

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0867894	(X3) Date Survey Completed 02/12/2019
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
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records from 2017 and 2018, and staff interview, it was revealed the laboratory failed to have documentation of monitoring quality control results performed on the Gem Premier 3500 blood gas analyzer over time to detect errors. The findings were: 1. A review of the laboratory's quality control records from 2017 and 2018 revealed the laboratory tested two levels of quality control material once each month for pH, PO2, and PCO2. The laboratory did not use a Levy Jennings graph or have some other means of monitoring the performance of the control material over time. The laboratory was asked to provide documentation of having a mechanism in place to monitor quality control values over time. No documentation was provided. 2. The laboratory was currently using CVP lot number 835 expiration September 30, 2019. 2. Interview of testing person two on the CMS report 209 laboratory personnel report conducted on February 12, 2019 at 09:25 AM confirmed the laboratory only assessed quality control results daily and did not monitor them over time.</p>