Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0707586	07/29/2026
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	A recertification survey was completed on July 29, 2026. The laboratory was found out of compliance with the following condition level deficiencie: D2000 - 42 C.F.R. 493.801 Condition: Enrollment and testing of [proficiency testing] samples;
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of the laboratory's American Proficiency Institute (API) proficiency testing records, the laboratory's records, and staff interview, the laboratory failed to enroll in the correct proficiency testing program for one of one analyte-Glycohemoglobin in 2025 and 2026. Findings include: 1. A review of the laboratory's API proficiency testing records revealed the following: "Reporting Instructions: If you are performing Glycohemoglobin testing using a moderately complex method, you must report proficiency results for 5 samples. These scores will be sent to CMS. Proficiency scores from the Glycohemoglobin A- 2 sample program #926 will not be sent to CMS." 2. Further review of the laboratory's API proficiency testing records from 2025, and 2026 revealed the laboratory was enrolled in the Glycohemoglobin A-2 sample program. 3. A review of the laboratory's records revealed the laboratory began Glycohemoglobin testing on the moderately complex Tosoh G8 analyzer in August 2024. 4. Further review of the laboratory's records revealed the laboratory

	estimated performing 2,500 Glycohemoglobin tests annually. 5. In an interview on 7 /29/26 at 10:15 a.m. in the conference room, after review of the records, the technical consultant confirmed the above findings.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on review of laboratory maintenance records, calibration records, and interview, the laboratory failed to ensure the retention of instrument analytical printouts for the calibration Hemoglobin A1C on the Tosoh Bioscience G8 chemistry analyzer for records reviewed from October 2024 through June 2026. The findings included: 1. Review of the laboratory "Tosoh HPLC G8 Analyzer Variant Analysis Mode Maintenance log" included the following 55 days where the "As Needed: Calibrate System" was checked off as completed: 2024: 15 days 10/07/2024 10/28 /2024 10/29/2024 10/30/2024 10/31/2024 11/04/2024 11/11/2024 11/18/2024 11/25 /2024 11/26/2024 11/27/2024 12/02/2024 12/09/2024 12/16/2024 12/30/2024 2025: 22 days 01/01/2025 01/02/2025 01/20/2025 01/24/2025 01/27/2025 02/03/2025 02/10 /2025 02/17/2025 02/24/2025 03/03/2025 03/10/2025 03/17/2025 03/24/2025 03/31 /2025 04/07/2025 04/14/2025 04/21/2025 05/05/2025 05/12/2025 05/19/2025 06/26 /2025 06/30/2025 2026: 18 days 01/29/2026 02/02/2026 02/09/2026 02/16/2026 02/23 /2026 03/03/2026 03/16/2026 04/06/2026 04/13/2026 04/27/2026 05/04/2026 05/11 /2026 05/26/2026 06/01/2026 06/08/2026 06/15/2026 06/22/2026 06/29/2026 2. Surveyor asked for the analytic record for the calibrations for the above days where it was indicated that calibration was performed and acceptable, and none could be provided. 3. In an interview on 7/29/2026 at 11:35 hours, in the laboratory, technical consultant 1 confirmed the laboratory did not retain the analytic data for the Hemoglobin A1C Calibration on the Tosho Bioscience G8 Hemoglobin A1C analyzer.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) (a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's American Proficiency Institute (API) proficiency testing records, and staff interview, the laboratory failed to retain the proficiency testing records for eight of eight events in 2024 and 2025. Findings include: 1. A review of the laboratory's policy titled 'Proficiency Testing' revealed the following: "Retainment of Records: The laboratory should retain an easily accessible record that contains: 1. Proficiency Testing Attestation Sheets 2. Control Data 3. PT Report 4. Record of review by Laboratory Director 5. Copy of report returned to the laboratory 6. Copies of cumulative reports 7. Copies of proficiency testing problem response form" 2. A review of the laboratory's API

	proficiency testing records for 2024 and 2025 included the following 8 events with no documentation of the above mentioned records: 2024: Hematology/ Coagulation 1st Event Hematology/ Coagulation 2nd Event Hematology/Coagulation 3rd Event 2025: Hematology/ Coagulation 1st Event Hematology/ Coagulation 2nd Event Hematology /Coagulation 3rd Event Chemistry- Core 1st Event Chemistry- Core 2nd Event 3. In an interview on 7/29/26 at 10:20 a.m. in the conference room, after review of the records, the technical consultant confirmed the above findings.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and forms, the laboratory's American Proficiency Institute (API) proficiency testing results, the laboratory's records, and staff interview, the laboratory failed to document corrective actions for one of one proficiency testing event with unsatisfactory scores for Glycated Hemoglobin testing in 2026. Findings include: 1. A review of the laboratory's policy titled 'Proficiency Testing' revealed the following: "Discrepancies noted are investigated. Each staff member who performed the analysis is asked to supply the laboratory manager with information concerning QC, other patient test on the day of analysis, instrument calibration and maintenance records if applicable, and any possible explanation for the unsatisfactory rating. The laboratory supervisor then writes a follow-up action that may include employee retraining, evaluation of methodology, QC etc. The laboratory supervisor signs and dates the report, which is then made available for the Laboratory Director review." 2. A review of the laboratory's API proficiency testing results from 2026 Chemistry- Core- 1st Event revealed the following unsatisfactory scores: Glycated Hemoglobin (GLY) 50% 3. A review of the laboratory's records revealed the laboratory failed to document corrective actions for the unsatisfactory scores received for the 2026 Chemistry- Core- 1st Event. 4. In an interview on 7/29/26 at 10:20 a.m. in the conference room, after review of the records, the technical consultant confirmed the above findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on a review of the Sysmex Automated Hematology Analyzer XP Series Instructions for Use, surveyor observation, and staff interview, the laboratory failed to document the open dates and revised expiration dates on three of three Eightcheck Hematology Control vials used on the Sysmex XP-300 hematology analyzer in July 2026. Findings include: 1. A review of the Sysmex Automated Hematology Analyzer XP Series Instructions for Use revealed the following: "Storage and shelf life after first opening: EIGHTCHECK-3WP X-TRA-N, EIGHTCHECK-3 WP X-TRA-L, and

	EIGHTCHECK-3WB X-TRA-H are to be stored at 2-8C before and after opening. After opening, the product is stable for 14 days if returned to the refrigerator promptly after use." 2. Surveyor observation of the laboratory's refrigerator on 7/29/26 at 12:35 p.m. revealed the following 3 Eightcheck hematology control vials currently in use for the XP-300 hematology analyzer with no documentation of an open date or revised expiration date: - EIGHTCHECK-3WP X-TRA-N Lot number: 61610711 - EIGHTCHECK-3 WP X-TRA-L Lot number: 61610710 - EIGHTCHECK-3 WP X-TRA-H Lot number: 61610712 3. In an interview on 7/29/26 at 12:35 p.m. in the laboratory, after review of the records, the technical consultant confirmed the above findings. Key: C = Degrees Celsius
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 calibration verification records, and confirmed in interview, the laboratory failed to ensure calibration verification was performed every six months for the Tosoh G8 chemistry analyzer, for records reviewed in 2025 and 2026. The findings included: 1. Review of the "Laboratory Quality Assessment" policy section "Quality Assessment / Performance Improvement Measures" included the following for review: "6. Laboratory Testing Cal/Ver (biannual)" 2. Review of laboratory records included an implementation date, for the Tosoh G8 chemistry analyzer of July 2024. Surveyor asked for the hemoglobin A1C calibration verification that would have been performed in January 2025, July 2025, and January 2026, and none was provided. 3. In an interview on 7/29/2026 at 11:15 hours, in the conference room, the technical consultant confirmed calibration verification had not been performed on the Tosoh G8 chemistry analyzer, for hemoglobin A1C testing.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, Sysmex Insight reports, the laboratory's records, and staff interview, the laboratory's quality assessment program failed to ensure that investigations were performed as required for four of four quality control lot numbers run on the Sysmex XP-300 hematology analyzer from October 2025 to June 2026. Findings include: 1. A review of the laboratory's policy titled 'Laboratory Quality Assessment' revealed the following: "Quality Assessment/Performance Improvement Measures: - Participation in Sysmex Insight Interlab QA program (quarterly reports)" 2. A review of the laboratory's policy titled 'Laboratory Internal Quality Control' revealed the following: "Monthly Decisions: - Review Inter-Laboratory reports for SDI and CVI. Any value over 2.0 needs to be addressed." 3. A review of the laboratory's Sysmex Insight reports revealed the following: "If your CV is 1.5 times greater than the Group CV, your result is presented in bold type and an investigation is warranted." 4. A review of the Sysmex Insight reports from October 2025 to June 2026 revealed the following Quality Control (QC) lot numbers included analytes with SDI values greater than 2.0 and the laboratory failed to have documentation of an investigation, per the laboratory's policy: a) Lot number: 5358 QC Data from: 12/16/25 - 4/1/26 Technical consultant review date: 7/26/26 - MCV Control level 1 SDI = 2.1 - MCV Control level 2 SDI = 2.0 b) Lot number: 6077 QC Data from: 3/18/25 - 6/24/26 Technical consultant review date: 7/26/26 - MCV Control level 1 SDI = 2.2 - MCV Control level 2 SDI = 2.1 c) Lot number: 6161 QC Data from: 6/10/26 - 7/12/26 Technical consultant review date: 7/27/26 - LYM# Control level 1 SDI = 18.7 - MXD# Control level 1 SDI = 2.1 5. Further review of the Sysmex Insight reports from October 2025 to June 2026 revealed the following Quality Control (QC) lot numbers included analytes with CV values 1.5 times greater than the Group CV and the laboratory failed to have documentation of an investigation, per Sysmex's requirements: a) Lot number: 5274 QC Data from : 10/1 /25 - 1/7/26 Technical Consultant review date: 7/26/26 - PLT Control level 1 CV = 11.9 - PLT Control level 2 CV = 8.5 - PLT Control level 3 CV = 4.9 - LYM% Control level 1 CV = 8.8 - LYM% Control level 2 CV = 5.4 - LYM% Control level 3 CV = 3.0 - MXD% Control level 1 CV = 24.7 - MXD% Control level 2 CV = 14.0 - MXD% Control level 3 CV = 10.3 b) Lot number: 6077 QC Data from: 3/18/25 - 6/24/26 Technical consultant review date: 7/26/26 - MCHC Control level 3 CV = 2.6 - LYM% Control level 1 CV = 9.3 - LYM% Control level 2 CV = 4.8 - LYM% Control level 3 CV = 3.3 - MPV Control level 1 CV = 5.8 - MPV Control level 2 CV = 4.4 c) Lot number: 6077 QC Data from: 3/18/25 - 6/24/26 Technical consultant review date: 7/26 /26 - WBC Control level 2 CV = 5.1 - WBC Control level 3 CV = 4.3 - PLT Control level 1 CV = 12.4 - PLT Control level 2 CV = 8.1 - PLT Control level 3 CV = 5.3 - MXD% Control level 1 CV = 25.5 - MXD% Control level 2 CV = 15.9 - MXD% Control level 3 CV = 11.3 - MXD# Control level 3 CV = 14.0 d) Lot number: 6161 QC Data from: 6/10/26 - 7/12/26 Technical consultant review date: 7/27/26 - HGB Control level 2 CV = 2.2 - HGB Control level 3 CV = 2.3 - HCT Control level 1 CV = 1.9 - HCT Control level 2 CV = 1.6 - HCT Control level 3 CV = 1.8 - MCV Control level 1 CV = 3.8 - MXD% Control level CV = 69.3 - LYM# Control level 1 CV = 494.2 - MXD# Control level 1 CV = 496.9 6. A review of the laboratory's records revealed the laboratory estimated performing 20,500 Hematology tests annually. 7. In an interview on 7/29/26 at 11:50 a.m. in the conference room, after review of the records, the technical consultant confirmed the above findings.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)

	(e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing records and staff interview, the laboratory director failed to ensure the laboratory was enrolled in the correct proficiency testing program for one of one analyte- Glycohemoglobin in 2025 and 2026. (Refer to D2000)
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing records and staff interview, the technical consultant failed to ensure the laboratory was enrolled in the correct proficiency testing program for one of one analyte- Glycohemoglobin in 2025 and 2026. (Refer to D2000)
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: Based on laboratory policy, laboratory competency assessment records, laboratory test volume, and confirmed in interview, the technical consultant failed to ensure the annual competency for the Tosoh G8 analyzer in 2025 for two of two testing personnel (TP) performing patient hemoglobin A1C testing. The findings included: 1. Review of the laboratory policy titled "Competency Assessments", section "Frequency" included the following information: "Competency assessments for personnel performing non-waived testing must be conducted at least semiannually during the first year of testing and annually thereafter." 2. Review of laboratory competency for TP1 and TP 2, did not include documentation of competency on the Tosoh G8 chemistry analyzer for 2025. Surveyor asked the technical consultant for documentation of competency for 2025, and none was provided. 3. Review of the laboratory reported test volumes included 2,500 patients tested annually on the Tosoh G8 chemistry analyzer for hemoglobin A1C testing. 4. In an interview on 7/29/2026 at 10:35 hours, the technical consultant confirmed that the competency assessment for TP1 and TP2 in 2025.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

	This STANDARD is not met as evidenced by: Based on laboratory policy, laboratory testing, laboratory competency assessment records, and confirmed in interview, the technical consultant failed to ensure the testing personnel competency after the implementation of the Tosoh G8 analyzer for patient hemoglobin A1C testing when the analyzer was put into use for patient testing began in July 2024. The findings included: 1. Review of the laboratory policy titled "Competency Assessments", section "Frequency" included the following information: "Competency assessments for personnel performing non-waived testing must be conducted at least semiannually during the first year of testing and annually thereafter ... When test methodologies or instrumentation change, affected personnel must be reassessed and deemed competent prior to reporting patient results." 2. Review of the Tosho G8 validation binder indicated hemoglobin A1C patient testing began in July 2024. Surveyor asked for competency assessments for the two personnel performing testing and none was provided. 3. In an interview on 7/29/2026 at 1030 hours, in the conference room, the Technical Consultant confirmed that the initial competency assessment had not been performed on the Tosoh G8 analyzer, for two of two personnel, prior to reporting patient testing.