Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D0495521	**(X3) Date Survey Completed** 09/08/2022
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: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6076 - 42 C.F.R. 493.1441 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 review of the Certification and Survey Provider Enhanced Reporting

	(CASPER) Report 155 Individual Laboratory Profile and a proficiency desk review of the American Association of Bioanalysts (AAB) proficiency testing (PT) records from 2021 and 2022, it was determined the laboratory had not successfully participated in a proficiency testing program, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory did not successfully participate in the specialty of immunohematology for the analyte Antibody ID (identification). Refer to D2190
D2190	ANTIBODY IDENTIFICATION CFR(s): 493.865(e) Failure to identify the same antibody in two consecutive or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and proficienty desk review of the laboratory American Association of Bioanalysts (AAB) proficiency test records from 2021 to 2022, the laboratory failed to achieve satisfactory scores (80%) for 4 of 5 consecutive PT events for Antibody ID which constitutes a non-initial unsuccessful test performance. Findings included: 1. Review of the CASPER Report 155 Individual Laboratory Profile from 2021 to 2022 revealed the laboratory failed to attain an acceptable score of 80% for 4 of 5 consecutive testing events for Antibody ID. 2021 1st event - Antibody ID (0%) 2021 2nd event - Antibody ID (0%) 2021 3rd event - Antibody ID (0%) 2022 2nd event - Antibody ID (20%) 2. Review of the laboratory AAB records from 2021 to 2022 confirmed the laboratory failed to attain an acceptable score of 80% for the above testing events for Antibody ID. 2021 1st event - (0% - Failure to Participate) 2021 2nd event - (0% - Failure to Participate) 2021 3rd event - (0% - Failure to Participate) 2022 2nd event - 20%
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 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 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 desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and verified with the laboratory's American Association of Bioanalysts (AAB) proficiency test results, it was revealed the laboratory director failed to ensure successful participation in a CMS-approved proficiency testing program. Refer to D2190