

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 26D0672735	<b>(X3) Date Survey Completed</b> 04/12/2021
<b>Name of Provider or Supplier</b> Western Missouri Correctional Center	<b>Street Address, City, State</b> 609 E Pence Rd, Cameron, MO	
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>D5211</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of troponin proficiency testing (PT) records for 2020 and interview with the technical consultant the laboratory failed to evaluate ungraded results received in the second testing event. Findings: 1. Review of the second PT event for 2020 showed the laboratory received a "Not Graded" result for specimen CM-10. The PT provider included the comment "See Data Summary." 2. The laboratory did not have documentation to show it evaluated the ungraded result for specimen CM-10 and review the data summary report. 3. Interview with technical consultant on April 12, 2021 at 1:00 PM confirmed the laboratory failed to evaluate ungraded results received in the second testing event of 2020.</p>
<b>D6019</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iv)</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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.</p> <p>This STANDARD is not met as evidenced by: Based on review of troponin proficiency testing (PT) records for 2020, PT policy, lack</p>

of corrective action documentation and interview with the technical consultant, the laboratory director failed to ensure the corrective action plan was followed for any proficiency testing results found to be unacceptable. The laboratory received an unacceptable result for one of five samples in the first event of 2020. Findings: 1. Review of troponin PT records for 2020 showed, the laboratory received an unacceptable result on specimen CM-02 in the first testing event. 2. Review of the PT policy showed corrective action must be initiated and maintained for a failure. 3. The laboratory did not have documentation to show it initiated corrective action for the unacceptable result received for the first event of 2020. 4. Interview with the technical consultant on April, 12, 2021 at 1:00 PM confirmed the laboratory director failed to ensure corrective actions were taken for the unacceptable result in first event of 2020.

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:  
Based on review of the quality control (QC) program, QC and patient records for 2020 and interview with the technical consultant, the laboratory director failed to maintain the QC program for monthly testing of positive and negative external QC materials for troponin testing. The laboratory did not perform and document external positive and negative QC for eight of twelve months during 2020. Findings: 1. Review of the QC program showed the technical consultant or lab director must inspect the result to log to ensure external positive and negative controls were completed and documented monthly. 2. Review of QC records for 2020 showed the laboratory did not perform and document positive and negative QC materials for troponin testing during January, April, May, August, September, October, November and December. 3. Review of patient records for 2020 showed the laboratory tested 43 troponin tests during January, April, May, August, September, October, November and December 4. Interview with the technical consultant on April 12, 2021 at 1:00 PM confirmed the laboratory director failed to ensure positive and negative external QC materials were performed monthly.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's personnel policy, lack of competency /performance evaluations and interview with the technical consultant, the technical consultant failed to evaluate and document the competency for 18 of 18 testing personnel performing moderate complexity troponin testing during 2020. Findings: 1.

The laboratory's personnel policy stated, " All personnel trained to perform the troponin test must complete a competency test semiannually during the first year that the person tests samples and annually thereafter." 2. No documentation was available to show technical consultant evaluated and documented the competency for 18 testing personnel performing moderate complexity troponin testing during 2020. 3. Interview with technical consultant on April 12, 2021 at 1:00 PM confirmed the technical consultant failed to evaluate and document the competency of all testing personnel for 2020 and follow the personnel policy.