

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0871783	(X3) Date Survey Completed 07/12/2023
Name of Provider or Supplier Boonville Correctional Center	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of chemistry individualized quality control plan (IQCP), quality control (QC) logs for 2021, 2022 and to date July 12, 2023 and interview with testing personnel (TP) #7, the laboratory failed to follow the IQCP for troponin quality control (QC) for 4 of 31 months. Findings: 1. Review of troponin IQCP stated troponin QC must be performed monthly. 2. Review of troponin QC showed no troponin QC documented from January 2021 to July 2023 for the following dates: 2021 -August -October 2022 -February -July 3. Interview with TP #7 on July 12, 2023 at 2:00 PM confirmed the laboratory failed to follow IQCP and perform troponin QC monthly.</p>
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</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)(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 2021, 2022, and 2023 testing personnel (TP) training documents and interview with TP#7, the LD failed to ensure two of six TP received the appropriate training before performing moderate complexity patient testing. Findings: 1. Review of TP training records showed TP #4 and TP #10 had no documented training before patient testing was performed. 2. Interview with TP #7 on July 12, 2023 at 2:00 PM confirmed the LD failed to ensure two of six TP received the appropriate training before performing moderate complexity patient testing.

D6034

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:
Based on lack of education, training, review of performance evaluations in 2021, 2022 and 2023 and interview with testing personnel (TP) #7, the laboratory failed to employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties of service in which the laboratory performs moderate complexity tests or procedures. Findings: 1. Lack of documentation for education and training showed the laboratory failed to document education and training needed to qualify the technical consultant. 2. Review of performance evaluations showed the semiannual performance evaluation for TP # 8 was not performed by a qualified TC. 3. Review of 2021, 2022 and to date July 12, 2023 performance evaluations showed no qualified TC performed annual performance evaluation for the following: -2021: Testing personnel #2 -2022: Testing personnel #2, #3, and #5 -2023: Testing personnel #2, #3, #4, #5, #9, and #10. 4. Interview with the TP #7 at 2:00 PM on July 12, 2023 showed the laboratory failed to have a qualified technical consultant with proof of education and training or experience.

D6053

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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on review of the performance evaluations for 2021, 2022 and to date July 12, 2023 and interview with testing personnel (TP) #7, the technical consultant (TC)

failed to evaluate and document performance evaluations at least semiannually during the first year for two of three testing personnel. Findings: 1. Review of performance evaluations showed no semiannual performance evaluation was documented for testing personnel #4 and TP #10. 2. Interview with testing personnel #7 on July 12, 2023 at 2:00 PM confirmed the TC failed to evaluate and document performance evaluations at least semiannually during the first year for two of three testing personnel.

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 2021, 2022 and to date July 12, 2023 performance evaluations and interview with testing personnel (TP) #7, the technical consultant (TC) failed to evaluate and document annual performance evaluations for one of four TP in 2022. Findings: 1. Review of 2022 performance evaluations showed no annual performance evaluation for testing personnel #9 in 2022. 2. Interview with testing personnel #7 on July 12, 2023 at 2:00 PM confirmed the technical consultant failed to evaluate and document annual performance evaluations for one of four TP in 2022.