Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0672729	04/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
Jefferson City Correctional Center	8200 No More Victims Rd, Jefferson City, 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
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1) This STANDARD is not met as evidenced by: Based on of proficiency records for 2021, 2022 and to date April 11, 2023, review of patient reports and interview with the technical consultant (TC) #1, the laboratory failed to establish a means to verify the accuracy of the non-regulated analyte for troponin I testing twice a year. Findings: 1. Review of proficiency records for 2021, 2022 and to date April 11, 2023, showed the laboratory failed to prove accuracy on the non-regulated analyte troponon I exam since the 2nd event Chemistry - Core for 2022. 2. Review of patient results confirmed the laboratory reports out results for urine microscopic exams. 3. Interview with the TC #1 on April 11, 2023 at 1:00 PM confirmed the laboratory failed to establish a means to verify the accuracy of the non-regulated analyte troponin I testing twice a year.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on review of laboratory procedures, pharmacy refrigerator, pharmacy refrigerator/room temperature logs for 2021/2022/2023, and interview with the technical consultant (TC) #1, the laboratory failed to monitor and document refrigerator temperature for proper storage requirements of troponin quality control material. Findings: 1. Review of laboratory procedure "Troponin Testing: Quality Management" states "Temperatures of all refrigerators in which reagents are stored must have the temperature recorded daily." 2. Review of the pharmacy refrigerator showed 1 box of troponin quality control material lot # 22ASB0028F expiration date 05/31/2024. 3. Review of pharmacy refrigerator/room temperature logs for 2021 and 2022 showed no documented temperatures from January 2021 to October 2022. 4. Review of pharmacy refrigerator/room temperature logs for 2023 showed no documented temperature for February 5, 2023. 5. Interview with the TC #1 on April 11, 2023 at 1:00 PM confirmed the laboratory failed to monitor and document refrigerator temperature for storage of troponin quality control materials.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the 2021/2022/2023 proficiency testing (PT) records, lack of an approved corrective action plan for proficiency testing (PT) results, review of laboratory procedures, and review of quality control (QC) records for 2021/2022, the laboratory director (LD) failed to provide overall management and direction to the laboratory. The laboratory director (LD) failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action (Refer to D6018); the LD failed to establish a corrective action plan for PT results found to be unacceptable or unsatisfactory (Refer to D6019); the LD failed to ensure the established QC program was maintained to assure the quality of the laboratory services provided for 15 of 24 months (Refer to D6020).
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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; This STANDARD is not met as evidenced by: Based on review of the 2021/2022/2023 proficiency testing (PT) records and interview with the technical consultant (TC) #1, the laboratory director (LD) failed to

	ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: 1. Review of PT records showed the laboratory director failed to document review of the evaluation reports obtained for all PT testing events in 2021, 2022 and to date April 11, 2023. 2. Interview with the TC #1 on April 11, 2023 at 1:00 PM confirmed, the LD failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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. This STANDARD is not met as evidenced by: Based on the lack of an approved corrective action plan for proficiency testing (PT) results, review of PT records for 2021 and 2022 and interview with the technical consultant (TC), the laboratory director failed to establish a corrective action plan for PT results found to be unacceptable or unsatisfactory. Findings: 1. The laboratory did not have a corrective action plan for the following unacceptable PT results: 2nd and 3rd Chemistry Core Events 2022. 2. The laboratory did not have a corrective action plan for the Not Graded PT result from the 1st Chemistry Core Event 2021. 3. Interview with the TC on April 11, 2023 at 1:00 PM confirmed the laboratory director failed to ensure an approved corrective action plan was followed for PT results found to be unacceptable or unsatisfactory.
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 laboratory procedures, quality control (QC) records for 2021 /2022, and interview with the technical consultant (TC) #1, the laboratory director (LD) failed to ensure the established QC program was maintained to assure the quality of the laboratory services provided for 15 of 24 months. Findings: 1. Review of laboratory procedure, "Troponin Testing: Quality Management" states, "Quality control must be performed for Troponin once a month according to the manufacturer, and the results recorded in a log book or recorded in a computer system." and "Quality control will be reviewed monthly by Lab Director or designee." 2 . Review of the QC records for 2021/2022 showed the laboratory failed to perform and document quality

	control for troponin testing from October 2021 to December 2022. The laboratory could not provide the number of patient troponin results that were reported during the time QC was not performed. 3. Review of the QC records for 2021/2022 showed no laboratory director or designee review from January 2021 to December 2022. 4. Interview with technical consultant #1 on April 11, 2023 at 1:00 PM confirmed the laboratory director (LD) failed to ensure the established QC program was maintained to assure the quality of the laboratory services provided.
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 2021/2022 performance evaluations and interview with technical consultant (TC) #1, the technical consultant failed to evaluate and document performance evaluations at least semiannually during the first year for two of two testing personnel (TP) in 2022. Findings: 1. Review of performance evaluations showed no semiannual performance evaluation was documented for TP #8 and #16 in 2022. 2. Interview with TC #1 on April 11, 2023 at 1:00 PM confirmed the technical consultant did not evaluate and document the semiannual performance evaluation for two TP.
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 performance evaluations and interview with technical consultant (TC) #1, the technical consultant failed to evaluate and document annual performance evaluations for ten of ten testing personnel(TP) in 2021 and eight of eleven testing personnel in 2022. Findings: 1. Review of 2021 performance evaluations showed no annual performance evaluation for TP #2, #3, #4, #5, #6, #7, #11, #12, #13, and #15 in 2021. 2. Review of 2022 performance evaluations showed no annual performance evaluation for TP #3, #5, #6, #7, #11, #13, #15, and #16 in 2022. 2. Interview with technical consultant #1 on April 11, 2023 at 1:00 PM confirmed the technical consultant failed to evaluate and document annual performance evaluation for TP.
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, and interview with the technical consultant (TC) #1, the laboratory failed to provide academic qualifications required to perform moderate complexity testing for one of sixteen testing personnel. (Refer to D6065)
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 academic credentials and interview with the technical consultant (TC) #1, the laboratory failed to provide academic credentials to qualify one of sixteen testing personnel (TP). Findings: 1. The laboratory could not provide academic credentials to show TP #9 was qualified to perform moderate complexity testing. 2. Interview with the technical consultant (TC) #1 on April 11, 2023 at 2:00 PM confirmed the laboratory failed to provide academic credentials for TP #9.