

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0867894	(X3) Date Survey Completed 08/25/2021
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
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Review of the CASPER report 155 Individual Proficiency Testing report, proficiency testing records and interview of facility personnel found the laboratory received an overall score of 0% for the analytes pH, PO2 and PCO2 in one of four Blood Gas/ Electrolytes testing events due to failure to participate. The findings included: 1. Review of the CASPER Report 155 found the laboratory received a score of 0% for pH, PO2 and PCO2 in the first testing event of 2021. 2. Review of the AccuTest proficiency testing records for 2020 and 2021 (three events per year) found the laboratory received a score of 0% for pH, PO2 and PCO2 in the Cycle 01 Blood Gas/ Electrolytes testing event due to non participation. 3. Interview of testing person one on the CMS report 209 Laboratory Personnel Report conducted on August 25, 2021 at 3:47 PM confirmed the laboratory did not test the proficiency specimens and submit the results to the proficiency agency for grading.. She stated that she "received the specimens but didn't know what they were for so they just didn't get run." She was asked if there was any documentation for the failure to participate and she stated " no, they just caught it the other day when they were going through everything to get ready for the survey."</p>
D2089	<p>ROUTINE CHEMISTRY CFR(s): 493.841(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended</p>

during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:
Review of the CASPER report 155 Individual Proficiency Testing report, proficiency testing records and interview of facility personnel found the laboratory received an overall score of 0% in one of four Blood Gas/ Electrolytes testing events due to failure to participate. The findings included: 1. Review of the CASPER Report 155 found the laboratory received an overall score of 0% for Routine Chemistry in the first testing event of 2021. 2. Review of the AccuTest proficiency testing records for 2020 and 2021 (three events per year) found the laboratory received an overall score of 0% in the Cycle 01 Blood Gas/ Electrolytes testing event due to non participation. 3. Interview of testing person one on the CMS report 209 Laboratory Personnel Report conducted on August 25, 2021 at 3:47 PM confirmed the above findings. She stated that she "received the specimens but didn't know what they were for so they just didn't get run." She was asked if there was any documentation for the failure to participate and she stated " no, they just caught it the other day when they were going through everything to get ready for the survey."

D6017

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(ii)

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)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:
Review of the CASPER report 155, proficiency testing records and interview of facility personnel found the laboratory director failed to ensure the proficiency testing results were submitted to the proficiency testing agency within the specified timeframe in one of four proficiency testing events in 2020 and 2021 (three events per year). (See D 2089 and D 2087)

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:
Review of the CMS report 209, personnel records and interview of facility personnel found the technical consultant failed to evaluate the competency of one of five testing

personnel performing blood gas analysis at least semi-annually in the first year of testing The findings included: 1. Review of the CMS report 209 Laboratory Personnel report found the laboratory listed five testing personnel performing moderate complexity testing. 2. Review of personnel files found no documentation of semiannual competency assessment for testing person one (hired March 17, 2020). Initial training was completed March 26,2020. An Incomplete competency assessment form signed by the Laboratory director and dated November 2, 2020 with no identification of testing personnel was offered as documentation of competency assessment. 3. Interview of testing person one on the CMS report 209 conducted August 28, 2021 at 3:17 AM confirmed there was no other competency assessments available for review.