

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2000387	<b>(X3) Date Survey Completed</b>  11/04/2021
<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 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; laboratory director
<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 review of the laboratory's American Proficiency Institute (API) proficiency testing records and confirmed in interview of facility personnel, it was determined that the laboratory has not successfully participated in a proficiency testing program</p>

	<p>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 subspecialty of endocrinology for analyte Free Thyroxine (refer to D2098).</p>
<p><b>D2098</b></p>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.843(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 review of the laboratory's American Proficiency Institute (API) proficiency testing records and confirmed in interview of facility personnel, it was determined that the laboratory failed to attain a score of 80% or greater for Free Thyroxine and Thyroid Stimulating Hormone (TSH) resulting in unsuccessful analyte performance. The findings included: 1. Review of the laboratory's API proficiency testing records found the following unsuccessful scores for Free Thyroxine and TSH: API 2021 - 2nd event the laboratory scored 20% for Free Thyroxine API 2021 - 3rd event the laboratory scored 0% for Free Thyroxine API 2021 - 2nd event the laboratory scored 0% for TSH 2. An interview with the technical consultant on November 4, 2021 at 10:00 hours in the break room confirmed the findings. It was confirmed he was aware of the regulated analyte failures and is in the process of performing the follow up. He stated that the laboratory is currently not testing Free T3 and Free Thyroxine.</p>
<p><b>D2107</b></p>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.843(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 review of the laboratory's American Proficiency Institute (API) proficiency testing records and confirmed in interview of facility personnel, it was determined that the laboratory failed to achieve satisfactory performance (80 % or greater) for the same analyte in the specialty of endocrinology in two consecutive testing events or two out of three consecutive testing events. Two out of three unsatisfactory scores results in unsuccessful PT performance. The findings included: 1. Review of the laboratory's API proficiency testing records found the following unsuccessful scores for Free Thyroxine: API 2021 - 2nd event the laboratory scored 20% for Free Thyroxine API 2021 - 3rd event the laboratory scored 0% for Free Thyroxine 2. An interview with the technical consultant on November 4, 2021 at 10:00 hours in the break room confirmed the findings. It was confirmed he was aware of the regulated analyte failures and is in the process of performing the follow up. He stated that the laboratory is currently not testing Free T3 and Free Thyroxine.</p>
<p><b>D2108</b></p>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.843(g)</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</p>

unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's American Proficiency Institute (API) proficiency testing records and confirmed in interview of facility personnel, it was determined that the laboratory failed to achieve a satisfactory score of at least 80% for the overall endocrinology testing event score. The findings included: 1. Review of the laboratory's API proficiency testing records found the following unsuccessful overall scores in the subspecialty of Endocrinology: API 2021 - 2nd event laboratory received an unsatisfactory event score of 10%. API 2021 - 3rd event laboratory received an unsatisfactory event score of 50%. 2. An interview with the technical consultant on November 4, 2021 at 10:00 hours in the break room confirmed the findings. It was confirmed he was aware of the regulated analyte failures and is in the process of performing the follow up. He stated that the laboratory is currently not testing Free T3 and Free Thyroxine.

**D5217**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's proficiency testing records from American Proficiency Institute (API), and confirmed in interview of facility personnel, the laboratory failed to perform twice annual accuracy for the unregulated analyte of Free T3. The findings included: 1. Review of the laboratory's API proficiency testing records found that the laboratory participated in three of three events in 2021 for the subspecialty of endocrinology. 2021 - 1st event laboratory scored 100% 2021 - 2nd event laboratory scored 0% 2021 - 3rd event laboratory scored 0% 2. The laboratory failed two of three events and therefore did not perform twice annual accuracy assessments for the analyte Free T3. 3. An interview with the technical consultant on November 4, 2021 at 10:00 hours in the break room confirmed the findings. It was confirmed he was aware of the regulated analyte failures and is in the process of performing the follow up. He stated that the laboratory is currently not testing Free T3 and Free Thyroxine.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**

CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on surveyor observations, review of manufacturer's instructions, review of the

	<p>laboratory's environmental records, and confirmed in interview with facility personnel, the laboratory failed to establish an accurate room temperature range for 200 of 200 blood collection tubes stored in the laboratory. The findings included: 1. Surveyor observation made on November 4, 2021 at 13:15 hours in the laboratory found the following blood collection tubes stored in the laboratory: 200 Vacuette red top tubes 200 Vacutainer red top tubes 2. Review of the manufacturer's instructions found on the package labeling stated to store the blood collection tubes at, "4-25 degrees Celsius" or 39.2 to 77.0 degrees Fahrenheit. 3. Review of the laboratory's environmental logs from November 2020 to September 2021 found the laboratory monitored the room humidity at a range of 68 to 86 degrees Fahrenheit. The laboratory's upper limit temperature range was set too high for monitoring of the blood collection tubes. 4. An interview with the technical consultant on November 4, 2021 at 13:15 hours in the laboratory confirmed the findings.</p>
<p><b>D5805</b></p>	<p><b>TEST REPORT</b> CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on random review of patient reports from September 2021 and October 2021, and confirmed in interview of facility personnel, the laboratory failed to include the testing facility's address on 10 of 10 patient reports reviewed. The findings were: 1. A random review of patient reports from September and October 2021 found the laboratory failed to include the testing facility's address on 10 of 10 patient test reports. 2. The laboratory was asked to provide documentation of patient reports which included the laboratory's address. No documentation was provided. 3. An interview with the technical consultant and the testing person on November 4, 2021 at 14:30 hours in the break room confirmed the findings.</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>

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;

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 an HHS approved proficiency testing program (refer to D2098).

**D6066**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:  
Based on review of instrument verification records, review of the laboratory's personnel records, and confirmed in interview of facility personnel, 1 of 1 testing persons failed to have documentation of training when the laboratory implemented a new hematology analyzer. The findings included: 1. Review of instrument verification records found the laboratory installed a new Horiba hematology analyzer in January 2020. 2. Review of personnel records for testing personnel #1 (as listed on Form CMS-209) found no documentation of training for the newly installed Horiba hematology analyzer. 3. The laboratory was asked to provide documentation of the required training. No documentation was provided. 4. An interview with the technical consultant on November 4, 2021 at 14:30 hours in the break room confirmed the findings.