Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0451118	08/01/2018
Name of Provider or Supplier	**Street Address, City, State**	
Medicine Lodge Memorial Hospital	710 North Walnut, Medicine Lodge, 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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of the manufacturers' package insert instructions, direct observation, laboratory's policy and procedure manual, and interview with Testing Personnel (TP) # 2, the laboratory failed to ensure that reagents were not used when they had exceeded their expiration dates. Findings Include: 1. Direct observation of the laboratory's reagent refrigerators at 10:23 AM on the date of survey found the following reagents: Dade Actin - dated 7/23 CA Clean - not dated Dade Innovin - dated 7/26 MAS Urinalysis level 1 and 2 quality control fluids - not dated Chemistry enzyme diluent - no reconstitution date 2. Review of the manufacturers' package insert instructions for the reagents Dade Actin, CA Clean, Dade Innovin, MAS urinalysis level 1 and 2 quality control fluids, and chemistry enzyme diluent found the following stability guidelines: Dade Actin: stable for 7 days once opened and stored at 2 - 8 degrees Celcius (C) CA Clean: stable for 1 month once opened and stored at 2 - 8 degrees C Dade Innovin: stable for 10 days once opened and stored at 2-8 degrees C MAS Urinalysis level 1 and 2 quality control fluids: stable for 3 months once opened and stored at 2 - 8 degrees C Chemistry enzyme diluent: stable for 7 days once opened and stored at 2 - 8 degrees C 3. Review of the laboratory's policy and procedure titled "Control Storage" found the following directions for the MAS urinalysis controls: "Opened bottles are stable for 3 months at 2 - 8 degrees C" Review of the laboratory's policy and procedure titled "Reagent Storage" found the following directions for the chemistry enzyme diluent: "Reagents: store at 2 - 8 degrees C until exp date." Review of the laboratory's policy and procedure titled "Sysmex CA-Series ACTIVATED PARTIAL THROMBOPLASTIN TIME" found the following directions for the Dade

	Actin, CA Clean, and Dade Innovin: "Dade Actin - Reagent Stability: 2 - 15 degrees C: 7 days [once opened] CA Clean - Stability once opened at 2 - 8 degrees C: 30 days in closed container" Review of the laboratory's policy and procedure titled "SYSMEX CA-SERIES - PROTHROMBIN TIME" found the following directions for the Dade Innovin: "Dade Innovin - Stability after Reconstitution: 2 - 8 degrees C 10 days (closed vial)" 4. Testing Personnel #2 stated the laboratory uses the above reagents until the bottles were empty and had not been adhering to the manufacturers' stability requirements. The interview occurred 08/01/2018 at 10:31 AM.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on direct observation, review of the laboratory's policies and procedures, and interview with Testing Personnel (TP) #2, the laboratory failed to perform two levels of quality control material each time the non-manual coagulation reagents were changed on the Sysmex CA-1500 analyzer. Findings Include: 1. Review of the laboratory's policies and procedures titled "Sysmex CA-series ACTIVATED PARTIAL THROMBOPLASTIN TIME and SYSMEX CA-SERIES PROTHROMBIN TIME" found directions stating that quality control should be performed once every eight hours of patient testing. Review of the procedures failed to find any mention of removing the reagents between each patient test or performing quality control when reagents had been loaded onto the analyzer. 2. Direct observation of the laboratory's Sysmex CA-1500 analyzer on the date of survey AT 10:15 AM found no reagents present on the analyzer. 3. TP #2 stated the laboratory did not leave the coagulation reagents on the analyzer in between patient testing. The TP removed the reagents after a patient's test was complete and placed the reagents back in the refrigerator. The reagents were only placed back on the instrument when a subsequent sample required analysis. TP #2 further stated the laboratory only performed quality control testing once per day of patient testing and did not perform quality control each time the reagents were placed back on the analyzer. The interview occurred 08/01 /2018 at 10:17 AM.
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: Based on review of the laboratory's policies and procedures, quality control data,

	patient test results, and interview with the General Supervisor (GS), the laboratory failed to take corrective action for patient test results when the results of control materials failed to meet the laboratory's established criteria for acceptability. Findings Include: 1. Review of the laboratory's policy and procedure titled "Siemens Dimension EXL" found a section titled "Quality Control" which stated two levels of controls should be run each 24 hours of patient testing. The procedure failed to address the acceptability of controls, corrective actions to be taken when controls fail to meet the laboratory's established acceptability criteria, or corrective actions for patient results when controls fail to meet the laboratory's established acceptability criteria. 2. Review of the laboratory's quality control data for total protein on June 18, 2018 found that quality control was performed at 8:26 AM, 9:50 AM, and 10:03 AM. On all three occasions quality control failed to fall within the laboratory's acceptable quality control reference ranges. Quality control was rerun again at 10:14 AM and the result fell within the laboratory's established reference ranges. 3. Review of patient test data from the Laboratory Information System (LIS) from June 18, 2018 found that patient samples were analyzed for total protein at 9:36 AM, 9:36 AM, 9:40 AM, 10:02 AM, 9:29 AM, and 10:08 AM. All of the aforementioned patient total protein levels were resulted and certified in the LIS at 10:08 AM and 10:09 AM, prior to acceptable quality control results being obtained. 4. The GS stated the laboratory runs patient samples simultaneously with the quality control samples. If the quality control fails to fall within the laboratory's acceptable reference ranges the patient results are held until acceptable quality control results are obtained. The GS also stated the laboratory does not reanalyze, assess, or take corrective actions for the patient test results obtained with the unacceptable quality control run prior to releasing the results into the LIS system. The patient results released and certified in the LIS system are the result obtained with the unacceptable quality control run. The interview occurred 08 /01/2018 at 11:25 AM.