

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0673101	<b>(X3) Date Survey Completed</b> 06/04/2019
<b>Name of Provider or Supplier</b> Cuero Regional Hospital	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Entrance and exit conferences were held with the laboratory representative. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. The laboratory was found to be in compliance for the specialties/subspecialties for which it was surveyed.
<b>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's WSLH (Washington State Laboratory of Hygiene) blood gas proficiency testing records from 2018 and 2019, and staff interview, it was revealed the laboratory failed to test proficiency testing samples using routine methods. The findings were: 1. Review of the laboratory's WSLH blood gas proficiency testing records from 2018 (events 1, 2, and 3) and 2019 (event 1) revealed the laboratory had documentation of each of the proficiency testing samples being tested on both analyzers. 2018 - Event 1 Sample ID: BG-1 Sample ID: BG-1 Serial #: 313246 Serial #: 313247 Date/Time: 03-19-18 @ 13:47 Date: 03-18-18 @ 13:47 pH = 7.02 pH = 7.03 pCO2 = 78.9 pCO2 = 73.6 PO2 = 17 PO2 = 23 Sample ID: BG-2 Sample ID: BG-2 Serial #: 313246 Serial #: 313247 Date/Time: 03-19-18 @ 15:24 Date: 03-18-18 @ 15:24 pH = 7.18 pH = 7.18 pCO2 = 66.3 pCO2 = 63.8 PO2 = 30 PO2 = 35 Sample ID: BG-3 Sample ID: BG-3 Serial #: 313246 Serial #: 313247 Date /Time: 03-19-18 @ 13:53 Date: 03-18-18 @ 13:52 pH = 7.32 pH = 7.32 pCO2 = 45.9 pCO2 = 46.7 PO2 = 193 PO2 = 173 Sample ID: BG-4 Sample ID: BG-4 Serial #: 313246 Serial #: 313247 Date/Time: 03-19-18 @ 15:27 Date: 03-18-18 @ 15:26 pH = 7.42 pH = 7.43 pCO2 = 36.3 pCO2 = 36.7 PO2 = 84 PO2 = 84 Sample ID: BG-5 Sample ID: BG-5 Serial #: 313246 Serial #: 313246 Date/Time: 03-19-18 @ 17:52</p>

Date: 03-18-18 @ 17:52 pH = 7.22 pH = 7.22 pCO2 = 57.0 pCO2 = 57.0 PO2 = 145 PO2 = 145 2018 - Event 3 Sample ID: BG-11 Sample ID: BG-11 Serial #: 313246 Serial #: 313247 Date/Time: 11-12-18 @ 15:01 Date: 11-12-18 @ 15:01 pH = 7.17 pH = 7.17 pCO2 = 65.3 pCO2 = 67.2 PO2 = 29 PO2 = 33 Sample ID: BG-12 Sample ID: BG-12 Serial #: 313246 Serial #: 313247 Date/Time: 11-12-18 @ 16:50 Date: 11-12-18 @ 16:50 pH = 7.43 pH = 7.42 pCO2 = 34.4 pCO2 = 35.9 PO2 = 81 PO2 = 83 Sample ID: BG-13 Sample ID: BG-13 Serial #: 313246 Serial #: 313247 Date/Time: 11-13-18 @ 08:31 Date: 11-13-18 @ 08:31 pH = 7.58 pH = 7.58 pCO2 = 21.6 pCO2 = 22.1 PO2 = 62 PO2 = 65 Sample ID: BG-14 Sample ID: BG-14 Serial #: 313246 Serial #: 313247 Date/Time: 11-13-18 @ 13:03 Date: 11-13-18 @ 13:03 pH = 7.32 pH = 7.32 pCO2 = 45.3 pCO2 = 46.3 PO2 = 194 PO2 = 196 Sample ID: BG-15 Sample ID: BG-15 Serial #: 313246 Serial #: 313247 Date/Time: 11-14-18 @ 10:03 Date: 11-14-18 @ 10:03 pH = 7.49 pH = 7.50 pCO2 = 31.5 pCO2 = 31.4 PO2 = 226 PO2 = 222 2019 - Event 1 Sample ID: BG-1 Sample ID: BG-1 Serial #: 313246 Serial #: 313247 Date/Time: 03-18-19 @ 18:03 Date: 03-18-19 @ 16:55 pH = 7.13 pH = 7.13 pCO2 = 74.6 pCO2 = 74.9 PO2 = 174 PO2 = 169 Sample ID: BG-2 Sample ID: BG-2 Serial #: 313246 Serial #: 313247 Date/Time: 03-18-19 @ 17:17 Date: 03-18-19 @ 17:17 pH = 7.5 pH = 7.5 pCO2 = 31.3 pCO2 = 31.3 PO2 = 215 PO2 = 221 Sample ID: BG-3 Sample ID: BG-3 Serial #: 313246 Serial #: 313247 Date/Time: 03-18-19 @ 18:03 Date: 03-18-19 @ 16:55 pH = 7.04 pH = 7.04 pCO2 = 71.2 pCO2 = 71.7 PO2 = 18 PO2 = 24 Sample ID: BG-4 Sample ID: BG-4 Serial #: 313246 Serial #: 313247 Date/Time: 03-19-19 @ 09:40 Date: 03-19-19 @ 09:40 pH = 7.56 pH = 7.55 pCO2 = 23.9 pCO2 = 24.9 PO2 = 68 PO2 = 67 Sample ID: BG-5 Sample ID: BG-5 Serial #: 313246 Serial #: 313247 Date/Time: 03-19-19 @ 18:03 Date: 03-19-19 @ 16:55 pH = 7.33 pH = 7.32 pCO2 = 44.6 pCO2 = 46.0 PO2 = 201 PO2 = 177 2. An interview with the Director of Respiratory Therapy on June 4, 2019 at 11:05 hours in the Conference Room confirmed the findings. She stated that the re-run was sometimes used as instrument correlations. She also confirmed that when testing patients, the laboratory would only repeat patient samples that had critical values.

**D3039**

**RETENTION REQUIREMENTS**  
CFR(s): 493.1105(a)(5)

Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's submitted Form CMS-209, review of personnel records, and confirmed in interview of facility personnel, the laboratory failed to have a policy for retention of employee education records. The findings were: 1. Review of the laboratory's submitted Form CMS-209 signed by the laboratory director on May 31, 2019 revealed 10 testing persons. 2. Random review of the laboratory's personnel records for 5 of 10 testing persons revealed the following: Testing Personnel 1 Start Date: 11-04-1994 Testing Personnel 2 Start Date: 05-22-1990 Testing Personnel 3 Start Date: 05-26-1990 Testing Personnel 4 Start Date: 05-26-2005 Testing Personnel 5 Start Date: 04-26-2002 3. The laboratory failed to have a policy for retaining all of an employee's education records. The facility had retained each employee's current licensure and Associate's degrees or higher. The facility failed to retain high school diplomas or transcripts. 4. An interview with the Director of Respiratory Therapy on June 4, 2019 at 10:50 hours in the Conference Room confirmed the findings.

**D5537**

**ROUTINE CHEMISTRY**

CFR(s): 493.1267(b)(d)

For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, review of manufacturer's instructions, review of quality control records, patient results, and confirmed in interview of facility personnel, the laboratory failed to test one level of control each 8 hours of patient testing for Arterial Blood Gases (ABGs). The findings were: 1. Review of the laboratory's policy titled, "ABG/Co-OX Calibrations & Quality Control ABL 80 Flex/Co-Ox" approved by the laboratory director on July 18, 2017 stated, "G. Manual External QC Schedule: External liquid QC must be run according to CLIA requirements: two levels of external QC on each test system for each day of testing, when a new sensor cassette or solution pack is installed and following instrument maintenance." The laboratory's quality control policy is less stringent than the CLIA regulations, the laboratory did not develop an Individualized Quality Control Plan (IQCP) to reduce the risk of quality control testing. Therefore, the laboratory must test one level of external quality control each eight hours of patient testing. 2. Review of laboratory quality control records for April and May 2019 revealed the following 5 of 41 patients were tested when QC had exceeded 8 hours. April 19, 2019 Two levels qc @ 00:20 Patient ID: Account F13762505 @ 17:03 (greater than 8 hours since qc) May 6, 2019 Two levels qc @ 03:01 Patient ID: Account F13784889 @ 15:44 (greater than 8 hours since qc) Patient ID: Account V13782396 @ 18:02 (greater than 8 hours since qc) May 12, 2019 Two levels qc @ 13:33 Patient ID: Account F13793385 @ 2330 (greater than 8 hours since qc) May 20, 2019 Two levels qc @ 05:34 Patient ID: Account F137851183 (greater than 8 hours since qc) 3. Interview with the Director of Respiratory Therapy on June 4, 2019 at 12:00 hours in the Conference Room confirmed the findings.