

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0047626	(X3) Date Survey Completed 04/02/2026
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
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 lack of performance specification records, review of chemistry calibration verification records, and review of chemistry quality control (QC) records the laboratory failed to verify performance specifications prior to patient testing as specified in D5421, failed to perform calibration verification as specified in D5439, and failed to perform QC each day of patient testing as specified in D5445.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by:

	Based on lack of documentation and interview with technical consultants, TC #1 and TC #3, as listed on the CMS 209, the laboratory failed to verify accuracy, precision, and reportable range for SureVue kit on analyte Human Chorionic Gonadotropin (HCG), serum and for iSTAT blood gas analyzer on analytes lactate, partial pressure of carbon dioxide (pCO₂), pH, and partial pressure of oxygen (pO₂) prior to reporting patient test results. The findings include: 1. The surveyor requested the performance specification verification documents for SureVue Kit and iSTAT blood gas analyzer. 2. Interview with TC #1 and TC #3 on 4/2/2026 at 12:00 p.m. confirmed the laboratory did not have documentation of accuracy, precision, and reportable range for SureVue kit on analyte Human Chorionic Gonadotropin (HCG), serum. 3. The laboratory reported 22 serum, HCGs from 1/31/2025 through 4/2/2026. 4. Interview with TC #1 and TC #3 on 4/2/2026 at 12:36 p.m. confirmed the laboratory did not have documentation of accuracy, precision, and reportable range for iSTAT blood gas analyzer on analytes lactate, pCO₂, pH, and pO₂. 5. The laboratory reported 32 lactates, 32 pCO₂s, 32 pHs, and 32 pO₂ from 7/1/2025 through 4/2/2026.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of calibration records, lack of calibration verification records, and interview with the technical consultants, TC #1 and TC #3, as listed on the CMS 209, the laboratory failed to perform calibration verification every 6 months on their chemistry instrument, Vitros 5600, on analytes procalcitonin and vitamin D in 2025. 1. Laboratory records of calibration records revealed the laboratory uses two calibrators for procalcitonin and vitamin D calibrations. 2. Review of laboratory records revealed the laboratory did not perform calibration verification on analytes procalcitonin and vitamin D in 2025. 3. Interview with the technical consultant on 4/2/2023 at 3:30 p.m. confirmed the laboratory failed to perform calibration verification on analytes procalcitonin and vitamin D every six months in 2025.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

This STANDARD is not met as evidenced by:

I. Based on surveyor review of Human Chorionic Gonadotropin (HCG), serum quality control (QC) records, lack of Individualized Quality Control Plan (IQCP), and interview with technical consultants TC #1 and TC #3, as listed on the CMS 209 form, the laboratory failed to perform quality control (QC) each day of patient testing Human Chorionic Gonadotropin (HCG), serum from 1/31/2025 through 4/2/2026. The findings include: 1. Review of HCG, serum QC records from 1/31/2025 through 4/2/2026, revealed QC performed with each new lot, each new shipment, and monthly. 2. Interview with TC #1 and TC #3 on 4/2/2026 at 12:00 p.m. confirmed the laboratory did not have an IQCP in place for HCG, serum. 3. Interview with TC #1 and TC #3 on 4/2/2026 at 12:00 p.m. confirmed the laboratory did not perform QC each day of patient testing HCG, serum from 1/31/2025 through 4/2/2026. 4. The laboratory reported 22 serum, HCGs from 1/31/2025 through 4/2/2026. II. Based on surveyor review of iSTAT quality control (QC) records, lack of Individualized Quality Control Plan (IQCP), and interview with the technical consultants TC #1 and TC #3, as listed on the CMS 209 form, the laboratory failed to perform quality control (QC) each day of patient testing on the iSTAT analyzer on analytes lactate, partial pressure of carbon dioxide (pCO₂), pH, and partial pressure of oxygen (pO₂) from 7/18/2025 through 4/2/2026. The findings include: 1. Review of iSTAT QC records from 7/18/2025 through 4/2/2026, revealed QC performed monthly. 2. Interview with TC #1 and TC #3 on 4/2/2026 at 1:54 p.m. confirmed the laboratory did not have an IQCP in place for iSTAT analyzer on analytes lactate, pCO₂, pH, and pO₂. 3. Interview with TC #1 and TC #3 on 4/2/2026 at 1:54 p.m. confirmed the laboratory did not perform QC each day of patient testing iSTAT analyzer on analytes lactate, pCO₂, pH, and pO₂ from 7/18/2025 - 4/2/2026. 3. The laboratory reported 32 lactates, 32 pCO₂s, 32 pHs, and 32 pO₂ using the iSTAT analyzer from 7/18/2025 through 4/2/2026.

D6055

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

(b)(9) 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 surveyor review of training documentation and interview with technical consultants TC #1 and TC #3, as listed on the CMS 209 form, the laboratory failed to evaluate performance of iSTAT analyzer prior to reporting patient test results on four out of four testing personnel. The findings include: 1. Review of training documentation revealed no documentation of training performed on the iSTAT. 2. Interview with technical consultants TC #1 and TC #3, on 4/2/2026 at 2:01 p.m.

confirmed the laboratory had no training documentation of iSTAT on four out four testing personnel prior to reporting patient test results. 3. The laboratory reported 32 patients using the iSTAT analyzer from 7/18/2025 through 4/2/2026.