

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0495521	(X3) Date Survey Completed 04/30/2019
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 CMS (Center for Medicare Services) national database and verified with the proficiency testing companies, American Proficiency Institute (API) and American Association of Bioanalysts (AAB) . The facility was found to be out of compliance with the conditions of participation of the CLIA program. The conditions not met were: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D2017 - 42 C.F.R. 493.807(a) - Reinstatement After Failure D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director;
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>

This CONDITION is not met as evidenced by:

A. 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 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 specialty of Immunohematology for Compatibility Testing . Refer to D2181. B. 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 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 specialty of Bacteriology. Refer to D2028. C. 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 Proficiency Institute (API), it was determined the laboratory had 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 specialty of Chemistry for the analytes Blood Gas PO₂, PCO₂, CL, NA, K. Refer to D2096. Note: Failure to successfully participate in the specialty of Chemistry for the analyte Blood Gas pH was cited on the 12/11/2018 survey. Key: PO₂- partial pressure of oxygen PCO₂- partial pressure of carbon dioxide CL- Chloride NA- Sodium K- Potassium

D2017

REINSTATEMENT OF NONWAIVED LABORATORIES
CFR(s): 493.807(a)(b)

(a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate.

This CONDITION is not met as evidenced by:

Based on a desk review of laboratory proficiency testing performance the laboratory failed to participate successfully in proficiency testing for the analyte blood gas pH. The laboratory failed to achieve satisfactory performance in the specialty of Chemistry in 2018 for the analyte blood gas pH for two of three consecutive testing events and has not demonstrated sustained satisfactory performance on two consecutive proficiency events since the unsuccessful scores. Findings were: 1. A review of proficiency testing records 2018 (a testing year consists of three testing

	<p>events) revealed that the laboratory attained the following scores: 40% on the first event in 2018 (Unsatisfactory). 0% on the third event in 2018 (Unsatisfactory). 2. A review of proficiency testing records 2019 (a testing year consists of three testing events) revealed that the laboratory attained the following scores: 0% on the first event in 2019 (Unsatisfactory). Key: pH-potential of Hydrogen</p>
<p>D2028</p>	<p>BACTERIOLOGY CFR(s): 493.823(e)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for 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 a desk review of CMS form 155 and AAB proficiency testing records, it was determined that laboratory failed to achieve satisfactory performance (80% or greater) for the specialty of bacteriology for two out of three consecutive testing events. Findings were: 1. The laboratory received a bacteriology score of 60% on the first event in 2018 (Unsatisfactory). 2. The laboratory received a bacteriology score of 100% on the second event in 2018 (Satisfactory). 3. The laboratory received a bacteriology score of 60% on the third event in 2018 (Unsatisfactory). Two out of three unsatisfactory scores results in unsuccessful PT performance. Key: CMS: Centers for Medicare & Medicaid Services AAB: American Association of Bioanalysts</p>
<p>D2087</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of CMS form 155 and American Proficiency Institute records found that the laboratory failed to attain a satisfactory score of at least 80% of acceptable responses for each analyte in the subspecialty of chemistry. Findings: 1. API 2018 - 1st testing event the laboratory received the following unsatisfactory scores: pH Blood Gas 40% 2. API 2018 - 3rd testing event the laboratory received the following unsatisfactory scores: pH Blood Gas 0% pO2 Blood Gas 0% pCO2 Blood Gas 20% CL (Chloride) 20% K (Potassium) 0% NA (sodium) 20% 3. API 2019 - 1st testing event the laboratory received the following unsatisfactory scores: pH Blood Gas 0% pO2 Blood Gas 20% pCO2 Blood Gas 0% CL (Chloride) 20% K (Potassium) 20% NA (sodium) 40% Note: pH Blood gas unsatisfactory scores for 2018-1 and 2018-3 were cited on the 12/11/2018 survey. Key: CMS: Centers for Medicare & Medicaid Services API: American Proficiency Institute</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</p>

unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on desk review of CMS form 155 and American Proficiency Institute 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 Blood Gas pH, PO₂, PCO₂, CL, NA and K. Two out of three unsatisfactory scores results in unsuccessful PT performance. Findings include: 1. A review of API proficiency testing records for 2018 (event 1,2,3) and 2019 (event 1) revealed the laboratory received the following unsatisfactory scores: pH Blood Gas 2018-1 40%(Unsatisfactory). 2018-3 0% (Unsatisfactory). 2019-1 0% (Unsatisfactory). pO₂ Blood Gas 2018-3 0% (Unsatisfactory). 2019-1 20% (Unsatisfactory). pCO₂ Blood Gas 2018-3 20% (Unsatisfactory). 2019-1 0% (Unsatisfactory). CL (Chloride) 2018-3 20% (Unsatisfactory). 2019-1 20% (Unsatisfactory). K (Potassium) 2018-3 0% (Unsatisfactory). 2019-1 20% (Unsatisfactory). NA (sodium) 2018-3 20% (Unsatisfactory). 2019-1 40% (Unsatisfactory). Note: pH Blood gas unsatisfactory scores for 2018-1 and 2018-3 were cited on the 12/11/2018 survey. Key: CMS: Centers For Medicare & Medicaid Services API: American Proficiency Institute

D2173

COMPATIBILITY TESTING

CFR(s): 493.863(a)

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 CMS and AAB proficiency testing records , it was found the laboratory failed to attain an overall compatibility testing event score of at least 100% which constitutes unsatisfactory performance. (2018- 3, 2019-1) Findings: 1. AAB 2018 - 3rd event lab received the unsatisfactory scored of 60% for Compatibility Testing. 2. AAB 2019 - 1st event lab received the unsatisfactory scored of 80% for Compatibility Testing Key: CMS: Centers for Medicare & Medicaid Services AAB: American Association of Bioanalysts

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 desk review of proficiency testing records, it was determined the laboratory failed to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events. The laboratory failed to achieve satisfactory performance (100 %) in the specialty of immunohematology for Compatibility Testing for 2 of 3 consecutive testing events. (2018-3, 2019-1) Findings were: 1. AAB 2018-3rd Event lab scored 60% for Compatibility Testing. 2. AAB

	<p>2019-1st Event lab scored 80% for Compatibility Testing. Two out of three unsatisfactory scores results in unsuccessful PT performance. Key: CMS: Centers for Medicare & Medicaid Services AAB: American Association of Bioanalysts</p>
D6000	<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 a desk review of laboratory proficiency testing performance it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016</p>
D6016	<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 required under Subpart H of this part;</p> <p>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</p>
D6076	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on a desk review of laboratory proficiency testing performance it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6089</p>
D6089	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i)</p> <p>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.</p>

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 D2028, D2181).