Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D0495521	**(X3) Date Survey Completed** 05/28/2024
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 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] 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 a desk review of proficiency testing records obtained from the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and verified with American Proficiency Institute (API), the

	laboratory failed to attain successful performance for two of three consecutive testing events in specialty of Immunohematology/Compatibility Testing for 2023 and 2024, resulting in unsuccessful performance. Refer to D2181.
D2181	COMPATIBILITY TESTING CFR(s): 493.863(e) 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 Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and a review of American Proficiency Institute (API) proficiency testing evaluations, the laboratory failed to attain of a score of 100% in two out of three consecutive testing events in compatibility testing between 2023 to 2024. The findings were: 1. Review of the CMS 155 report from 2023 to 2024 revealed the following results: 2023 - 2nd Event laboratory received an overall unsatisfactory score 80% for Compatibility testing. 2024 - 1st Event laboratory received an overall unsatisfactory score of 80% for Compatibility testing. 2. Review of the laboratory's API proficiency testing records for each event revealed the following results: API 2023 Immunology/Immunohematology 2nd Event : 80% for Compatibility testing. Sample: SER-06 Report Result: Compatible/AHG Expected Result: Incompatible Performance: Unacceptable API 2024 Immunology/Immunohematology 1st Event : 80% for Compatibility testing. Sample: SER-01 Report Result: Compatible Expected Result: Incompatible Performance: Unacceptable
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 laboratory proficiency testing performance, 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 results, 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 D2181.