Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0382761	09/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Guthrie County Hospital	710 North 12th Street, Guthrie Center, IA	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 8: 30 am on 9/17/2019; the laboratory director failed to attest to the routine integration of PT samples into the patient workload for three out of five proficiency testing events (2018 events 2 and 3, and 2019 event 1) from 1/1/2018 - 9/17/2019. The findings include: 1. For 2018 testing event 2, the laboratory director failed to sign the chemistry-miscellaneous and hematology PT attestation statements. 2. For 2018 testing event 3, the laboratory director failed to sign the immunohematology PT attestation statement. 3. For 2019 testing event 1, the laboratory director failed to sign the chemistry-miscellaneous and immunohematology PT attestation statements.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the Laboratory Test List & Annual Volume form, proficiency testing (PT) records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 8:30 am on 9/17/2019, the laboratory

	failed to verify the accuracy of the analytes, manual white blood cell differential and qualitative serum human chorionic gonadotropin (hCG), at least twice annual for three out of three time periods from 1/1/2018 - 9/17/2019. The findings include: 1. The laboratory performed both automated white blood cell differentials and manual white blood cell differentials. 2. The laboratory enrolled in PT for their primary method, automated white blood cell differentials. 3. The laboratory performed quantitative serum hCG, qualitative urine hCG, and qualitative serum hCG testing. 4. The laboratory enrolled in PT for their primary methods quantitative serum hCG and qualitative urine hCG. 5. At the time of the survey, the laboratory did not have records verifying the accuracy twice annually for their non-primary methods, manual white blood cell differentials and qualitative serum hCG testing, from 1/1/2018 - 9/17/2019.