

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1071902	(X3) Date Survey Completed 04/30/2024
Name of Provider or Supplier Chg Hospital Conroe Llc DbA	Street Address, City, State 1500 Grand Lake Dr, Conroe, 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	Based on an announced validation survey on 4/30/2024, the laboratory was found to be in compliance with the CLIA regulations found at 42 CFR 493.1 through 493.1780.
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory records from 2022 and 2024, and confirmed in interview, the laboratory failed to document three of four calibration verification for the iSTAT G3+ (pH, pCO2, pO2) tests every 6 months in</p>

2022 and 2023. Findings included: 1. Review of the Abbott I-stat operator's manual (Art: 71436-00M), under Calibration Verification, states the following: "Calibration Verification is a procedure intended to verify the accuracy of results over the entire measurement range of the test. The performance of this procedure over defined intervals may be required by regulatory or accreditation bodies." 2. Review of records from 2022 and 2023 revealed no documentation of the three of four required calibration verification for G3+ (pH, pCO2, pO2). 3. In review of the CMS116, the laboratory performed 1800 chemistry tests annually. 4. In an interview with Testing Person #1 on 04/30/2024 at 1310 hours in the conference room, she confirmed the above findings.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory quality control records from 2023 and 2024, patient test records, the laboratory failed to monitor the accuracy and precision of the quality control of two of two tests on the iSTAT analyzer: CG8 + (Sodium (NA), Potassium (K), ionized Calcium (iCA), Glucose, Hematocrit (HCT), pH, pCO2, pO2) and G3+ (pH, pCO2, pO2). a) iSTAT - CG8+ b) iSTAT - G3+ Findings included: 1. Review of the laboratory records from 2023 to 2024 revealed no documentation the laboratory monitored the accuracy and precision of quality control for the following seven lot numbers for CG8+ and G3+ testing for fourteen of fourteen months reviewed. G3+ Tri control Level 1 lot #301151, exp 07/31/2023 Tri control Level 3 lot #121145, exp 01/31/2023 Tri control Level 1 lot #301151, exp 07/31/2023 Tri Control Level 3 lot #121152, exp 08/31/2023 CG8+ Tri control Level 1 lot #301151, exp 07/31/2023 Tri Control Level 3 lot #121152, exp 08/31/2023 Tri control Level 1 lot #301154, exp 10/31/2023 Tri Control Level 3 lot #121152, exp 08/31/2023 Tri control Level 1 lot #301151, exp 07/31/2023 Tri Control Level 3 lot #121156, exp 12/31/2023 Tri control Level 1 lot #301161, exp 05/31/2024 Tri Control Level 3 lot #121156, exp 12/31/2023 2. Random review of laboratory results from January 2023 to March 2024 confirmed the laboratory performed the following 12 patients for CG8+ and/or G3+. 07/05/2023 PT# 1255516 07/19/2023 PT # 1255542 07/21/2023 PT # 1255543 07/26/2023 PT # 1255516 07/28/2023 PT # 1255544 08/05/2023 PT # 1255558 08/12/2023 PT # 1255566 08/22/2023 PT # 1255571 10/12/2023 PT # 20000479 10/17/2023 PT # 20000602 01/02/2024 PT # 200192 01/06/2024 PT # 2002897 3. In an interview with TP #1 on 04/30/2024 at 12100 hours in the conference room, she confirmed the above findings.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

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.

This STANDARD is not met as evidenced by:

A. Based on review of the laboratory policy, laboratory quality control records from 2022 and 2024, patient test records, and confirmed in interview, the laboratory IQCP (Individualized Quality Control Plan) failed to document a complete quality control study to include external quality control material for each analyte and each day of the quality control plan prior to modifying the frequency of quality control testing for two of two tests on the iSTAT analyzer: CG8 + (Sodium (NA), Potassium (K), ionized Calcium (iCA), Glucose, Hematocrit (HCT), pH, pCO2, pO2) and G3+ (pH, pCO2, pO2) to every 30 days. a) iSTAT - CG8+ b) iSTAT - G3+ Findings included: 1. Review of the IQCP summary report for the iSTAT CG8+ and G3+ stated "based on the risk assessment performed, identification of potential errors and supporting data, the laboratory has defined the control procedures to be followed as reviewed and approved by the laboratory director at least annually. At minimum, the laboratory must follow manufacturer's instructions and [lab] policy and procedures at a minimum, monitor ongoing data, and perform a routine review of data, issues, and risks on an annual basis as defined in our quality control plan." 2. In an interview with Testing Person (TP) 1 on 04/30/2024 at 1120 hours in the conference room, she stated that the external controls for the iSTAT were performed every 30 days. She also confirmed that the laboratory received a new iSTAT analyzer (SN 21-325469) in January 2022. a) iSTAT - CG8+ 3. Review of the laboratory quality control study of the IQCP revealed no documentation of the quality control study to support their IQCP with the new iSTAT analyzer. b) iSTAT - G3+ 4. Review of the laboratory quality control study of the IQCP revealed no documentation of the quality control study to support their IQCP with the new iSTAT analyzer. 5. Random review of laboratory results from January 2023 to March 2024 confirmed the laboratory performed the following 12 patients for CG8+ and/or G3+. 07/05/2023 PT# 1255516 07/19/2023 PT # 1255542 07/21/2023 PT # 1255543 07/26/2023 PT # 1255516 07/28/2023 PT # 1255544 08/05/2023 PT # 1255558 08/12/2023 PT # 1255566 08/22/2023 PT # 1255571 10/12/2023 PT # 20000479 10/17/2023 PT # 20000602 01/02/2024 PT # 200192 01/06/2024 PT # 2002897 6. In an interview with TP #1 on 04/30/2024 at 1140 hours in the conference room, she confirmed the above findings. She was unaware that an IQCP study needed to be repeated when the laboratory received a new analyzer. B. Based on review of the laboratory policy, laboratory quality control records from 2023 and 2024, patient test records, the laboratory IQCP (Individualized Quality Control Plan), and confirmed in interview, the laboratory failed to document external quality control every 30 days for two of two tests on the iSTAT analyzer: CG8 + (Sodium (NA), Potassium (K), ionized Calcium (iCA), Glucose, Hematocrit (HCT), pH, pCO2, pO2) and G3+ (pH, pCO2, pO2). a) iSTAT - CG8+ b) iSTAT - G3+ Findings included: 1. Review of the IQCP summary report for the iSTAT CG8+ and G3+ stated "based on the risk assessment performed, identification of potential errors and supporting data, the laboratory has defined the control procedures to be followed as reviewed and approved by the laboratory director at least annually. At

minimum, the laboratory must follow manufacturer's instructions and [lab] policy and procedures at a minimum, monitor ongoing data, and perform a routine review of data, issues, and risks on an annual basis as defined in our quality control plan." 2. In an interview with Testing Person (TP) 1 on 04/30/2024 at 1120 hours in the conference room, she stated that the external controls for the iSTAT were performed every 30 days. 3. Review of the laboratory quality control records from 2023 to 2024 revealed no documentation the laboratory performed quality control for CG8+ and G3+ every 30 days per the laboratory IQCP for the following four of six months reviewed for G3+ and five of fourteen months for CG8+. G3+ Tri control Level 1 lot #301151, exp 07/31/2023 Tri control Level 3 lot #121145, exp 01/31/2023 01/06/2023 No control performed in 02/2023 Tri control Level 1 lot #301151, exp 07/31/2023 Tri Control Level 3 lot #121152, exp 08/31/2023 03/02/2023, 56 days after previous control 04/08/2023, 36 days after previous control 05/11/2023, 33 days after previous control CG8+ Tri control Level 1 lot #301151, exp 07/31/2023 Tri Control Level 3 lot #121152, exp 08/31/2023 03/02/2023 04/08/2023, 36 days after previous control 05/11/2023, 33 days after previous control 06/08/2023 Tri control Level 1 lot #301154, exp 10/31/2023 Tri Control Level 3 lot #121152, exp 08/31/2023 06/27/2023 08/07/2023, 40 days after previous control Tri control Level 1 lot #301151, exp 07/31/2023 Tri Control Level 3 lot #121156, exp 12/31/2023 09/20/2023, 43 days after previous control 10/10/2023 Tri control Level 1 lot #301161, exp 05/31/2024 Tri Control Level 3 lot #121156, exp 12/31/2023 11/17/2023, 37 days after previous control 4. Random review of laboratory results from January 2023 to March 2024 confirmed the laboratory performed the following 12 patients for CG8+ and/or G3+. 07/05/2023 PT# 1255516 07/19/2023 PT # 1255542 07/21/2023 PT # 1255543 07/26/2023 PT # 1255516 07/28/2023 PT # 1255544 08/05/2023 PT # 1255558 08/12/2023 PT # 1255566 08/22/2023 PT # 1255571 10/12/2023 PT # 20000479 10/17/2023 PT # 20000602 01/02/2024 PT # 200192 01/06/2024 PT # 2002897 5. In an interview with TP #1 on 04/30/2024 at 1140 hours in the conference room, she confirmed the above findings.

D5463

CONTROL PROCEDURES
CFR(s): 493.1256(d)(7)(g)

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--
Over time, rotate control material testing among all operators who perform the test.
(g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of quality control records and interview with laboratory personnel, the laboratory failed to rotate the performance of quality control among all operators who perform point of care testing for 19 of 19 testing personnel between January 2023 and March 2024. The findings included: 1. Based on a review of quality control records for the laboratory Abbott I-stat CG8+ and G3+ cartridges, Testing Person 1 (as listed on the CMS-209 Laboratory Personnel Report) performed quality control for 15 of the 15 months between January 2023 and March 2024. 2. Based on the CMS-209 laboratory personnel report, the laboratory listed 19 individuals who perform point of care testing with Abbott I-stats. No other point of care personnel performed the monthly quality control between January 2023 and March 2024. 3. In an interview on 04/30/2024 at 1230 hours in the conference room, Testing Person 1 confirmed she had performed all of the monthly Abbott I-stat point of care quality control.