Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0667024	09/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
Johnson County Dept Of Health & Environment	11875 S Sunset Drive-Suite 300, Olathe, KS	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on the review of the laboratory's non-waived test list, lack of approved procedure for the Abbott Determine HIV-1/2 Ag/Ab Combo test system, patient test reports for 2022 and to date of survey 2023, and interview with Technical Consultant (TC) #1, the laboratory failed to have a written procedure available to and followed by laboratory personnel for the operation of the Abbott Determine HIV-1/2 Ag/Ab Combo test system used for the detection of human immunodeficiency virus (HIV) p24 antigen (Ag) and antibody (Ab) for HIV Type 1 and Type 2 before reporting patient results. Findings: 1. Review of the non-waived test list included a "Rapid HIV" from Abbott. a. The panel included detection of HIV-1 p24 Ag, and Ab for HIV Type 1 and Type 2. 2. Request was made for the procedure for the Abbott Determine HIV-1/2 Ag/Ab Combo test system. No approved procedure was made available at the time of survey. 3. Review of patient results reported from 5/16/22 to 9/6/23 revealed 6 patient reports were released. 4. Interview with TC #1 on 9/6/23 at 12:25 p. m. confirmed, the laboratory failed to have a written procedure available to and followed by laboratory personnel for the operation of the Abbott Determine HIV-1/2 Ag/Ab Combo test system used for the detection of human immunodeficiency virus (HIV) p24 antigen (Ag) and antibody (Ab) for HIV Type 1 and Type 2 before reporting patient results.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)

	Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 the review of "Internal Quality Control and Patient Record" documentation for the Abbott Determine HIV-1/2 Ag/Ab Combo test system, lack of documentation of verification performance specification, and interview with TC #1, the laboratory failed to verify the performance specifications on the Abbott Determine HIV-1/2 Ag /Ab Combo test system used for the detection of human immunodeficiency virus (HIV) p24 antigen (Ag) and antibody (Ab) for HIV Type 1 and Type 2 before reporting patient results. Findings: 1. Review of the QC documentation for Abbott Determine HIV-1/2 Ag/Ab Combo test system revealed an additional document named "Alere Determine HIV-1/2 Ag/Ab Combo Verification Form." Alere is a company owned by Abbott. The form contained 18 test results. This document contained no review or approval of the TC or laboratory director (LD). 2. Request was made for all documentation for the verification study. No documentation for the accuracy, precision, or normal value determination for this test system, approved by the LD or TC was made available at the time of survey. 3. Patient testing began on 5 /16/22. From 5/15/22 to 9/6/23 a total of six patient results were reported. 4. Interview with the TC #1 on 9/6/23 at 12:25 p.m. confirmed, the laboratory failed to verify the performance specifications on the Abbott Determine HIV-1/2 Ag/Ab Combo test system used for the detection of human immunodeficiency virus (HIV) p24 antigen (Ag) and antibody (Ab) for HIV Type 1 and Type 2 before reporting patient results.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on an absence of thermometer function check records, certificates of accuracy, protocols for thermometer function checks, lack of accuracy checks for calibrated pipettes, lack of accuracy checks for the centrifuges and interview with TC #1, the laboratory failed to perform a function check protocol for three of five thermometers, one of one pipettes and two of two centrifuges. Findings: 1. No documentation was available for function checks on three of five thermometers for 2022 or 2023 at the time of survey. 2. No documentation was available for the certification of accuracy (NIST traceable) on three of five thermometers for 2022 or 2023 at the time of survey.

	3. Protocols for the function checks of thermometers were not made available at the time of survey. 4. No documentation of accuracy check was available for one of one pipettes for 2022 and 2023 at the time of survey. 5. No documentation for the 6 month function checks, as defined in the laboratory procedures, on two of two centrifuges for 2022 or the first 6 months of 2023 was available at the time of survey. Documentation for function checks for two of two centrifuges was performed 9/6/23. 4. Interview with TC #1 on 9/6/23 at 3:50 p.m. confirmed, the laboratory failed to perform a function check protocol for three of five thermometers, one of one pipettes and two of two centrifuges.
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 QC documentation for the Abbott Determine HIV-1/2 Ag/Ab Combo test system, lack of an individualized quality control plan (IQCP), patient test results and interview with TC #1, the laboratory failed to perform QC at least once each day of patient testing for the Abbott Determine HIV-1/2 Ag/Ab Combo test system. Findings: 1. Review of the QC documents for the Abbott Determine HIV-1/2 Ag/Ab Combo test system revealed the laboratory performed external QC on two dates: 7/28/22 and 2/23/23, since the test system was made a available for patient testing on 5/16/22. 2 . No IQCP for the Abbott Determine HIV-1/2 Ag/Ab Combo test system was provided at the time of survey. 3. Review of the patient test results revealed the laboratory failed to perform QC on six of six days of patient testing for the Abbott Determine HIV-1/2 Ag/Ab Combo test system for six of six patients from 5 /16/22 to date of survey for a total of 12 test results. No documentation of review by the TC was present on any patient and QC logs for this assay at the time of survey. 4. Interview with TC #1 on 9/6/23 at 12:25 p.m. confirmed the laboratory failed to perform QC at least once each day of patient testing for the Abbott Determine HIV-1 /2 Ag/Ab Combo test system.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a review of CMS116 multiple site listing and test lists, lack of test

	comparison documentation and interview with TC #1, the laboratory failed to perform comparison studies two times a year for gram stain and rapid plasma reagin (RPR) testing in 2022. Findings: 1. Review of the CMS116 revealed this laboratory performed gram stains and RPR testing at both the main and the second test site laboratory locations. 3. No 2022 comparison studies were made available at the time of survey. 4. TC #1 stated that testing at the second test site was discontinued "since the beginning of 2023." The main laboratory site did not provide notification to the Kansas CLIA office of this site closure. 5. Based on the CMS116 test volumes, annual patient test volume for RPR is 1736 patients and gram stain for 64 patients. 6. Interview with TC #1 on 9/6/23 at 9:25 a.m. confirmed the laboratory failed to perform comparison studies two times a year for gram stain and rapid plasma reagin (RPR) testing in 2022.
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: The technical consultant (TC) failed to provide technical oversight of the laboratory. The TC failed to perform a verification study for the Abbott Determine HIV-1/2 Ag /Ab Combo test system (see D6040), failed to evaluate proficiency testing results (see D6041), failed to ensure QC was performed each day of patient testing (see D6042), failed to address technical problems and calibration requirements for hematology testing (See D6043), and failed to document the six month competency for testing personnel (TP) #3 (see D6053).
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: The technical consultant failed to perform a verification study for the Abbott Determine HIV-1/2 Ag/Ab Combo test system. (cross reference to D5421).
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) from the provider Wisconsin State Laboratory of Hygiene (WSLH) performed 1/2/22 to 9/6/23, delegation of duties

	document, and interview with TC #1, the TC failed to evaluate two of two 2022 proficiency testing events scores that included UA sediment identification, wet prep and KOH prep. Findings: 1. Review of the 2022 and 2023 evaluation reports for PT from WSLH revealed no documentation of result evaluation for the following 2022 events: a. WSLH 2022Misc QA=POC1. No documentation of the results or its evaluation were provided at the time of survey. b. WSLH 2022Misc QA=POC2. No documentation of the results or its evaluation were provided at the time of survey. 2. Delegation of duties documents revealed enrollment and participation in proficiency testing has been delegated to the TC position. 3. Interview with TC#1 on 9/6/23 at 2: 35 p.m. confirmed, the TC failed to evaluate two of two 2022 proficiency testing events scores that included UA sediment identification, wet prep and KOH prep.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based upon the lack of quality control (QC) testing and lack of TC review documentation for the Abbott Determine HIV-1/2 Ag/Ab Combo test system for each day of patient testing, the TC failed to establish and monitor a QC program for HIV patient testing (cross reference to D5445).
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on the review of five Sysmex Insight quality assurance (QA) reports for the pocH-100i hematology analyzer for 2022 and 2023 data, lack of corrective action completion documents, lack of six month calibration documents and interview with TC #1, the TC failed to resolve technical problems and perform corrective actions when the Sysmex pocH-100i deviated from established criteria. Findings: 1. Review of two Sysmex Insight QA reports for QC values from 10/5/22 to 1/11/23 signed by TC #1 on 3/20/23 revealed documentation by the TC for bias in platelet, hemoglobin, and hematocrit. The TC documented the six month calibration was due 3/1/23. 2. Review of two Sysmex Insight QA reports for QC values from 12/28/22 to 3/20/23 signed by TC #1 on 3/20/23 revealed documentation by the TC for bias in platelet, hemoglobin, and hematocrit. The TC documented the six month calibration was due 3 /1/23. 3. Review of one Sysmex Insight QA reports for QC values from 3/22/23 to 6 /28/23 signed by TC #1 on 6/28/23 revealed documentation by the TC for bias in platelet, hemoglobin, and hematocrit. The TC documented the six month calibration was due 3/1/23. 4. Request was made for the 6 month calibration documents for the pocH-100i hematology analyzer. The calibration document provided was performed

	on 2/11/22. No other document for six month calibration for this analyzer was provided at the time of survey. 5. When the surveyor asked TC #1 if a six month calibration was performed in 2023, the TC responded that the calibrator was ordered in March 2023 but was not used before it expired. He also stated that no additional calibrator had been ordered. 6. Interview with TC #1 on 9/6/23 at 11:45 a.m. confirmed, the TC failed to resolve technical problems and perform corrective actions when the Sysmex pocH-100i deviated from established criteria.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of CMS form 209, competencies, and interview with TC #1, the TC failed to evaluate and document competency at least semiannually during the first year the individual tests patient specimens for one of one new testing personnel (TP). Findings: 1. Review of the site's CMS for 209 for personnel revealed one new testing personnel that had worked at least six months since last survey. 2. Review of personnel competency records revealed no completed semiannual competency during the first year for TP#3. The document provided did have some evaluation data but determination of competency or approval by the TC or LD was not present. 3. Interview with TC #1 9/6/23 at 10:30 a.m. confirmed, the TC failed to evaluate and document competency at least semiannually during the first year the individual tests patient specimens for one of one new testing personnel (TP).