

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 26D0672735	<b>(X3) Date Survey Completed</b> 05/30/2018
<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>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 director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on review of the quality control (QC) program (plan), QC records and patient records for 2017 and interview with the laboratory director, the laboratory director failed to ensure the laboratory performed troponin QC at monthly intervals as stated in the program. The laboratory failed to perform external QC for thee of nine months during 2017. Findings: 1. The QC plan (QCP) states, " Two levels of external controls (positive and negative) will be used once a month or each day of testing depending on the volume of testing." 2. Review of QC records for 2017 revealed the laboratory performed a positive and negative troponin QC on January 30, 2017 and not again until May 17, 2017. No documentation was available to show the laboratory performed a positive and negative control in February, March and April of 2017. 3. Review of patient records for 2017 showed the laboratory tested five patient samples in February, thirteen patient samples in March and three patient samples in April. 4. Interview with the laboratory director on May 30, 2018 at 09:30 AM confirmed the laboratory director failed to ensure testing personnel perform QC as stated in the QC plan.</p>
<b>D6029</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(11)</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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on review of personnel records, training documentation for 2017 and to date 2018 and interview with testing personnel # 20, the laboratory director failed to ensure prior to testing patients' specimens, eleven of eleven new testing personnel have appropriate education and experience for performing moderate complexity troponin testing. Findings: 1. Review of personnel records revealed four of eleven new testing personnel did not have academic credentials required to perform moderate complexity troponin testing. 2. Review of training documentation revealed no date of initial training for eleven of eleven new testing personnel. No documentation was available to show the laboratory director / technical consultant evaluated training records for eleven new testing personnel for 2017 and to date 2018. 3. Interview with testing personnel # 20 at 09:00 AM confirmed, the director failed to ensure each testing personnel have appropriate education and experience prior to testing patients' specimens.

**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 the the lack of competency/performance evaluations for 2017 and to date May 30, 2018, review of laboratory policy/ technical consultant checklist and interview with the technical consultant, the technical consultant failed to evaluate and document the performance of nine of nine testing personnel performing moderate complexity troponin testing at least annually, after the first year. Findings: 1. The laboratory did not have competency/performance evaluations for nine testing personnel for 2017 and to date May 30, 2018 performing the troponin test after the first year. 2. The laboratory policy states, " All personnel trained to perform the troponin test must complete a competency test every 12 months-semiannually during the first year that the person tests samples and annually thereafter. This competency must be conducted by the technical consultant and should include the following: a) Direct observation of routine testing b) Monitoring, recording and reporting test results c) Reviewing worksheets, quality control records and proficiency testing d) Assessment of problem solving skills" 3. Review of the technical consultant checklist for 2017 and 2018 showed no signature/date by the technical consultant for annual review of testing personnel. 4. Interview with the technical consultant on May 30, 2018 at 09:30 AM confirmed, the technical consultant failed to conduct competency/performance evaluations for nine testing personnel after the first year and follow laboratory policy.

**D6063**

**LABORATORY TESTING PERSONNEL**

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on review of personnel records revealed and interview with the laboratory director, the laboratory failed to have academic credentials required to qualify four of twenty testing personnel performing moderate complexity troponin testing. (refer to tag #6065).

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on review of personnel records, personnel policy and interview with the laboratory director, the laboratory failed to have academic credentials required to qualify four of twenty testing personnel for moderate complexity testing. Findings: 1. Review of the personnel records revealed the laboratory did not have academic credentials required to qualify four testing personnel performing moderate complexity troponin testing. 2. The personnel policy states, "Each testing personnel will have a copy of their highest degree. The minimum requirement is a high school diploma." 3. Interview with the laboratory director on May 30, 2017 at 09:30 AM confirmed, the laboratory failed to have the required documentation to qualify the four testing personnel.