Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0502535	11/13/2020
Name of Provider or Supplier	**Street Address, City, State**	
Corpus Family Practice	2202 Morgan Ave, Corpus Christi, 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 CMS (Center for Medicare Services) national database and verified with the proficiency testing company, American Proficiency Institute (API). The facility was found to be out of compliance with the conditions of participation of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.803 successful participation in a proficiency testing program 493.1403 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 desk review of proficiency testing records, it was determined that the laboratory has not successfully participated in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory did not successfully participate in the specialties of chemistry and endocrinology (refer to D2096 and D2107).
D2088	ROUTINE CHEMISTRY CFR(s): 493.841(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: Review of the Casper 155 Report and API proficiency testing records found that the laboratory failed to achieve a satisfactory score of at least 80% for the overall chemistry testing event score. Findings include: 1. API 2020 - 2nd event - laboratory received an unsatisfactory chemistry event score of 0%. 2. API 2020 - 3rd event - laboratory received an unsatisfactory chemistry event score of 0%.
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Review of the Casper 155 Report and API proficiency testing records found that the laboratory failed to participate in the 2020 2nd and 3rd testing events resulting in a score of 0% for analytes in the specialty of Chemistry, constituting unsatisfactory performance. Findings: 1. API 2020 - 2nd event reported failure to participate resulting in the following unsatisfactory scores: Chloride 0% Cholesterol, HDL 0% Cholesterol, Total 0% Creatinine 0% Glucose 0% LDL, Cholesterol (measured) 0% Potassium 0% Sodium 0% Triglycerides 0% Urea Nitrogen 0% 2. API 2020 - 3rd events reported failure to participate resulting in the following unsatisfactory scores: Chloride 0% Cholesterol, HDL 0% Cholesterol, Total 0% Creatinine 0% Glucose 0% LDL, Cholesterol (measured) 0% Potassium 0% Sodium 0% Triglycerides 0% Urea Nitrogen 0%
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 desk review of proficiency testing records, it was determined the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two consecutive testing events or two out of three consecutive testing events in the specialty of Chemistry for the analytes Chloride, Cholesterol (HDL), Cholesterol (Total), Creatinine, Glucose, Cholesterol (LDL, measured), Potassium, Sodium, Triglycerides, and Urea Nitrogen. Two out of three unsatisfactory scores results in unsuccessful PT performance. Findings include: 1. API 2020 - 2nd event reported failure to participate resulting in the following unsatisfactory scores: Chloride 0% Cholesterol, HDL 0% Cholesterol, Total 0% Creatinine 0% Glucose 0% LDL, Cholesterol (measured) 0% Potassium 0% Sodium 0% Triglycerides 0% Urea Nitrogen 0% 2.API 2020 - 3rd events reported failure to participate resulting in the following unsatisfactory scores: Chloride 0% Cholesterol, HDL 0% Cholesterol, Total 0% Creatinine 0% Glucose 0% LDL, Cholesterol (measured) 0% Potassium 0% Sodium 0% Triglycerides 0% Urea Nitrogen 0%
D2099	ENDOCRINOLOGY CFR(s): 493.843(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: Review of the Casper 155 Report and proficiency testing records found that the laboratory failed to participate in the 2nd and 3rd events of 2020 resulting in a score of 0% for the overall Endocrinology testing event score. Findings: 1. API 2020 - 2nd event: lab received an Endocrinology testing event score of 0%. 2. API 2020 - 3rd event: lab received an Endocrinology testing event score of 0%
D2100	ENDOCRINOLOGY CFR(s): 493.843(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Review of the Casper 155 Report and proficiency testing records found that the laboratory failed to participate in the 2nd and 3rd testing events in 2020 in Endocrinology, resulting in a score of 0% for all regulated analytes for the specialty of Endocrinology, constituting unsatisfactory performance. Findings: 1. Laboratory

	received the following unsatisfactory scores from API 2020 - 2nd event: Thyroid Stimulating Hormone (TSH) - 0% 2.Laboratory received the following unsatisfactory scores from API 2020 - 3rd event: Thyroid Stimulating Hormone (TSH) - 0%
D2107	ENDOCRINOLOGY CFR(s): 493.843(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 desk review of proficiency testing records, it was determined the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two consecutive testing events or two out of three consecutive testing events in the specialty of Endocrinology for the analyte Thyroid Stimulating Hormone (TSH). Two out of three unsatisfactory scores results in unsuccessful PT performance. Findings include: 1. Laboratory received the following unsatisfactory scores from API 2020 - 2nd event: Thyroid Stimulating Hormone (TSH) - 0% 2. Laboratory received the following unsatisfactory scores from API 2020 - 3rd event: Thyroid Stimulating Hormone (TSH) - 0%
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: Review of the Casper 155 Report and API proficiency testing records found that the laboratory failed to participate in the 2nd event of 2020 resulting in a score of 0% for the overall Hematology Endocrinology testing event score. Findings: 1. API 2020 - 2nd event reported a Hematology testing event score of 0%.
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Review of the Casper 155 Report and API proficiency testing records found that the laboratory failed to achieve a satisfactory score of at least 80% for the overall

	hematology testing event score. Findings include: 1. API 2020 - 2nd event reported an unsatisfactory event hematology score of 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 desk review of laboratory proficiency testing it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. Findings: Review of the laboratory proficiency testing results revealed the laboratory director failed to ensure that the laboratory participated successfully (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 proficiency testing results it was revealed that the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in a HHS approved proficiency testing program (refer to D2096 and D2107).