Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0707586	06/21/2018
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	Based on the survey conducted 06-20-2018 through 06-21-2018, the laboratory was found to be out of compliance with the following conditions of 42 CFR: 493.1250 Analytic Systems Moderate Complexity 493.1403 Laboratory Director Moderate Complexity .
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: . Based on review of American Proficiency Institute (API) proficiency testing (PT) documentation for the 2nd testing event of 2017, confirmed by staff interview, the laboratory failed to score at least 80 percent on the analyte total bilirubin. Findings: 1. API chemistry PT documentation for the 2nd event 2017 showed the following score: Bilirubin, Total-60% 2. In an interview at the site on 06-20-2018, testing person 1 (CMS form 209) stated she had performed the testing and reported the results. .
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

	This STANDARD is not met as evidenced by: . Based on review of API proficiency testing documentation for chemistry testing using the Alfa Wasserman Alera analyzer in the 2nd event of 2017, confirmed by staff interview, the laboratory failed to take corrective action for unsatisfactory testing scores. Findings: 1. API chemistry PT documentation for the 2nd event 2017 showed the following unacceptable responses: Bilirubin, Total Sample Reported Expected CH-06 3.3 3.4-5.2 CH-09 2.9 3.0-4.6 2. Documentation for this event showed no corrective action for unsatisfactory scores. In an interview at the site on 06-20-2018, testing person 1 stated no such action had been taken. .
D2122	HEMATOLOGY CFR(s): 493.851(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: . Based on review of API PT documentation for hematology testing using the Sysmex XP-300 analyzer in the third event of 2017, confirmed by staff interview, the laboratory failed to attain an overall testing score of at least 80 percent. Findings: 1. API PT results for hematology in the 3rd event 2017 showed the following scores: Erythrocyte Count-0% Hematocrit-0% Hemoglobin-0% Leukocyte Count-0% White Blood Cell Differential-53% Lymphocytes-20% Neutrophils/Granulocytes-40% 2. The cumulative score for hematology in this event was 25%. In an interview at the site on 06-20-2018, testing person 1 stated she had performed the testing and reported the results. .
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: . Based on review of API proficiency testing documentation for hematology testing using the Sysmex XP-300 in the third event of 2017, confirmed by staff interview, the laboratory failed to take corrective action for unsatisfactory testing scores. Findings: 1. Review of API hematology PT results for the 3rd event 2017 showed the following unacceptable results: Hematocrit (percent) Sample Reported Expected HSY-11 66 41-47 HSY-12 38 31-37 HSY-13 62 41-47 HSY-14 24 15-19 HSY-15 32 26-30 Hemoglobin (grams per deciliter) Sample Reported Expected HSY-11 25.0 15.1-17.5 HSY-12 14.6 11.4-13.3 HSY-13 23.3 15.0-17.4 HSY-14 9.4 5.6-6.5 HSY-15 11.6 9.5-11.0 Lymphocytes (percent) Sample Reported Expected HSY-11 32.4 33.4-37.2 HSY-13 37.3 33.5-36.9 HSY-14 20.7 21.9-28.2 HSY-15 26.2 27.3-31.7 Neutrophils (percent) Sample Reported Expected HSY-11 53.0 45.4-52.2 HSY-14 69.6 59.6-69.2

	HSY-15 63.0 54.9-61.8 Red Cell Count (10^12 per liter) Sample Reported Expected HSY-11 7.80 4.99-5.64 HSY-12 4.80 4.09-4.62 HSY-13 7.28 4.97-5.61 HSY-14 3.18 2.22-2.52 HSY-15 4.15 3.57-4.04 White Cell Count (10^9 per liter) Sample Reported Expected HSY-11 19.5 10.3-14.0 HSY-12 9.0 6.0-8.2 HSY-13 23.5 14.8-20.1 HSY-14 6.2 2.6-3.6 HSY-15 10.5 6.6-9.0 2. Documentation for this event showed no corrective action for unsatisfactory scores. In an interview at the site on 06-20-2018, testing person 1 stated no such action had been taken. .
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: . Based on review of API PT documentation for 2017, confirmed by staff interview, the laboratory failed to evaluate testing results for chemistry using the Alfa Wasserman Alera analyzer in the 2nd event of 2017 and hematology using the Sysmex XP-300 analyzer in the 3rd event of 2017. Findings: I. API 2nd event 2017 1. API PT results for chemistry in the 2nd event of 2017 included an unsatisfactory score of 60% for total bilirubin. (refer to D 2087) 2. Documentation for the testing event did not show evidence of result evaluation. The form for recording performance review and corrective action, signed and dated 11-20-2017, was otherwise blank. 3. In an interview at the site on 06-20-2018, testing person 1 stated that to her knowledge no evaluation of the results had been performed. II. API 3rd event 2017 1. API PT results for hematology in the 3rd event of 2017 included an unsatisfactory score of 25% overall. (refer to D 2122) 2. Documentation for the testing event did not show evidence of result evaluation. The form for recording performance review and corrective action was blank and unsigned. 3. In an interview at the site on 06-20-2018, testing person 1 stated that to her knowledge no evaluation of the results had been performed. . .
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . I. Based on review of laboratory procedures and staff interview, the laboratory failed to include control procedures for the Sysmex XP-300 hematology instrument in the procedure manual. Refer to D 5403. II. Based on review of performance verification documentation for the Sysmex XP-300 hematology analyzer, the laboratory failed to verify that the manufacturer's reference intervals are appropriate for the laboratory's patient population. Refer to D 5421. .
D5401	PROCEDURE MANUAL

	CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: . I. Based on review of laboratory procedure, surveyor observation and staff interview, the laboratory failed to follow its own procedure regarding establishment of quality control ranges for chemistry testing using the Alfa Wasserman Alera analyzer. Findings: 1. Laboratory procedure states: "New lot numbers of the Alfa Wasserman chemistry control will be run simultaneously with the current lot lot number in use. The current lot number in use is performed once daily to verify instrument function while the new lot is performed twice daily to establish new means. Continue perfoming lot numbers in conjunction for 10 days or until 20 data points are obtained." (Gulf Coast Health Center procedure manual, Establishment of Quality Control Ranges, Page 1) 2. Review of chemistry control documentation for 2018 showed no parallel control testing at lot changes. In an interview at the site on 06-20-2018, testing person 1 stated that laboratory practice was to key in the manufacturer's assay ranges at lot change. II. Based on review of laboratory procedure for proficiency testing corrective action, API PT documentation for 2017 and staff interview, the laboratory failed to follow its own procedure for evaluation of PT results and corrective action for unsatisfactory scores in chemistry and hematology. Findings: 1. The laboratory procedure manual states: "19. Any outlier/unnacceptable result(s) is /are investigated. If the survey had any unacceptable results, a Proficiency Testing Investigative Form is generated by the technical consultant or laboratory director to identify the cause of error. 20. All corrective actions are documented on the Proficiency Testing Investigative Form. 21. The Proficiency Testing Investigative Form is forwarded to the laboratory director for final review of unacceptable results and appropriateness of corrective actions. The laboratory director signs and dates the Proficiency Testing Investigative Form. 22. The Proficiency Testing Investigative Form is filed in the proficiency testing binder along with the survey evaluation with the previous data for that survey kit." (Gulf Coast Health Center procedure manual, Proficiency Testing, page 3) 2. Documentation of evaluation and corrective action for unsatisfactory PT results occurring in the second and third events of 2017 was not found and could not be offered at the time of the survey. Refer to D 2094 and D 2128. .
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or

	control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on review of laboratory procedures and staff interview, the laboratory failed to include control procedures for the Sysmex XP-300 hematology instrument in the procedure manual. Findings: 1. The laboratory procedure manual, in the procedure titled, "Establishment of quality control ranges," refers to Coulter 4C ES Cell Controls, the procedure for which consists of verification of the manufacturer's acceptable limits. In an interview at the site on 06-20-2018, testing person 1 stated that the Coulter instrument compatible with these controls was no longer in use, having been replaced with a Sysmex XP-300 in May of 2017. 2. No procedure for establishment of quality control ranges for the Sysmex XP-300 was included in the procedure manual. .
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on review of performance verification documentation for the Sysmex XP-300 hematology analyzer and staff interview, the laboratory failed to verify that the manufacturer's reference intervals are appropriate for the laboratory's patient population. Findings: 1. Performance verification documentation for the Sysmex XP-300 hematology analyzer was reviewed. No study for verification of reference intervals was found or could be offered. 2. In an interview at the site on 06-20-2018, testing person 1 stated that to her knowledge no such verification study had been performed. .
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: . I. Based on review of API PT documentation from 2017 and staff interview, the

	laboratory director failed to ensure that proficiency testing reports were reviewed and evaluated by the appropriate staff. Refer to D 6018. II. Based on review of API PT documentation from 2017 and staff interview, the laboratory director failed to ensure that the laboratory corrective action policy was folowed when proficiency testing results were found to be unsatisfactory. Refer to D 6019. III. Based on review of laboratory quality control procedure for hematology and staff interview, the laboratory director failed to ensure establishment of a quality control program for the Sysmex XP-300 analyzer. Refer to D6020. .
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: . Based on API PT testing documentation from 2017 and staff interview, the laboratory director failed to ensure that proficiency testing reports were reviewed and evaluated by the appropriate staff. Refer to D 5211. .
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: . Based on review of API PT documentation from 2017 and staff interview, the laboratory director failed to ensure that the laboratory corrective action policy was folowed when proficiency testing results were found to be unsatisfactory. Refer to D5211. .
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: . Based on review of laboratory quality control procedure for hematology and staff interview, the laboratory director failed to ensure establishment of a quality control program for the Sysmex XP-300 analyzer. Refer to D 5403. .