

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0867894	<b>(X3) Date Survey Completed</b>  01/16/2025
<b>Name of Provider or Supplier</b>  Mitchell County Hosp Blood Gas Lab	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard deficiencies were cited.
<b>D5221</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's AccuTest proficiency testing (PT) records, laboratory policy, and confirmed in interview, the laboratory failed to provide documentation of corrective actions for one of three unacceptable blood gas proficiency testing events in 2024. Findings Included: 1. Review of laboratory AccuTest PT records in 2024, revealed the following: Cycle 2 of 3 2024 "Analyte: pCO2 Samples/Grades: D/Unacceptable E/Unacceptable Score: 73.33% Attention all participants: ...Any unsatisfactory performance for a designated PT analyte/specialty /subspecialty requires specific remedial action and documentation." Further review of the PT records in 2024, revealed the laboratory director failed to document corrective actions for the above unacceptable grades in 2024. 2. Review of laboratory policy, "Blood Gas Laboratory Director" (Approved by the laboratory director on 01/12 /2017) revealed the following: " ...Proficiency Testing (PT) Duties ...Ensure that PT results are reviewed by the appropriate staff and the corrective action plan is followed when PT results are found to be unsatisfactory." 3. In an interview on 01/16/2025 at 09:58 AM with the laboratory technical consultant (TC-1), TC-1 confirmed the laboratory failed to provide documentation of corrective actions for one of three unacceptable blood gas proficiency testing events in 2024.</p>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p>

(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on surveyor observation, review of laboratory policy, laboratory quality control (QC) documentation, and confirmed in interview, the laboratory failed to follow their own policy for document review of chemistry QC records for three of three analytes performed on the GEM 3500 Blood Gas analyzer in 2024. Findings Included: 1. During a tour of the facility on 01/15/2024, revealed the laboratory performed arterial and venous blood gas analysis (Analytes: pH, pCO<sub>2</sub>, and pO<sub>2</sub>) on the GEM 3500 Blood Gas Analyzer (Serial Number: 21014898). 2. Review of laboratory policy, "Monthly Quality Control Reports" (Approved by the laboratory director on 01/12/2017) revealed the following: "...IV. Policy: ...At the beginning of each month, the previous months iQM (Intelligent Quality Management) report will be printed off and reviewed by Respiratory Care Manager. Any problems will have an error log and corrective action printout with it." 3. Review of laboratory blood gas QC documentation printouts for 2024, revealed the following months QC was not documented or reviewed for errors over time for three of three analytes performed: January 2024 March 2024 October 2024 The facility was asked to provide documentation of monthly iQM reports printed and reviewed on the above dates in 2024, and none were provided. 4. During an interview on 01/16/2025 at 12:35 PM with TC-1 in the conference room, TC-1 confirmed the laboratory failed to follow their own policy for document review of chemistry QC records for three of three analytes performed on the GEM 3500 Blood Gas analyzer in 2024. Word Key pH- potential of hydrogen pCO<sub>2</sub>- partial pressure of carbon dioxide pO<sub>2</sub>- partial pressure of oxygen