

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0707586	(X3) Date Survey Completed 03/23/2023
Name of Provider or Supplier Gulf Coast Health Center, Inc	Street Address, City, State 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 a proficiency testing desk review survey performed on March 23, 2023, the laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D2016 - 42 C.F.R. 493.803 Condition: Successful participation D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director, moderate complexity
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on a review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, the American Proficiency Institute (API) testing records, the facility failed to achieve successful performance for

	two of three consecutive proficiency testing events for the specialty of Routine Chemistry, resulting in unsuccessful performance. Refer to D2097.
D2097	ROUTINE CHEMISTRY CFR(s): 493.841(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, American Proficiency Institute (API) testing records for 2022 and 2023, the laboratory failed to achieve an overall testing event score of satisfactory performance (80% or greater) for two of three consecutive proficiency testing (PT) events for the specialty of Routine Chemistry. Two out of three testing event scores of unsatisfactory performance result in unsuccessful PT performance. Findings were: 1. A review of the CASPER Report 155 lists the following unsatisfactory scores for the specialty of Routine Chemistry in 2022 and 2023: 2022 - Event 2 - Routine Chemistry - 0% 2023 - Event 1 - Routine Chemistry - 0% 2. A proficiency desk review of American Proficiency Institute (API) proficiency testing (PT) records from 2022 and 2023 confirmed that the laboratory received the following unsatisfactory scores for the specialty of Routine Chemistry: 2022 - Event 2 - Routine Chemistry - 0% 2023 - Event 1 - Routine Chemistry - 0%
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: Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile American Proficiency Institute (API) testing records, the laboratory director failed to ensure successful participation in an HHS-approved proficiency testing program for Routine Chemistry. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by:

Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile American Proficiency Institute (API) proficiency testing records, the laboratory director failed to ensure successful participation in an HHS-approved proficiency testing program for Routine Chemistry for two of three consecutive events in 2022 to 2023. Refer to D2097.