

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D0871783	<b>(X3) Date Survey Completed</b>  04/23/2019
<b>Name of Provider or Supplier</b>  Boonville Correctional Center	<b>Street Address, City, State</b>  1216 East Morgan Street, Boonville, 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>D6022</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES 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 director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's individualized quality control plan (IQCP), quality control (QC) and patient records for 2018, and interview with technical consultant #2, the laboratory director failed to maintain the quality control / quality assessment programs and identify failures when they occur. Findings: 1. The IQCP policy, "Monthly review of results and control documentation" shows the technical consultant is responsible to ensure external positive and negative control materials are completed and documented monthly. The "Quarterly Quality Assessment (QA) Record Review", stated, "results will be reviewed by the CQI Committee. Identification of problems should be discussed and actions to correct the problem should be implemented." 2. Review of QC records for 2108 revealed the laboratory performed and documented an external positive and negative QC result on January 11, 2018 and not again until April 16, 2018. The laboratory performed and documented an external positive and negative QC results on July 25, 2018 and not again until October 29, 2018. The laboratory did not have documentation to show it performed a monthly positive and negative QC for February, March, August and September 2018. 3. Review of patient troponin records for 2018 revealed the laboratory tested and reported ten patient specimens from January 14, 2018 through April 15, 2018. Nine patient specimen were tested and reported from August 19, 2018 through October 13, 2018. 4. No documentation was available to show the laboratory detected the QC</p>

problems and implemented corrective action as required by the established QC/ QA program. 5. Interview with technical consultant #2 on April 23, 2019 at 11:00 AM confirmed the director failed to maintain the QC and QA programs to ensure monthly testing of external positive and negative QC materials.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of personnel performance (competency) evaluations, laboratory policy and interview with technical consultant #2, the technical consultant failed to evaluate and document the performance for five of seven selected testing personnel performing moderate complexity troponin testing for 2019. Findings: 1. Review of seven selected competency evaluations for 2019 revealed five testing personnel competency evaluations were conducted by an individual not listed as a technical consultant on personnel roster CMS form 209. 2. The laboratory policy states, "The competency test must be conducted by the technical consultant." 3. Interview with technical consultant #2 confirmed individuals serving as technical consultants failed to evaluate and document the performance of all testing personnel and follow written policy.