Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0707586	07/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
Gulf Coast Health Center, Inc	2548 Memorial Blvd, Port Arthur, 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 onsite survey conducted 07/21/2022 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories. .
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the laboratory's American Proficiency Institute's (API) proficiency testing (PT) records from 2022, and confirmed in interview, the laboratory failed to have documentation of testing proficiency testing samples the same number of times as patient samples for two of two events reviewed. The findings were: 1. A review of the laboratory's policy Proficiency Testing (LAB005) under Testing Personnel Responsibilities revealed "Guidelines for PT testing are the same as for patients, if patient's samples are normally run in duplicate, so are the PT samples...If a very high or low otherwise unusual result would normally be rechecked with a patient sample, the same rule applies to the PT samples" 2. Review of the laboratory LIS settings revealed the following values as critical lab values: Potassium (K) high 6 mmol/L and low 3 mmol /L Chloride (Cl) high 120 mmol/L Sodium (Na) high 160 mmol/L 3. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2022 revealed the following four proficiency testing sample with results which met the laboratory's criteria for repeat testing with no documentation of the repeat testing. API Event 1 CH-01 K 2.96 mmol/L CH-02 Na 161 mmol/L Cl 123.7 mmol/L K 7.24 mmol /L API Event 2 CH-06 K 7.04 mmol/L CH-07 K 2.86 mmol/L 4. An interview with the technical consultant on 7/21/2022 at 1430 hours in the laboratory confirmed the above findings.

D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) 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. This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory documents, the Centers for Medicaid and Medicare Services (CMS) form 116, and confirmed in interview, the laboratory failed to perform calibration twice annually for the Sysmex XP-300 hematology analyzer from August 2021 to June 2022 as described in their policy. The findings include: 1. Review of the laboratory policy titled "Method Validation" section "I" stated the following: "4. Criteria for frequency of recalibration or calibration verification, (v.) At least every 6 months." 2. Review of laboratory documents had the previous calibration verification for the Sysmex XP-300 hematology analyzer being performed on February 10, 2021, with the next calibration verification to be performed on August 9, 2021. Surveyor queried the technical consultant (TC), on 6/21 /2022 at 11:30 hours, for the calibration documentation for August 2021 to current and none was provided. 3. Review of the CMS-116, section VII. "Non-Waived Testing" listed an estimated annual volume for the specialty of hematology at 44,000. 4. In an interview on 6/21/2022 at 12:46 hours, in the conference room, the TC confirmed that the calibration verification had not been performed every six months since February of 2021.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on a review of laboratory documents, the Centers for Medicaid and Medicare Services (CMS) form 116, and confirmed in an interview, the laboratory failed to

	document corrective action when the refrigerator used for the storage of hematology and chemistry reagents was out of temperature for 67 out of 117 days reviewed from January to June of 2022. The findings include: 1. Review of the laboratory temperature logs had the following temperature range for the refrigerator where chemistry and hematology reagents are stored: "2-10 (degrees) Celsius (35.6 to 50.0 degrees Fahrenheit (F))" Review of the temperature logs from January to June 2022 had the following 67 days where the temperature was outside of the specified range without corrective action documented: January 2022 - 15 days 1/3/2022 - 33 (degrees) F 1/4/2022 - 31 (degrees) F 1/5/2022 - 34 (degrees) F 1/6/2022 - 35 (degrees) F 1/11 /2022 - 33 (degrees) F 1/12/2022 - 33 (degrees) F 1/13/2022 - 33 (degrees) F 1/14 /2022 - 34 (degrees) F 1/19/2022 - 34 (degrees) F 1/20/2022 - 35 (degrees) F 1/21 /2022 - 33 (degrees) F 1/24/2022 - 34 (degrees) F 1/25/2022 - 33 (degrees) F 1/26 /2022 - 34 (degrees) F 1/31/2022 - 35 (degrees) F February 2022 - 9 days 2/1/2022 - 34 (degrees) F 2/3/2022 - 35 (degrees) F 2/4/2022 - 34 (degrees) F 2/10/2022 - 35 (degrees) F 2/15/2022 - 35 (degrees) F 2/17/2022 - 35 (degrees) F 2/22/2022 - 35 (degrees) F 2/25/2022 - 35 (degrees) F 2/28/2022 - 35 (degrees) F March 2022 - 12 days 3/1/2022 - 34 (degrees) F 3/4/2022 - 34 (degrees) F 3/7/2022 - 34 (degrees) F 3/8 /2022 - 35 (degrees) F 3/9/2022 - 34 (degrees) F 3/14/2022 - 35 (degrees) F 3/15/2022 - 35 (degrees) F 3/16/2022 - 34 (degrees) F 3/18/2022 - 35 (degrees) F 3/22/2022 - 35 (degrees) F 3/29/2022 - 33 (degrees) F 3/30/2022 - 35 (degrees) F April 2022 - 12 days 4/1/2022 - 34 (degrees) F 4/6/2022 - 34 (degrees) F 4/7/2022 - 32 (degrees) F 4/8 /2022 - 34 (degrees) F 4/12/2022 - 34 (degrees) F 4/13/2022 - 32 (degrees) F 4/14 /2022 - 67 (degrees) F 4/18/2022 - 34 (degrees) F 4/19/2022 - 34 (degrees) F 4/20 /2022 - 34 (degrees) F 4/26/2022 - 34 (degrees) F 4/27/2022 - 33 (degrees) F 4/29 /2022 - 34 (degrees) F May 2022 - 13 days 5/3/2022 - 34 (degrees) F 5/4/2022 - 33 (degrees) F 5/5/2022 - 35 (degrees) F 5/9/2022 - 34 (degrees) F 5/10/2022 - 35 (degrees) F 5/11/2022 - 33 (degrees) F 5/12/2022 - 34 (degrees) F 5/13/2022 - 34 (degrees) F 5/17/2022 - 35 (degrees) F 5/19/2022 - 35 (degrees) F 5/20/2022 - 34 (degrees) F 5/27/2022 - 33 (degrees) F 5/31/2022 - 33 (degrees) F June 2022 - 6 days 6 /6/2022 - 35 (degrees) F 6/8/2022 - 34 (degrees) F 6/9/2022 - 34 (degrees) F 6/10 /2022 - 35 (degrees) F 6/16/2022 - 33 (degrees) F 6/29/2022 - 34 (degrees) F 2. Surveyor observed on 6/21/2022 at 13:30 hours, in the laboratory refrigerator, the following nine sampling of reagents with reagent storage requirements of 2-8 (degrees) Celsius (C) (35.6 - 46.4 (degrees) F): Alkaline Phosphatase Reagent -, Lot F4595, EXP 5/31/2023 Cholesterol Reagent - Lot F4599, EXP 2/28/2023 Carbon Dioxide Reagent - Lot F4623, Exp 4/30/2023 Uric Acid Reagent - Lot F4540, Exp 8 /31/2022 Level 1 Chemistry Control - Lot F4510, Exp 11/28/2024 Level 2 Chemistry Control - Lot F4515, Exp 11/28/2024 Lipid Controls - Lot F4620, Exp 8/31/2023 Gemcal reference Serum - Lot F4575, EXP 12/28/2023 Eightcheck - 3WP X-TRA - Lot 2194, Exp 10/19/2022 3. Review of the CMS-116, section VII. "Non-Waived Testing" listed a total estimated annual volume for the specialty of hematology and chemistry at 94,000. 4. In an interview on 6/21/2022 at 11:37 hours, in the conference room, the technical consultant (TC) confirmed that corrective action was not documented when the proper storage of reagents was not met.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on review of the laboratory policy, manufacturer's instructions, random review of the quality control records from January to July 2022, and confirmed in interview, the laboratory quality assessment policy failed to review the effectiveness of corrective actions to resolve quality control (QC) problems for two of four analytes reviewed (Potassium and Chloride) on the Ace Alera chemistry analyzer. Findings included: 1. Review of the laboratory policy Internal Quality Control (LAB108) revealed "For Quantitative Assays: Adhere to recommendations provided by the manufacturer's analytical systems or reagents regarding the national justification and appropriateness of control materials." 2. Review of the ACE Clinical Chemistry System Operator's Manual (P/N 701164 Rev 6/04) under Corrective Action revealed: "Corrective action must be taken and documented whenever the results on one or more of the controls are outside of the acceptable range of values. The corrective actions that should be taken are summarized below: Repeat Same Control(s) - Do not assay or report patient results until the same control(s) are repeated. If results from the repeated tests are within the acceptable range of values, patient results may be reported. Test Freshly-Prepared Controls - If results from the tests on freshly-prepared controls are within the acceptable range of values, patient results may be reported. Re-calibrate (where applicable) - If control results from the re-calibrated tests are within the acceptable range of values, repeat the tests with patient specimens. Prepare Fresh Reagents - If control results from the tests using freshly prepared reagents are within the acceptable range of values, repeat the tests using patient specimens 3. Random review of quality control records from January 2022 to July 2022 revealed the following quality control failures with the corresponding corrective actions: Potassium (K) acceptable range 7.4 - 8.06 mmol/L 3/29/2022 (repeat 8 times) 7.2 mmol/L - rerun QC 7.2 mmol/L - rerun QC 7.3 mmol/L - rerun QC 7.4 mmol/L - rerun QC 7.3 mmol/L - rerun QC 7.3 mmol/L - rerun QC 7.3 mmol/L - rerun QC 7.3 mmol/L - rerun QC 3/30/2022 (repeat 16 times) 7.2 mmol/L - controls will be repeated using the same vial of material 7.2 mmol/L - controls will be repeated using the same vial of material 7.4 mmol/L - controls will be repeated using the same vial of material 7.2 mmol/L - controls will be repeated using the same vial of material 7.2 mmol/L - controls will be repeated using the same vial of material 7.2 mmol/L - controls will be repeated using the same vial of material 7.2 mmol/L - controls will be repeated using the same vial of material 7.2 mmol/L - controls will be repeated using the same vial of material 7.3 mmol/L - controls will be repeated using the same vial of material 7.2 mmol/L - controls will be repeated using the same vial of material 7.2 mmol/L - controls will be repeated using the same vial of material 7.3 mmol/L - controls will be repeated using the same vial of material 7.4 mmol/L - controls will be repeated using the same vial of material 7.4 mmol/L - controls will be repeated using the same vial of material 7.2 mmol/L - controls will be repeated using the same vial of material Chloride (CL) acceptable range 75.3-86.1 mmol/L 1/12/2022 (repeat 19 times) 87 mmol/L - controls will be repeated using the same vial of material 91 mmol/L - controls will be repeated using the same vial of material 92 mmol/L - controls will be repeated using the same vial of material 91 mmol/L - controls will be repeated using the same vial of material 91 mmol/L - controls will be repeated using the same vial of material 87 mmol/L - controls will be repeated using the same vial of material 91 mmol/L - controls will be repeated using the same vial of material 86 mmol/L - Rerun QC 89 mmol/L - Rerun QC 88 mmol/L - Rerun QC 88 mmol/L - Rerun QC 86 mmol /L - Rerun QC 91 mmol/L - controls will be repeated using the same vial of material 91 mmol/L - controls will be repeated using the same vial of material 95 mmol/L -

	controls will be repeated using the same vial of material 93 mmol/L - controls will be repeated using the same vial of material 92 mmol/L - controls will be repeated using the same vial of material 92 mmol/L - controls will be repeated using the same vial of material 92 mmol/L - controls will be repeated using the same vial of material 3/30 /2022 (repeat 26 times) 88 mmol/L - controls will be repeated using the same vial of material 89 mmol/L - controls will be repeated using the same vial of material 90 mmol/L - controls will be repeated using the same vial of material 90 mmol/L - controls will be repeated using the same vial of material 88 mmol/L - controls will be repeated using the same vial of material 88 mmol/L - controls will be repeated using the same vial of material 94 mmol/L - controls will be repeated using the same vial of material 91 mmol/L - controls will be repeated using the same vial of material 92 mmol/L - controls will be repeated using the same vial of material 92 mmol/L - controls will be repeated using the same vial of material 88 mmol/L - controls will be repeated using the same vial of material 89 mmol/L - controls will be repeated using the same vial of material 92 mmol/L - controls will be repeated using the same vial of material 91 mmol/L - controls will be repeated using the same vial of material 91 mmol/L - controls will be repeated using the same vial of material 92 mmol/L - controls will be repeated using the same vial of material 92 mmol/L - controls will be repeated using the same vial of material 90 mmol/L - controls will be repeated using the same vial of material 90 mmol/L - controls will be repeated using the same vial of material 89 mmol/L - controls will be repeated using the same vial of material 89 mmol/L - controls will be repeated using the same vial of material 89 mmol/L - controls will be repeated using the same vial of material 92 mmol/L - controls will be repeated using the same vial of material 92 mmol/L - controls will be repeated using the same vial of material 88 mmol/L - controls will be repeated using the same vial of material 88 mmol/L - controls will be repeated using the same vial of material 4. Review of the laboratory quality assessment records for the above dates revealed it failed to prevent recurrence of quality control problems. 5. Review of the CMS116 revealed the laboratory performed 22000 chemistry tests annually. 6. An interview with the testing person #1 on 7/21/2022 at 1410 hours in the laboratory confirmed the above findings. She stated that she was unable to find the root cause of the QC problems and repeated the controls numerous times instead of following the manufacturer's instructions to resolve QC issues.