Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0667024	06/25/2019
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
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of proficiency testing records from the period 05/18/2018to 06/25 /2019, proficiency evaluation reports for 2018 Chem/Hemo QA/Urinalyis 2 and interview with Technical Consultant #1, the laboratory failed to complete and retain evidence of remedial actions for missed analyte Fern test. Findings were: A. Review of evaluation reports revealed that the laboratory scored a 50 percent (%); 1 of 2 samples correct for Fern Test. A score of 80% or greater is successful. B. Upon request by the surveyor that the technical consultant (TC) #1 provide evidence that remedial action was taken for the missed analyte, the TC was unable to provide this documentation. D. The technical consultant #1 confirmed these findings on 06/25 /2019at1030 am in the laboratory following interview and review of stated records.
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: Request for records of 2018 and 2019 thermometers, and interview with Technicial Consultant #1 on June 25, 2019 at 1100 am reveals that the laboratory failed to define a function check protocol for the thermometers used for temperature monitoring. The Technicial Consultant #1 stated that she had no records of function check for the thermometers used in the laboratory for the past two years.