Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0453249	06/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Satanta District Hospital & Ltcu Nur	401 Cheyenne, Satanta, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Review of the Sysmex XS1000i calibration records for 2017 and 2018 and interview with testing personnel #1 (laboratory personnel report CMS-209), the laboratory failed to retain the calibration assay sheets for the required two year period. Findings were: 1. Sysmex XS1000i calibration records for February 20, 2017. 2. Sysmex XS1000i calibration records for February 7, 2018. 3. Assay sheets were not available was verified during interview with testing personnel #1 at 1:30 PM on June 20th, 2018.
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 American Association of Bioanalysts (AAB) proficiency tests (PT) and interview with testing personnel #1 (refer to laboratory personnel report CMS-209) at 09:00 am on June 20, 2018, the laboratory failed to have two passing scores during 2017 to verify the accuracy of the urine sediment test. Findings were:. 1.

	Review of AAB PT Urinalysis for 2017: 1st Quarter Urine Sediment had a score of 50% 3rd Quarter Urine Sediment had a score of 50% 2. Testing personnel confirmed that the laboratory didn't perform any other accuracy for urine sediment.
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 on review of American Association of Bioanalysts (AAB) proficiency testing (PT) records for 2017 and confirmed by laboratory testing personnel #1 (refer to the Laboratory Personnel Report CMS-209) at 08:30 am on June 20, 2018, the laboratory failed to ensure that evaluation of an unacceptable proficiency testing event was documented. The Findings include: 1. AAB 2017 1st Event Urinalysis, Urine Sediment - Image 1 & Image 2 - score 50% Coagulation, specimen 2 - score 36.2 - grading range (41.4 to 56.0) 2. AAB 2017 2nd Event Basic Chemistry, Bicarbonate (Total CO2), specimen 4 - score 26 - grading range (27 to 40) Hematology, Cell Identification, specimen 2 3. AAB 2017 3rd Event Urinalysis, Urine Sediment - Image 1 - score 50% 4. No corrective action documentation was provided per interview with testing personnel #1 at 08:30 am on June 20, 2018.
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 Bio- Rad Liquicheck Cardiac Markers Plus Control LT revealed the laboratory failed to follow manufacture's instructions for storage. . Findings were as follows a. Based upon Bio-Rad Cardiac Quality Control package insert states " Do not store this product in a Frost Free freezer'.At the time of the survey 3 packages were stored in a standard refrigerator freezer (frost free freezer) This was confirmed in interview with Testing Person #1 the CMS form 209 #1 on 06 /20/2018 at 10:30 hrs
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration

	verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: A review of the calibration records for the Sysmex XS-1000i, review of Sysmex e-CHECK quality control (QC) reports and interview with testing personnel #1 (refer to laboratory personnel report CMS-209) at 01:30 PM on June 20, 2018 revealed that the laboratory failed to correctly perform calibration during 2017 and 2018. Finding were as follows 1. Based upon review of the XS-1000i calibration documentation from August 10, 2017 revealed the laboratory failed to enter the correct target values listed on the calibrator assay sheet. Sysmex XCAL Lot. 71990557 Expired 8/20/2017 Assay Sheet Target Values Actual Values White Blood Cells (WBC) 7.10 Same Red Blood Cells (RBC) 4.30 4.32 (standard deviation 0.02) Hemoglobin (HGB) 11.9 11.8 Hematocrit (HCT) 34.1 34.9 (standard deviation 0.2) Mean Corpuscular Volume (MCV) 79.2 83.3 (outside acceptable limits) Platelet (PLT) 233 Same 2. Upon review of QC reports following the August 10, 2017 calibration, there were shifts in QC and warning flags on the platelet QC the laboratory failed to address. The Sysmex Insight e-CHECK report for QC showed the following: Lot 7213 8/9/17 to 10/6/17 had shifts for PLT Lot 7269 10/4/17 to 12/17/17 had shifts for RBC, MCV, MCH and PLT (Warning flag on PLT) Lot 7325 11/29/17 to 2/2/18 had shifts for RBC, MCV, MCH, and PLT (Warning flags on all three PLT levels) 3. Based upon a review of the XS-1000i calibration documentation from February 7, 2018. The calibrator assay sheet was not available to verify target values. Calibration was accepted without addressing QC problems and inconsistencies with calibration runs. Sysmex XCAL lot 80300557 expired 3/4/2018. 4. Upon review of QC reports following the February 7, 2018 calibration, there were shifts in QC and warning flags the laboratory failed to address. The Sysmex Insight e-CHECK report for QC showed the following: Lot 8016 1/24 /2018 to 4/8/2018 had shifts for PLT Lot 8072 3/21/2018 to 5/9/2018 had shifts for MCH and PLT 5. Therefore the accuracy and the reliability of the hematology testing can not be verified.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: A review of the Quality Control (QC) procedure and interview with staff revealed the laboratory failed to produce a policy concerning a failed QC concerning patient results Finding were as follows a. Interview with Testing Person #1 from the CMS 209 06/20 //2018 at 09:30 hrs. confirmed the laboratory failed to have the policy, (All patients test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected).
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)

	(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based upon a review of the laboratory Quality Assurance (QA) Plan and Quality Control (QC) policy, analyzer quality control records and interview with testing personnel #1 (refer to laboratory personnel report CMS-209) the laboratory failed to follow the laboratory's Quality Control plan and Quality Assurance plan. Therefore, the accuracy or reliability of the QC plan cannot be verified. Finding were as follows: 1. The QC policy of the laboratory failed to define the parameters of acceptable and unacceptable QC and did not including patient remediation and corrective action documentation for any QC failure. 2. The laboratory's Monthly QA Checklist documents failed to be completed after October 31, 2017. 3. Quality Control review was not performed and documented per laboratory policy resulting in shifts and trends in both analyts on the Chemistry (Siemens Dimension EXL 200) and Hematology (Sysmex XS 1000i) Analyzers. 4. This was confirmed by testing personnel #1 at 2:45 on June 20, 2018.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: A review of Hematology Calibration and Quality Control for the Sysmex XS1000i from August 10, 2017 until June 20, 2018 revealed the laboratory Director failed to properly and timely review the Calibration and Quality Control records that had unacceptable calibrations and quality control values. Findings were as follows: 1. Upon review of the Sysmex XS-1000i calibration performed August 10, 2017 and was not reviewed until March 8, 2018 by the laboratory director. The laboratory director failed to review the calibration in a timely manner and to identify the error regarding the calibration values and the unacceptable calibration results. 2. Upon review, Certificate of Calibration performed February 7, 2018 was reviewed March 8, 2018 by the laboratory director and no documentation of the calibration problems were noted or the unacceptable values. 3. Upon review of the e-CHECK Quality Control records from November 29, 2017 to May 9, 2018, the Laboratory Director failed to properly review, identify and document problems regarding the Quality Control warnings and problems flagged and seen on the Sysmex Insight e-CHECK quality control records.