

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0495521	(X3) Date Survey Completed 09/16/2022
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	<p>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] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director;</p>
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the CMS (Center for Medicare Services) national database and a</p>

	<p>proficiency desk review of the American Proficiency Institute (API) proficiency testing records from 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 chemistry for the analyte pCO₂. Refer to D2096</p>
<p>D2096</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>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.</p> <p>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 American Proficiency Institute (API) proficiency testing records from 2022, the laboratory failed to attain 80% (passing) for the analyte pCO₂ for 2 of 2 testing events in Chemistry for 2022 resulting in unsuccessful performance for pCO₂. Findings included: 1. Review of the CMS database revealed the laboratory scored less than 80% for the analyte pCO₂ for the Chemistry Core Event 1 and Event 2. pCO₂ Chemistry 1st event - 60% Chemistry 2nd event - 60% 2. Review of the API proficiency test records from 2022 confirmed the above failures for pCO₂. Chemistry Core 1st event - 60% pCO₂ BG-01 - lab result 42 mmHg (acceptable range 31-41 mmHg) BG-02 - lab result 61 mmHg (acceptable range 64-76 mmHg) Chemistry Core 2nd event - 60% pCO₂ BG-07 - lab result 31 mmHg (acceptable range 19-30 mmHg) BG-10 - lab result 60 mmHg (acceptable range 49-59 mmHg)</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION 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 American Proficiency Institute (API) proficiency testing records, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program for the analyte pCO₂. Refer to D6016</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>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</p>

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