Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0667024	05/17/2018
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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) 2016 and 2017 events and confirmed by technical consultant (refer to the Laboratory Personnel Report (CMS-209)) at 10:20 AM on May 17, 2018, the laboratory failed to evaluate ungraded PT scores for three out of six PT testing events (2016 event one and 2017 events one and two). The findings include: 1. For WSLH PT 2016 testing event one, the laboratory received ungraded PT test scores for the following: Specimen: SS-3 Syphilis Serology 2. For WSLH PT 2017 testing event one, the laboratory received ungraded PT test scores for the following: Specimen: HVC-2 Anti-human immunodeficiency virus (HIV) 3. For WSLH PT 2017 testing event two, the laboratory received ungraded PT test scores for the following: Specimen: GS-6 and GS-10 Gram Stain 4. There was no documentation of evaluation available.
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: Review of the Alere Determine HIV-1/2 Ag/Ab Combo Test records and confirmed by interview with the technical consultant at 11:30 AM on May 17, 2018, revealed that the laboratory failed to verify the performance specifications for the Alere Determine HIV-1/2 Ag/Ab Combo Test. Findings include: 1. The laboratory began reporting patient test results on April 1, 2017 for Anti-human immunodeficiency virus (HIV). 2. There was no documentation of the verification of performance specifications for the Alere Determine HIV-1/2 Ag/Ab Combo Test.
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 upon review of the centrifuge maintenance plan, the urine sediment procedure, preventive maintenance records from the period December 4, 2015 to May 17, 2018 and confirmed by interview with the technical consultant at 9:09 AM on May 17, 2018, the laboratory failed to ensure that the Unico/Select centrifuge was checked for appropriate revolutions per minute (RPM) and duration (time in minutes). Findings were: 1. Review of the urine sediment procedure revealed the centrifuge settings should be 2000 - 2200 +/- 100 RPM. 2. Review of the maintenance records had the following documented tachometer RPM checks: Date RPM setting RPM reading 12/4 /2015 2000 2054 at 5 minutes 8/11/2017 2000 2057 no time documented Based upon review of Unico rotator maintenance plan, preventive maintenance records from the period March 20, 2014 to May 17, 2018 and confirmed by interview with the technical consultant at 9:09 AM on May 17, 2018, the laboratory failed to provide documentation that the Unico rotator timer was checked for accuracy in accordance with the manufacturer's instructions and procedure manual before performing syphilis patient testing. Findings were: 1. Review of the maintenance plan stated every six months the timer should be checked for accuracy with a stopwatch. The time should be 8 minutes +/- 30 seconds. 2. Review of the maintenance records showed no documented timer checks had been performed from March 2014 to May 2018.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where

	the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of one patient report, worksheet for syphilis serology testing for that patient, and confirmed by interview with the technical consultant at 11:50 AM on May 17, 2018, the report date on the test report reviewed was the date that the report was printed, not the date the result was originally reported.