

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0047626	(X3) Date Survey Completed 04/03/2024
Name of Provider or Supplier Johnson County Hospital	Street Address, City, State 202 High Street, Tecumseh, NE	
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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's MedTox individualized quality control plan (IQCP), review of MedTox manufacturer's instructions, review of MedTox quality control results, and interview with the technical consultant the laboratory established and performed quality control procedures that are less stringent than those specified by the manufacturer from 1/24/2024 - 4/3/2024. 1. Review of the laboratory's MedTox IQCP state "one external positive and one external negative control will be performed per lot or shipment. 2. MedTox manufacturer's instructions state "run external controls routinely or as needed for any of the following reasons: (1) to practice the test with a known control, (2) when you open a new lot of test devices, (3) once a week..." 3. Review of MedTox quality control results from 1/24/2024 - 4/3/2024 revealed the laboratory performed quality control on 2/12/2024. 4. Interview with the technical consultant on 4/3/2024, at 1:52PM, confirmed the laboratory established and performed quality control procedures that are less stringent than those specified by the manufacturer.</p>
D6128	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p>

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on lack of documentation and interview with the technical consultant, the laboratory failed to document blood bank competency assessment (CA) in 2022 and 2023, for four out of four testing personnel (TP) performing high complexity blood bank testing. 1. Review of CMS 209 form revealed four testing personnel performing high complexity testing. 2. Interview on 4/3/2024, at 11:15 AM, with technical consultant confirmed the four testing personnel perform high complexity blood bank testing. 3. No documentation of blood bank CA was found on the four TP performing high complexity blood bank testing. 4. Interview with the technical consultant on 4/3/2024, at 11:15 AM, confirmed blood bank CA was not documented in 2022 and 2023.