

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0659838	<b>(X3) Date Survey Completed</b>  04/12/2023
<b>Name of Provider or Supplier</b>  Throckmorton County Memorial Hospital	<b>Street Address, City, State</b>  802 North Minter Avenue Box 729, Throckmorton, 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>	Based on a proficiency testing desk review survey performed on April 12, 2023, the laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D2016 - 42 C.F.R. 493.803 Condition: Successful participation D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director, moderate complexity
<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 CONDITION is not met as evidenced by: Based on a proficiency testing desk review of Center for Medicare and Medicaid Services (CMS) form 0155 and American Proficiency Institute (API) records, it was</p>

	<p>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 Routine Chemistry for the analyte Bilirubin, Total. Refer to D2096.</p>
<p><b>D2096</b></p>	<p><b>ROUTINE CHEMISTRY</b> 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 a proficiency testing desk review of Center for Medicare and Medicaid Services (CMS) form 0155 and American Proficiency Institute (API) 2021 (2nd and 3rd Event), 2022 (2nd Event) and 2023 (1st Event) records, it was revealed that the laboratory failed to achieve satisfactory performance (80% or greater) in four out of six consecutive testing events in the specialty of Routine Chemistry for the analyte Bilirubin, Total, resulting in unsuccessful PT performance. Findings included: 1. Review of the CMS 0155 report revealed the following results for the analyte Bilirubin, Total: Routine Chemistry 2021 - 2nd Event the laboratory received an unsatisfactory score of 40% for Bilirubin, Total. Routine Chemistry 2021 - 3rd Event the laboratory received an unsatisfactory score of 40% for Bilirubin, Total. Routine Chemistry 2022 - 2nd Event the laboratory received an unsatisfactory score of 40% for Bilirubin, Total. Routine Chemistry 2023 - 1st Event the laboratory received an unsatisfactory score of 60% for Bilirubin, Total. 2. A review from American Proficiency Institute 2021, 2022 and 2023 proficiency testing records confirmed the above scores.</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 proficiency testing desk review of Center for Medicare and Medicaid Services (CMS) form 0155 and American Proficiency Institute (API) records, the Laboratory Director failed to fulfill their responsibilities. The Laboratory Director failed to ensure proficiency testing was tested as required under subpart H. 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</p>

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 proficiency testing desk review of Center for Medicare and Medicaid Services (CMS) form 0155 and American Proficiency Institute (API) records, the Laboratory Director failed to ensure proficiency testing was tested as required. The laboratory failed to achieve satisfactory performance (80% or greater) in four out of six consecutive testing events in the specialty of Routine Chemistry for the analyte Bilirubin, Total, resulting in unsuccessful performance. Refer to D2096.