Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0871614	07/19/2023
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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of proficiency testing records for 2021, 2022, and to date July 19, 2023 and interview with the the director of operations (DO), the laboratory failed to maintain a copy of records for proficiency testing (PT), including the signed attestation statement and a copy of the PT program report forms used by the laboratory to record PT results (raw data), and results from PT agency for a minimum of two years. Findings: 1. Review of 2021/2022 PT records showed the laboratory failed to provide a signed attestation form for following four of six PT testing events: -2021 Chemistry Core: first event, second event, and third event -2022 Chemistry Core: first event 2. Review of 2021/2022 PT records showed the laboratory failed to provide a copy of the PT program report forms used by the laboratory to record PT results (raw data) for the following five of six PT testing events: -2021 Chemistry Core: first event, second event, and third event -2022 Chemistry Core: first event and third event 3. Review of 2021/2022 PT records showed the laboratory failed to provide results from the PT agency for the following three of six PT testing events: -2021 Chemistry Core: first event, second event, and third event 4. Review of PT

	records for 2023 show no attestation, raw data, or results to date July 19, 2023 3. Interview with DO on July 19, 2023 at 2:00 PM confirmed the laboratory failed to maintain a copy of all records for proficiency testing, including the attestation statement and a copy of the PT program report forms used by the laboratory to record PT results (raw data), and results from PT agency for a minimum of two years.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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. 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 19, 2023, patient result logs for 2021, 2022, and to date July 19, 2023 and interview with Director of Operations (DO), the laboratory failed to follow the IQCP for troponin QC for four of thirty months for negative QC and twenty-four of thirty for positive QC. 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: Negative QC 2021 -March -April -May 2022 -February Positive QC 2021 -No quality control available 2022 -No quality control available 3. Review of patient logs showed number of patient testing for the following: -2021: 118 patient results -2022: 84 patient results -to date July 19, 2023: 65 patient results 4. Interview with DO on July 19, 2023 at 2:00 PM confirmed the laboratory failed to follow IQCP and perform troponin QC monthly.