Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0992315	08/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Southeast Correctional Center	300 E Pedro Simmons Drive, Charleston, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the written personnel policy, lack of documentation and interview with testing personnel #2, the laboratory failed to follow the policy for conducting personnel competency evaluations for 20 of 20 testing personnel for 2017 and to date August 7, 2018. Findings: 1. The written personnel policy states, " All personnel trained to perform the troponin test must complete a competency test every twelve months - semiannually during the first year that the person tests samples and annually thereafter. The competency must be conducted by the technical consultant." 2. The laboratory did not have documentation to show that a qualified technical consultant conducted competency evaluations for 20 testing personnel during 2017 and to date August 7, 2018. 3. Interview with testing personnel # 2 on August 7, 2018 at 10:30 AM confirmed the laboratory failed to follow written policies for evaluating the competency of testing personnel performing moderate complexity troponin testing.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with testing personnel # 2 on

	August 7, 2018 at 10:30 AM confirmed, the current laboratory director failed to approve, sign and date the troponin test procedure and the laboratory's individualized quality control plan (IQCP).
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of criteria for proper storage of refrigerated quality control (QC) material, daily temperature documentation, laboratory policy and interview with testing personnel #2, the laboratory failed to document corrective action for temperatures that failed the laboratory's criteria for storage. The laboratory did not document corrective action for refrigator temperatures that failed to meet proper storage criteria for 28 of 41 days from June 18, 2018 through July 31, 2018. Findings: 1. Review of the refrigerator temperature criteria for storage of QC materials showed the acceptable temperature range is 36 to 46 degrees Fahrenheit (F). 2. Review of the temperature checklist log showed personnel documented temperatures below the minimum temperature of 36 degrees F for 28 days from June 18, 2018 through July 31, 2018. The laboratory did not have documentation to show corrective actions were taken for temperatures that were too cold. 3. The laboratory policy states, "Daily refrigerator temperatures must be maintained, reviewed and kept of file for the director and CLIA review. Corrective action must be taken and documented for any deviation from the established temperature range." 4. Interview with testing personnel #2 on August 7, 2018 at 10:30 AM confirmed the laboratory failed to document corrective actions taken for refrigerator temperatures that did not meet the criteria for proper storage.
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 quality control (QCP) program, quality assessment (QA) program and personnel records the director failed to provide overall management of the laboratory. The director failed to maintain the QC program (refer to # D6020); failed to maintain the QA program (refer to #D6021); and failed to ensure testing personnel receive appropriate training prior to testing patient specimens for moderate complexity troponin testing (refer to #D6029).
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 the laboratory's quality control plan (QCP), quality control (QC) and patient records for 2018 and interview with the laboratory director, the director failed to maintain the QCP to ensure testing personnel perform two levels of external QC material at the frequency established by the the laboratory. The laboratory failed to perform monthly QC for two of seven months from January 1, 2018 through July 31, 2018. Findings: 1. The QCP states," Two levels of external controls will be used once a month or each testing day depending on the volume of testing." The QCP requires the technical consultant to inspect the troponin result log to ensure external QC is performed monthly or with each testing event as appropriate. 2. Review of QC documentation for 2018 showed the laboratory did not perform and document two levels of external controls for April 2018 and May 2018. 3. Review of patient records showed the laboratory tested and resulted 5 patient specimens during April 2018. 4. Interview with the laboratory director on August 7, 2018 at 11:00 AM confirmed, the director failed to ensure the QCP was maintained and followed for testing two levels of QC material at the frequency established by the laboratory.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment (QA) program, lack of QA activities for 2017 and to date August 7, 2018 and interview with testing personnel #2, the laboratory director failed to ensure the written QA plan was maintained and followed. Findings: 1. The QA program states, " On a monthly basis the testing system should be reviewed by the technical consultant and/or director. Determine that the controls were appropriately documented and run at the appropriate intervals and with each lot. If failures are found corrective action should be taken and reviewed to see if the corrective action solved the problem. When the laboratory discovers a testing process failure, it must determine the impact on patient care, document corrective actions, and evaluate the effectiveness of the corrective actions performed to be sure the failures does not happen again." 2. The laboratory did not have documentation to show the technical and/or laboratory director reviewed testing system QA activities on a monthly basis to identify problems when they occur. (Refer to # D6020) 3. Interview with the laboratory director on August 7, 2018 at 11:00 AM confirmed no review of QA activities by the technical consultant and/or director as required by the written QA program.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(11) 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 and interview with testing personnel #2, the director failed to ensure eight of eight testing personnel newly hired in 2017 and 2018 had received appropriate training and demonstrated competency for moderate complexity troponin testing prior to testing patient specimens. Findings: 1. Review of personnel records revealed no documentation to show eight testing personnel receive appropriate initial training prior to testing patient specimens. 2. Interview with testing personnel # 2 on August 7, 2018 at 10:30 AM confirmed the director failed to ensure all personnel received appropriate initial training for performing moderate complexity troponin testing.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on the lack of credentials and interview with the laboratory director, the laboratory failed to have documentation to qualify the individual serving as technical consultant.(refer to #D6035) and the technical consultant failed to evaluate and document the competency for 20 of 20 testing personnel performing moderate complexity troponin testing for 2017 and to date August 7, 2018 (refer to # D6046)
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for

	example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on review of personnel records revealed and interview with the laboratory director confirmed, the laboratory failed to have documentation to show the technical consultant obtained at least one year of laboratory training or experience, or both, in the specialty of chemistry. Findings: 1. The laboratory failed to have documentation to show the laboratory director obtained the required laboratory training and/or experience for the position of technical consultant for the speciality of chemistry 2. Interview with the laboratory director on August 7, 2018 at 11:30 AM confirmed, the laboratory failed to have the required documentation to qualify the individual serving as technical consultant responsible for troponin (chemistry) testing.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of competency evaluations and interview with the laboratory director on August 7, 2018 at 11:00 AM confirmed, the technical consultant failed to evaluate and document the competency for 20 of 20 testing personnel performing moderate complexity troponin testing for 2017 and to date August 7, 2018.