

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2000387	<b>(X3) Date Survey Completed</b>  08/05/2020
<b>Name of Provider or Supplier</b>  Texas Internal Medicine And Diagnostic Center	<b>Street Address, City, State</b>  4502 N Laurent St, Victoria, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the Casper 155 Report and verified with the proficiency testing company, American Proficiency Institute (API). The facility was found to be out of compliance with the conditions of participation of the CLIA program. The following <b>CONDITION LEVEL DEFICIENCIES</b> were found to be out of compliance: 493.803 successful participation in a proficiency testing program 493.1403 laboratories performing moderate complexity testing; lab
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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 <b>CONDITION</b> is not met as evidenced by: Based on a desk review of proficiency testing records, it was determined that the</p>

	<p>laboratory has 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 analyte Sodium (Na) (refer to D2096).</p>
<p><b>D2087</b></p>	<p><b>ROUTINE CHEMISTRY</b> 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 Casper Report 155 and American Proficiency Institute (API) proficiency testing (PT) 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 2020 - 1st event the laboratory received an unsatisfactory score of 60% for Sodium. 2. API 2020 - 2nd event the laboratory received an unsatisfactory score of 0% for Sodium. 3. API 2020 - 2nd event the laboratory received an unsatisfactory score of 0% for ALT. 4. API 2020 - 2nd event the laboratory received an unsatisfactory score of 0% for Albumin. 5. API 2020 - 2nd event the laboratory received an unsatisfactory score of 0% for Alkaline Phosphatase. 6. API 2020 - 2nd event the laboratory received an unsatisfactory score of 0% for Amylase. 7. API 2020 - 2nd event the laboratory received an unsatisfactory score of 0% for AST. 8. API 2020 - 2nd event the laboratory received an unsatisfactory score of 0% for Total Bilirubin. 9. API 2020 - 2nd event the laboratory received an unsatisfactory score of 0% for Total Calcium. 10. API 2020 - 2nd event the laboratory received an unsatisfactory score of 0% for Chloride. 11. API 2020 - 2nd event the laboratory received an unsatisfactory score of 0% for Total Cholesterol. 12. API 2020 - 2nd event the laboratory received an unsatisfactory score of 0% for HDL Cholesterol. 13. API 2020 - 2nd event the laboratory received an unsatisfactory score of 0% for Creatine. 14. API 2020 - 2nd event the laboratory received an unsatisfactory score of 0% for Glucose. 15. API 2020 - 2nd event the laboratory received an unsatisfactory score of 0% for Potassium. 16. API 2020 - 2nd event the laboratory received an unsatisfactory score of 0% for Total Protein. 17. API 2020 - 2nd event the laboratory received an unsatisfactory score of 0% for Triglycerides. 18. API 2020 - 2nd event the laboratory received an unsatisfactory score of 0% for BUN.</p>
<p><b>D2088</b></p>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Review of the Casper 155 Report and American Proficiency Institute (API) proficiency testing (PT) records found that the laboratory failed to achieve a satisfactory score of at least 80% for the overall chemistry testing event score. Findings: 1. API 2020 - 2nd event reported an event chemistry score of 0%.</p>
<p><b>D2089</b></p>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(c)</p>

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:  
Review of the Casper 155 Report and American Proficiency Institute (API) proficiency testing (PT) records found that the laboratory failed to participate in 2020 (2nd Event) resulting in a score of 0% for the all analytes in the specialty of Chemistry, constituting unsatisfactory performance. Findings: 1. API 2020 - 2nd event reported No Data Received resulting in the following unsatisfactory scores: Alanine aminotransferase ALT 0% Albumin 0% Alkaline Phosphatase 0% Amylase 0% Aspartate aminotransferase AST 0% Bilirubin, Total 0% Calcium, Total 0% Chloride 0% Total Cholesterol 0% Cholesterol HDL (high density lipoprotein) 0% Creatinine 0% Glucose 0% Potassium 0% Sodium 0% Total Protein 0% Triglycerides 0% Blood Urea Nitrogen BUN 0%

**D2096**

**ROUTINE CHEMISTRY**  
CFR(s): 493.841(f)

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.

This STANDARD is not met as evidenced by:  
Based on a desk review of American Proficiency Institute (API) proficiency testing (PT) records, it was determined that laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two out of three consecutive testing events. The laboratory failed to achieve satisfactory performance in the specialty of chemistry for the analyte Sodium. Two out of three unsatisfactory scores results in unsuccessful PT performance. Findings: 1. API 2020 - 1st event the laboratory received an unsatisfactory score of 60% for Sodium. 2. API 2020- 2nd event the laboratory received an unsatisfactory score of 0% for Sodium.

**D2099**

**ENDOCRINOLOGY**  
CFR(s): 493.843(b)

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:  
Review of the Casper Report 155 and American Proficiency Institute (API) proficiency testing (PT) records found that the laboratory failed to achieve a satisfactory score of at least 80% for the overall endocrinology testing event score.

	<p>Findings: 1. API 2020 - 2nd event lab received an unsatisfactory event score of 0% for Endocrinology.</p>
<p><b>D2100</b></p>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.843(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Review of the Casper 155 Report and American Proficiency Institute (API) proficiency testing (PT) records found that the laboratory failed to participate in 2020 (2nd Event) resulting in a score of 0% for the all analytes in the specialty of Endocrinology, constituting unsatisfactory performance. Findings: 1. API 2020 - 2nd event reported No Data Received resulting in the following unsatisfactory scores: Thyroxine, Free 0% Thyroid Stimulating Hormone 0%</p>
<p><b>D6000</b></p>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> 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>
<p><b>D6016</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> 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</p>

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