Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D0495521	**(X3) Date Survey Completed** 05/04/2022
Name of Provider or Supplier El Campo Memorial Hospital	**Street Address, City, State** 303 Sandy Corner Road, El Campo, 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 participation of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.803 D2016 Condition: Successful participation [proficiency testing] 493.1403 D6076 Condition: Laboratories performing high 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 obtained from the CMS (Center

	for Medicare Services) national database and verified with the proficiency testing company, American Association of Bioanalysts (AAB), it was determined the laboratory had not successfully participated in a proficiency testing program approved by CMS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory did not successfully participate in the sub-specialty of ABO AND RHo(D) GROUPS. Refer to D2163.
D2153	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(a) Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on a desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the laboratory's American Association of Bioanalysts (AAB) proficiency test results, it was revealed the laboratory failed to attain a satisfactory score of at least 100% for each analyte in each testing event in 2021 and 2022. Findings included: 1. 2021 2nd Event Nc21Q2 (Immunohematology) participant results' evaluation revealed: Analyte: D (Rho) Typing Score: 80.0 Spec:7 Reported Value:* Negative, weak D (Du) not performed Intended Result: Positive 2. 2022 1st Event Nc22Q1 (Immunohematology) participant results' evaluation revealed: Analyte: ABO Group Score: 80.0 Spec:1 Reported Value: * B Intended Result: A Note: Proficiency testing failure for 2021 was cited during the 07/09/2021 onsite survey.
D2154	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(b) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on a desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the laboratory's American Association of Bioanalysts (AAB) proficiency test results, it was revealed the laboratory failed to attain an overall testing score of at least 100% in the sub-specialty of ABO AND RHo (D) GROUPS, resulting in an unsatisfactory performance. Findings include: 1. 2021 2nd Event Nc21Q2 - overall ABO AND RHo (D) GROUPS sub-specialty score of 90% 2. 2022 1st Event Nc22Q1 - overall ABO AND RHo (D) GROUPS sub-specialty score of 90% Note: Proficiency testing failure for 2021 was cited during the 07/09/2021 onsite survey.
D2163	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(g) Failure to achieve an overall testing event score of satisfactory 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 proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the laboratory's American Association of Bioanalysts (AAB) proficiency test results, it was revealed the laboratory failed to achieve an overall satisfactory testing event score for 2 of 3 consecutive testing events resulting in an unsuccessful performance in the Immunohematology sub-specialty of ABO AND RHo (D) GROUPS. Findings include: 1. 2021 2nd Event Nc21Q2 - unsatisfactory overall ABO AND RHo (D) GROUPS sub-specialty score of 90% 2. 2022 1st Event Nc22Q1 - unsatisfactory overall ABO AND RHo (D) GROUPS subspecialty score of 90% Note: Proficiency testing failure for 2021 was cited during the 07/09/2021 onsite survey.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the laboratory's American Association of Bioanalysts (AAB) proficiency test results, it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6089.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure 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 records obtained from the CMS (Center for Medicare Services) national database and verified with the laboratory's American Association of Bioanalysts (AA) proficiency test results, it was revealed the laboratory director failed to ensure successful participation in a CMS-approved proficiency testing program. Refer to D2153, D2154 and D2163.