Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0695714	04/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
Cheyenne County Hospital	210 W First Street, St Francis, 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: A review of proficiency testing records from American Proficiency Institute (API) (a year consists of three testing events) and interview with laboratory Supervisor revealed the laboratory failed to verify the accuracy of analytes for which the proficiency testing program does not obtain the agreement required for scoring. Findings were as follows: a. Proficiency testing records form API for the third event of 2016, revealed that the proficiency testing program failed to obtain the agreement required for scoring the Urine ID , Susceptibility Testing and Thyroid Stimulating Hormone). : At the time of survey (04/02/2018), there was no evidence of verification activities of accuracy by self grade (comparison to the published expected results) for any of these analytes available for review. An interview with the Testing Person #2 from the CMS form 209 on 04/02/2018, at 10:20 hrs confirmed that no verification of accuracy.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by:

	Based upon a review of the laboratory's proficiency test reports performed through the provider American Proficiency Institute (API) laboratory policy/procedures and staff interview, the laboratory failed to ensure that evaluation of an unacceptable proficiency testing event was documented. Findings were: a...Based upon proficiency testing results for API 2-2016, Chemistry .Acetaminophen specimen CH-10 reported 33.0 acceptable range 27.4---32.5 no corrective action documentation was provided. b. Based upon proficiency results for API 2-2017 Chemistry PO2 BG-06 reported 32 acceptable range 5--27. no corrective action documentation was provided c. The above findings were confirmed by interview with the testing person #2 from the CMS form 209 t on 4/02/2018 at 1140 hours in the laboratory.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: A review of manufacture's package insert for MEDTOX revealed the laboratory failed to follow manufacture's instructions for positive drug screen results. . Findings were as follows 1. Based upon MEDTOX package insert states " The Profile-II/verdict-II drugs of abuse provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result"The Testing Person #2 stated not all positive result are sent out". . This was confirmed in interview with Testing Person #2 from the CMS form 209 #2 on 04/02 /2018 at 10:30 hrs.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: A review of Temperature and humidity logs and interview with staff revealed the laboratory failed the humidity for the laboratory as the XS-1000i hematology analyzer requires Findings were as follows: a. Based upon review of manufacture's operators guide the laboratory failed the humidity 30% to 85% . The laboratory failed to define the acceptable humidity range according to the manufacture's range b. At the time of the survey 04/02/2018 the laboratory failed to produce corrective action documentation of humidity, This was confirmed by the Testing Person#2 from the CMS 209 form on 04/02/2018 at 1200 hours.
D5473	CONTROL PROCEDURES

	CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A review of Quality Control and interview with staff revealed the laboratory failed to document quality control of the Differential stain for hematology Findings were as follows: a . Based upon Quality Control of the differential stain for hematology the laboratory failed to produce documentation that the quality control was being performed. This was confirmed in interview with Testing person #1 on 04/02/2018 at 10:20