

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D0960031	<b>(X3) Date Survey Completed</b>  04/19/2021
<b>Name of Provider or Supplier</b>  Farmington Correctional Center	<b>Street Address, City, State</b>  1012 West Columbia, Farmington, 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>D6018</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iii)</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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by: Based on review of troponin proficiency testing (PT) records for 2020 and interview with technical consultant #3 the laboratory director failed to ensure appropriate staff evaluated 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. 3. Interview with technical consultant #3 on April 19, 2021 at 09:30 AM confirmed the laboratory director failed to ensure appropriate staff evaluated ungraded results received in the second testing event of 2020.</p>
<b>D6020</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</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)(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 test records for 2019 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. Findings: 1. Review of the QC program showed the laboratory must perform and document external positive and negative controls for troponin testing each month. 2. Review of troponin QC records for 2019 showed the laboratory performed external positive and negative controls on August 1, 2019 and not again until October 10, 2019. No external positive and negative controls were performed and documented during September 2019. 3. Review of patient troponin test records for 2019 showed the laboratory tested 13 patient specimens during September 2019. 4. Interview with technical consultant #3 on April 19, 2021 at 09:30 AM confirmed the laboratory director failed to ensure external positive and negative QC materials were performed each month.