Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0981246	03/27/2019
Name of Provider or Supplier	**Street Address, City, State**	
Northeast Correctional Center	13698 Pike 46 Airport Road, Bowling Green, 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
D0000	493.51 Notification requirements for laboratories issued a certificate of compliance Laboratories issued a certificate of compliance must meet the following condition: (a) Notify HHS or its designee within 30 days of any change in-- (1) Ownership (2) Name (3) Location (4) Director (5) Technical Supervisor Based on review of CMS 209 personnel roster and interview with testing personnel #3 and #12, the laboratory failed to notify the CLIA State Agency (SA) of a change in the position of laboratory director. Findings: 1. Review of the CMS 209 personnel roster showed a change in the position of laboratory director. 2. Interview with testing personnel #3 and #12 on March 18, 2019 at 11:00 AM confirmed the laboratory director filled the position on November 1, 2018. The laboratory failed to notify the SA of the change in laboratory director.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory policies, procedures, quality control records, patient records for 2017 and 2018, and interviews with testing personnel #3 and #12, the laboratory failed to follow the procedure for quality control on Troponin I kits (Refer to D5401); failed to have an approved procedure manual (Refer to D5407); failed to monitor and document the room temperature where the Troponin I kits were stored (Refer to D5413); failed to follow, monitor, document, and access the quality control plan for Troponin I kit testing (Refer to D5791).

D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the procedure manual, quality control (QC) logs, the Individualized Quality Control Plan (IQCP), patient records and interview with the testing personnel #3 and #12, the laboratory failed to follow the procedure for performing external QC monthly for 12 of 21 months, and with each new lot of Troponin I kits prior to patient use. Findings: 1. Review of the procedure manual revealed instruction to perform "QC with each new lot number of Cardiac Status Troponin I kits before using on patient samples." 2. Review of the IQCP revealed the instruction "Two levels of external control will be used once a month or each testing day depending on the volume of testing." 3. Review of the QC logs for April 2017 through March 2019 revealed the laboratory failed to perform QC on a monthly basis for the months of April and December 2017, February through September, November, and December 2018 for Cardiac Status Troponin I test. Review of patient test results showed the laboratory failed to run monthly QC for 24 patients for the months of April and December 2017 and 93 patients for February 2018-December 2018. 4. Review of the QC logs showed the laboratory did not perform QC on the following lot numbers for Troponin testing, 17CTK0033H and 18CTK0026D. Review of patient test results showed 6 patient test reports were reported on lot 17CTK0033H and 33 patient test reports were reported on lot 18CTK0026D. 5. Review of the QC log showed the laboratory failed to perform QC on lot 18CTK0022H prior to testing patient samples. 12 patient test reports were reported on lot 18CTK0022H before QC was performed. 6. Interview with the testing personnel #3 and #12 on March 18, 2019 at 11:00 AM confirmed the laboratory failed to follow the procedure for QC on Troponin I kits. This is a repeat deficiency, previously cited on November 15, 2016.
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 the testing personnel #3 and #12, the laboratory director failed to approve the procedures. Findings: 1. Review of the procedure manual revealed the laboratory director failed to approve the procedures for Troponin I testing. 2. Interview with the testing personnel #3 and #12 on March 18, 2019 at 11:00 AM confirmed the director had failed to document any review of the procedure manual.
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 the manufacturer's inserts, Individualized Quality Control Plan (IQCP), and interview with the testing personnel #3 and #12, the laboratory failed to monitor and document the temperature of the room used to store troponin kits. Findings: 1. Review of the Cardiac Status Troponin I manufacturer's product inserts revealed the product must be stored between 4-30 degrees centigrade. 2. Cardiac Status Troponin reagents were stored in the triage room. 3. Review of the triage room temperature documentation showed the laboratory failed to document room temperature for 2017 and to date March 18, 2019. 4. Review of the Individualized Quality Control Plan(IQCP) revealed "temperatures of spaces involved with storage of the troponin kits should be monitored on a daily basis." 5. Interview with testing personnel #3 and #12 on March 18, 2019 at 11:00 AM confirmed the laboratory failed to document the room temperature in the laboratory where the Cardiac Status Troponin I kits were stored. This is a repeat deficiency, previously cited on November 15, 2016.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control plan (QCP), 2017 and 2018 quality control (QC) logs, and patient records for 2017 and 2018, and interview with the testing personnel #3 and #12, the laboratory 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 12 of 21 months. 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. Lot numbers and expiration dates of both the controls and test kits used must be documented as well as who performed the control testing and date performed." "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 failure does not happen again." "Every month the technical consultant at each facility must inspect the troponin result log to ensure external QC is performed monthly or with each testing event as appropriate." 2. Review of the procedure manual states to perform "QC with each new lot of Cardiac Status Troponin I kits before using on patient samples." 3. Review of the QC logs for April 2017 through March 2019 revealed the laboratory failed to perform 2 levels of QC on a monthly basis for the months of April and December 2017, February through September, November, and December 2018 for Cardiac Status

	Troponin I test. Review of patient test results showed the laboratory failed to run monthly QC for 24 patients for the months of April and December 2017 and 93 patients for February 2018-December 2018. 4. Review of the QC logs showed the laboratory did not perform QC on the following lot numbers for Troponin testing, 17CTK0033H and 18CTK0026D. Review of patient test results showed 6 patient test reports were reported on lot 17CTK0033H and 33 patient test reports were reported on lot 18CTK0026D. 5. Review of the QC log showed the laboratory failed to perform QC on lot 18CTK0022H prior to testing patient samples. 12 patient test reports were reported on lot 18CTK0022H before QC was performed. 6. Interview with testing personnel #3 and #12 on March 18, 2019 at 12:00 PM confirmed, the laboratory failed to follow, monitor, access, and document QC for troponin testing.
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 personnel records and interview with the testing personnel #3 and #12, the laboratory failed to have documentation of laboratory training or experience, or both, required to qualify the individual serving as laboratory director (Refer to D6003); and failed to ensure all personnel received appropriate initial training for performing moderate complexity troponin testing (Refer to D6029).
D6003	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1405 AND 493.1406 The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director 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 had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or (b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or (b)(2)(ii)(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and (b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the

American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing; (b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; (b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under 493.1406; or (b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located. Laboratory director qualifications on or before February 28, 1992 The laboratory director must be qualified to manage and direct the laboratory personnel and test performance. (a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (b)(1) Be a physician certified in anatomical 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; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification; (b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (b)(4)(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or (b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either: (b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (b)(6) Qualify under State law to direct the laboratory in the State in

	which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the testing personnel #3 and #12, the laboratory failed to have documentation to show the laboratory director obtained at least one year of laboratory training or experience, or both, in moderate complexity testing. 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 laboratory director. 2. Interview with the testing personnel #3 and #12 on March 18, 2019 at 11:00 AM confirmed, the laboratory failed to have the required documentation to qualify the individual serving as laboratory director.
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 #3 and #12, the director failed to ensure eight of eight testing personnel hired in 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 #3 and #12 on March 18, 2019 at 11:30 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 review of personnel records revealed and interview with the testing personnel #3 and #12 confirmed, the laboratory failed to have documentation of laboratory training or experience, or both, required to qualify the individual serving as technical consultant (Refer to D6035); and failed to perform competencies for 2017, 2018 (Refer to D046).
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 and interview with the testing personnel #3 and #12, the laboratory failed to have documentation to show the technical consultant obtained at least two years of laboratory training or experience, or both, in moderate complexity testing. Findings: 1. The laboratory failed to have documentation to show the technical consultant obtained the required laboratory training and/or experience for the specialty of chemistry. 2. Interview with the testing personnel #3 and #12 on March 18, 2019 at 11:00 AM confirmed, the laboratory failed to have the required documentation to qualify the individual serving as technical consultant.
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 personnel documentation and interview with the technical consultant, the technical consultant failed to perform 24 of 24 competency assessment evaluations for 2017 and 2018. Findings: 1. Review of 2017 and 2018 employee competencies revealed the technical consultant failed to perform 24 of 24 competency assessments for testing personnel of moderate complexity testing. 2. Interview with the testing personnel #3 and #12 on March 18, 2019 at 12:00 PM confirmed the technical consultant failed to perform annual competencies for 2017 and 2018 for 24 of 24 testing personnel.
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 testing personnel #3 and #12, the laboratory did not have academic credentials required to qualify four of 24 testing personnel for the specialty of chemistry for moderate complexity 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 and interview with the testing personnel #3 and #12, the laboratory failed to have documentation of academic credentials to qualify four of 24 testing personnel for moderate complexity testing. Findings: 1. Review of the personnel records for four of 24 testing personnel for the specialty of chemistry revealed the laboratory failed to have academic credentials to qualify these

	individuals. 2. Interview with the testing personnel #3 and #12 on March 18, 2019 at 11:00AM confirmed, the laboratory failed to have the required documentation to qualify the four individuals serving as testing personnel of moderate complexity.