

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0673101	(X3) Date Survey Completed 08/10/2021
Name of Provider or Supplier Cuero Regional Hospital	Street Address, City, State 2550 North Esplanade, Cuero, 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	Noted deficiencies and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiency, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and certification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, review of the laboratory's verification studies on the GEM4000 analyzer, and staff interview, it was revealed the laboratory failed to have documentation of verifying 52 of 2 patient normal values currently in use. The findings were: 1. A review of the laboratory's procedures for the GEM4000 analyzer revealed the laboratory defined patient normal values for 2 different samples</p>

types tested for blood gas analysis. They were: Arterial Blood Gas pH 7.35-7.45 pCO₂ 35-45 pO₂ 80-100 HCO₃ 22-28 O₂ Sat >95 Venous Blood Gas pH 7.31-7.41 pCO₂ 41-51 pO₂ 30-40 HCO₃ 23-29 O₂ Sat 75 2. A review of the laboratory's verification studies performed on the GEM4000 (placed into use in July 2020) revealed the laboratory had no documentation of verifying patient normal values for arterial blood gas or venous gas specimens. 3. The laboratory was asked to provide documentation of verifying the identified patient normal values. No documentation was provided. 4. An interview with the Director of Respiratory Therapy on 08/10 /2021 at 1130 hours in the conference room confirmed the laboratory most likely used the previous normal ranges from the previous analyzer. She stated those were the ranges currently in use. This confirmed the findings. Key: pH - determines if acid or base pO₂ - partial pressure of oxygen pCO₂ - partial pressure of carbon dioxide HCO₃ - bicarbonate O₂ Sat - oxygen saturation