AccuTest testing services. The blood gas lab shall maintain all records in accordance with AccuTest testing services. Samples are run 3 times per year: April/June/ October Samples will be stored, handled, analyzed, and submitted according to AccuTest testing services. The Medical Director of the Blood Gas Lab will review and sign all outgoing and incoming results. " 2. Based on review of the AccuTest proficiency testing records, the laboratory participated in the second and third events of 2022. There were no scores or documentation of the first event of 2022. 3. In an interview at 15:15 hours on 1/12/2023, Testing Person 1 (as listed on the CMS-209 Laboratory Personnel Report) stated the laboratory failed to enroll at the end of 2021 for the 2022 calendar year and didn't realize the laboratory had failed to enroll until they did not receive event one in April 2022. Key: CMS -

