Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0707586	(X3) Date Survey Completed 11/03/2023
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	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database and verified with the proficiency testing company. The facility was found to be out of compliance with the conditions of the CLIA program The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director;
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, American Proficiency Institute (API) records, the facility failed to successfully participate in three of five consecutive testing events for the chemistry analytes chloride (Cl) and sodium (Na), resulting in a non-initial unsuccessful performance. Refer to D2096.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in 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) records from 2022 and 2023, the laboratory failed to satisfactorily perform (80% or greater) three of five testing events for the chemistry analytes chloride (Cl) and sodium (Na). Three out of five unsatisfactory testing event scores result in non-initial unsuccessful PT performance. Findings were: 1. A review of the CASPER Report 155 listed the following scores for the chemistry analytes Cl and Na from 2022 and 2023: 2022 Event 2: CL: 0% Na: 0% 2023 Event 1: CL: 0% Na: 0% 2023 Event 3: CL: 20% Na: 20% 2. A proficiency testing desk review of American Proficiency Institute (API)proficiency testing records from 2022 and 2023 confirmed the above scores for the chemistry analytes Cl and Na.
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 proficiency testing desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, American Proficiency Institute (API) proficiency testing records from 2022 and 2023, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program for three out of five testing events for the chemistry analytes chloride (Cl) and sodium (Na). 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 a HHS approved proficiency testing program for the chemistry analytes chloride (Cl) and sodium (Na) for three of five events from 2022 to 2023, resulting in non-initial unsuccessful performance. Refer to D2096.