

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0487752	(X3) Date Survey Completed 09/02/2021
Name of Provider or Supplier Clay County Memorial Hospital Lab	Street Address, City, State 310 W South St, Henrietta, 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	An entrance conference was held with the laboratory representative. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, 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 recertification 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.
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of OPTI CCA TS2 operator's manual, laboratory's Individualized Quality Control Plan (IQCP), quality control (QC) records, patient</p>

records, and confirmed in interview, the laboratory failed to have in house data in the risk assessment to support its reduction in QC frequency to every 31 days and failed to perform one level of liquid QC material each 8 hours of operation for the OPTI CCA TS2 blood gas analyzer. Findings included: 1. During a tour of the laboratory area on 09/02/2021 at 10:30am, an OPTI CCA TS2 blood gas analyzer (Serial Number 4042) was observed. The laboratory used the OPTI CCA TS2 to analyze arterial blood specimens for pH, PCO2 and PO2. 2. The OPTI CCA TS2 operator's manual (PD7301, Rev F) stated the following: "4.5 QC Recommendations NOTE: Hospitals should develop their own policy and procedures on the number of QC samples to be run on a daily basis as mandated by the regulatory agency under which they operate. After a shipment of cassettes and at monthly intervals thereafter, validation should be performed by analysis of OPTI CHECK or OPTI CHECK PLUS Blood Gas Controls ..." 3. The laboratory's Individualized Quality Control Plan (IQCP) for the OPTI CCA TS2 blood gas analyzer (signed by the laboratory director 05/31/2020) stated the following: "3. External liquid controls (level 1 and level 3) run with each new lot/shipment, with each new untrained operator and every 31 days (done 1st of the month)." 4. Further review of the laboratory's Individualized Quality Control Plan (IQCP) for the OPTI CCA TS2 blood gas analyzer (signed by the laboratory director 05/31/2020) revealed the following dates and times when external liquid QC material was run as part of the IQCP risk assessment: Date/Time Level 1/ Time Level 3 03/18/2020; 15:29:20; 15:35:31 03/18/2020; 16:33:29; 16:38:00 03/19/2020: 07:23:35; 07:08:37 03/20/2020: 11:42:08; 11:46:11 03/21/2020: 03:59:17; 04:05:41 03/22/2020: 10:32:03; 10:38:41 03/23/2020: 09:05:39; 09:12:50 03/24/2020: 08:18:33; 08:22:59 03/25/2020: 08:50:55; 08:55:54 03/25/2020: 15:03:23; 15:07:48 03/26/2020: 11:52:06; 11:56:59 03/27/2020: 15:48:46; 15:52:51 03/28/2020: 10:36:06; 10:45:29 03/29/2020: 11:18:15; 11:25:53 03/30/2020: 08:28:26; 08:33:17 03/31/2020: 07:03:08; 07:07:47 04/01/2020: 06:33:33; 06:39:35 04/02/2020: 05:05:07; 05:10:44 04/03/2020: 20:11:40; 20:15:35 04/04/2020: 11:19:37; 11:27:55 04/05/2020: 08:56:27; 09:00:55 04/06/2020: 08:44:59; 08:50:42 04/07/2020: 06:08:03; 06:13:06 04/08/2020: 16:39:27; 13:36:12 04/09/2020: 02:05:56; 02:10:58 04/10/2020: 13:42:39; 13:46:45 04/11/2020: 01:22:55; 01:27:48 04/12/2020: No documentation of QC 04/13/2020: 08:51:00; 08:57:00 04/14/2020: 02:47:00; 02:56:00 04/15/2020: 02:30:00; 02:34:00 04/16/2020: No times indicated 04/17/2020: 03:14:17; 03:19:52 04/18/2020: 02:08:10; 02:12:25 04/19/2020: 07:44:31; 07:49:06 04/20/2020: 10:04:23; 10:36:47 The laboratory failed to perform one level of liquid QC material each 8 hours of operation for the OPTI CCA TS2 blood gas analyzer to support its reduction in QC frequency to every 31 days. 5. Review of QC records from January 2021 through September 2021 revealed the laboratory performed external quality control once on the following dates on the OPTI CCA TS2 blood gas analyzer: Date: 01/06/2021 QC level 1 OPTI CHECK; Lot number 9159 QC level 3 OPTI CHECK; Lot number 9369 Date: 02/01/2021 QC level 1 OPTI CHECK; Lot number 9159 QC level 3 OPTI CHECK; Lot number 9369 Date: 03/01/2021 QC level 1 OPTI CHECK; Lot number 9159 QC level 3 OPTI CHECK; Lot number 9369 Date: 03/16/2021 QC level 1 OPTI CHECK; Lot number 9159 QC level 3 OPTI CHECK; Lot number 9369 Date: 04/01/2021 QC level 1 OPTI CHECK; Lot number 9159 QC level 3 OPTI CHECK; Lot number 9369 Date: 05/03/2021 QC level 1 OPTI CHECK; Lot number 9159 QC level 3 OPTI CHECK; Lot number 9369 Date: 06/01/2021 QC level 1 OPTI CHECK; Lot number 9159 QC level 3 OPTI CHECK; Lot number 9369 Date: 06/02/2021 QC level 1 OPTI CHECK; Lot number 9159 QC level 3 OPTI CHECK; Lot number 9369 Date: 07/07/2021 QC level 1 OPTI CHECK; Lot number 9159 QC level 3 OPTI CHECK; Lot number 9369 Date: 08/02/2021 QC level 1 OPTI CHECK; Lot number 9159 QC level 3 OPTI CHECK; Lot number 9369 Date: 08/17/2021 QC level 1 OPTI CHECK; Lot number 9159 QC level 3 OPTI CHECK; Lot number 9369 Date: 09/01/2021 QC level 1 OPTI

CHECK; Lot number 1189 QC level 3 OPTI CHECK; Lot number 1399 The laboratory failed to perform one level of external quality control each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing, as required for blood gas test systems, per CFR 493.1267. 6. A random review of patient test records from 08/23/2021 through 09/02/2021 revealed the following 11 patients tested on the OPTI CCA TS2 blood gas analyzer with no QC performed each 8 hours of testing using a combination of control materials that include both low and high values on each day of patient testing: Date: 08/23/2021; Patient 10080316 Date: 08/23/2021; Patient 10080315 Date: 08/25/2021; Patient 10080426 Date: 08/25/2021; Patient 10080425 Date: 08/26/2021; Patient 10080451 Date: 08/28/2021; Patient 10080580 Date: 08/29/2021; Patient 10080580 Date: 08/29/2021; Patient 10080582 Date: 08/30/2021; Patient 10080582 Date: 08/31/2021; Patient 10080663 Date: 09/02/2021; Patient 10080820 7. In an interview on 09/01/2021 at 3:00PM in the conference room, the laboratory manager stated that the laboratory did not perform at least one level of external quality control material every 8 hours for 31 days for the IQCP to support its reduction in frequency to every 31 days. This confirmed the above findings. Word Key: PCO2= Partial pressure of carbon dioxide PO2= Partial pressure of oxygen

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 direct observation, review of OPTI CCA TS2 operator's manual, laboratory's Individualized Quality Control Plan (IQCP), quality control (QC) records, a random review of patient records, and confirmed in interview, the laboratory failed to 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 on the OPTI CCA TS2 blood gas analyzer. Findings Included: 1. During a tour of the laboratory area on 09/02/2021 at 10:30am, an OPTI CCA TS2 blood gas analyzer (Serial Number 4042) was observed. The laboratory used the OPTI CCA TS2 to analyze arterial blood specimens for pH, PCO2 and PO2. 2. The OPTI CCA TS2 operator's manual (PD7301, Rev F) stated the following: "4.5 QC Recommendations NOTE: Hospitals should develop their own policy and procedures on the number of QC samples to be run on a daily basis as mandated by the regulatory agency under which they operate. After a shipment of cassettes and at monthly intervals thereafter, validation should be performed by analysis of OPTI CHECK or OPTI CHECK PLUS Blood Gas Controls ..." 3. Review of laboratory's Individualized Quality Control Plan (IQCP) to modify the quality control frequency from each day of patient testing to implement monthly quality control revealed the IQCP failed to support its reduction in frequency to every 31 days for the OPTI CCA TS2 blood gas analyzer. Refer to D5445 4. Review of laboratory quality control records and a random review of patient test records from 08/23/2021 through 09/02/2021 revealed the following 11 patients tested on the OPTI CCA TS2 blood gas analyzer with no QC performed each 8 hours of testing using a combination of control materials that include both low and high values on each day of patient testing: QC last performed on 08/17/2021 Date: 08/23/2021; Patient 10080316 Date: 08/23/2021; Patient 10080315 Date: 08/25/2021;

Patient 10080426 Date: 08/25/2021; Patient 10080425 Date: 08/26/2021; Patient 10080451 Date: 08/28/2021; Patient 10080580 Date: 08/29/2021; Patient 10080580 Date: 08/29/2021; Patient 10080582 Date: 08/30/2021; Patient 10080582 Date: 08/31/2021; Patient 10080663 QC last performed on 09/01/2021 Date: 09/02/2021; Patient 10080820 5. In an interview on 09/01/2021 at 3:00PM in the conference room, the laboratory manager stated that the laboratory did not perform at least one level of external quality control material every 8 hours for 31 days for the IQCP to support its reduction in QC frequency to every 31 days and that external QC for the OPTI CCA TS2 was performed with each new lot/shipment, with each new untrained operator and every 31 days at the first of each month. This confirmed the above findings. Word Key: PCO₂= Partial pressure of carbon dioxide PO₂= Partial pressure of oxygen