

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0981246	(X3) Date Survey Completed 05/11/2023
Name of Provider or Supplier Northeast Correctional Center	Street Address, City, State 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records for 2021, 2022, and 2023 to date May 11, 2023 and interview with the Director of Nursing (DON), the laboratory showed two of twenty-one full-time testing personnel (TP) participated in the PT process who routinely perform patient testing. Findings: 1. Review of PT records for 2021, 2022, and 2023 to date May 11, 2023 show TP # 1 and TP #2 participated in Chemistry Core PT for 2021, 2022 and 2023. 2. Interview with DON on May 11, 2023 at 10:30 AM, confirmed the laboratory failed to include all personnel who routinely perform patient testing in the PT process.</p>
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(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.</p>

This STANDARD is not met as evidenced by:
 Based on review of proficiency testing records for 2021, 2022, and 2023 to date May 11, 2023 and interview with the Director of Nursing (DON), 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 for a minimum of two years. Findings: 1. Review of PT records showed the laboratory failed to provide a signed attestation form for the following PT testing events: 2021 Chemistry Core - first event 2021 Chemistry Core - second event 2021 Chemistry Core - third event 2022 Chemistry Core - first event 2022 Chemistry Core - second event 2. Review of PT records showed the laboratory failed to provide a copy of the PT program report forms used by the laboratory to record PT results for the following PT testing events: 2021 Chemistry Core - first event 2021 Chemistry Core - second event 2021 Chemistry Core - third event 2022 Chemistry Core - first event 2022 Chemistry Core - second event 2022 Chemistry Core - third event 2023 Chemistry Core - first event 3. Interview with DON on May 11, 2023 at 10:30 AM 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 for a minimum of two years.

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, and 2023 to date May 11, 2023 proficiency testing (PT) records and interview with the Director of Nursing (DON), 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 2023 to date May 11, 2023 for the following PT events: 2021 Chemistry Core - first event 2021 Chemistry Core - second event 2021 Chemistry Core - third event 2022 Chemistry Core - first event 2022 Chemistry Core - second event 2022 Chemistry Core - third event 2023 Chemistry Core - first event 2. Interview with the DON on May 11, 2023 at 10:30 AM 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.