Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0871614	05/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Chillicothe Correctional Center	3151 Litton Road, Chillicothe, 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
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the personnel competency policy, personnel records for 2019 and interview with testing personnel # 7 (Director of Nursing) (DON) the laboratory failed to meet the condition of general laboratory systems. (Refer to D5209) This is a repeat deficiency cited during previous survey conducted March 28,2017.
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 laboratory's personnel policy, annual competency/performance evaluations conducted during 2019 for nineteen of nineteen testing personnel and interview with testing personnel # 7 (DON), the laboratory failed to follow the personnel competency policy. Findings: 1. The laboratory policy states," the competency tests (evaluation) must be conducted by the technical consultant." 2.

	Review of personnel competency evaluations revealed the technical consultant listed on CMS form 209 did not conduct the annual competency evaluations for nineteen testing personnel from January 2019 through May 6, 2019. Documentation showed the DON conducted all competency evaluations during this timeframe. 3. Interview on May 6, 2019 at 11:30 AM, the DON said the technical consultant did not conduct the competency evaluations. Interview confirmed the laboratory failed to follow the personnel competency policy.
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 the individual quality control plan (IQCP) lack of director approval and interview with testing personnel # 7 (DON), the laboratory failed to meet the condition of analytic systems. (Refer to D5407) This is a repeat deficiency cited during previous survey conducted March 28, 2017.
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 individualized quality control plan (IQCP) procedures and interview with testing personnel # 7 (DON), the current laboratory director failed to approve, sign and date the IQCP. Findings: 1. The laboratory did not have documentation to show the current director approved, signed and and dated the IQCP procedures. 2. Interview with the DON on May 6, 2019 at 11:30 AM confirmed the current director failed to review and approve the IQCP before use.
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 laboratory individual quality control plan (IQCP), quality control (QC) records for 2018, and the troponin procedure manual and interview with testing

	personnel #7 (DON) the laboratory director failed to maintain the QC program (refer to D6020) and failed to approve the troponin procedure manual. (Refer to D6031) Deficiency D6020 cited during previous survey conducted March 28, 2017.
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 individualized quality control plan (IQCP), quality control (QC) logs/patient records for 2018 and interview with testing personnel # 7 (DON) the laboratory director failed to maintain the quality of troponin testing and follow written procedure. Findings: 1. The written IQCP states," two levels of external controls will be used once a month or each testing day depending on the volume of testing." 2. Review of QC records for 2018 revealed the laboratory performed two levels of external controls on June 2, 2018 and not again until August 6, 2018. No documentation was available to show the laboratory performed two levels of QC during July 2018. No documentatation was available to show the laboratory performed two levels of QC for two patients specimens reported on June 23, 2018. 3. Interview on May 6, 2019 at 11:30 AM, the DON agreed the laboratory did not perform two levels of QC during July 2018 or perform two levels of QC on patient specimens tested June 23, 2018. The interview confirmed the laboratory director failed to maintain the QC program to ensure testing personnel perform external QC at frequency specified in the IQCP.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of the troponin procedure manual and interview with testing personnel # 7 (DON), the laboratory director failed to ensure an approved procedure manual was available to all testing personnel. Findings: 1. Review of the troponin procedure manual revealed no documentation the director approved the step by step troponin procedure manual. 2. Interview with the DON on May 6, 2019 confirmed the laboratory director failed to ensure testing personnel had access to an approved procedure manual for all aspects of the troponin testing procedure.
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 competency evaluations for 2019, personnel policy and interview with testing personnel #7 (DON), the technical consultant failed to evaluate the competency/performance for testing personnel performing moderate complexity troponin testing. (Refer to D6046) This is a repeat deficiency cited during previous survey conducted March 28, 2017.
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 annual personnel competency / performance evaluations conducted during 2019, laboratory policy and interview with testing personnel # 7 (DON), the technical consultant failed to evaluate and document the competency for nineteen of nineteen testing personnel performing moderate complexity troponin testing. 1. Review of annual personnel competency evaluations from January 2019 through May 6, 2019 revealed no documentation to show the technical consultant evaluated and documented the competency for nineteen testing personnel performing patient troponin testing. 2. The personnel policy states, "All personnel trained to perform the troponin test must complete a competency test (evaluation) every twelve months-semiannually during the first year. This competency must be conducted by the technical consultant." 3. Interview on May 6, 2019 at 11:30 AM, the DON said the individual serving as technical consultant did not conduct any competency evaluations. The interview confirmed the technical consultant failed to evaluate the competency of testing personnel performing troponin testing per written policy.