Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475880	04/18/2019
Name of Provider or Supplier	**Street Address, City, State**	
Holdenville General Hospital	100 Mcdougal Drive, Holdenville, OK	

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
D0000	The recertification survey was performed 04/16/19 - 04/18/19. The laboratory was found to in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory manager, the technical consultant, testing person #1, and testing person #2 at the conclusion of the survey.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager and the technical consultant, the laboratory failed to perform maintenance procedures as required by the manufacturers of the analyzers used for patient testing. Findings include: SYSMEX XS-1000i (1) On the first day of the survey, the laboratory manager stated to the surveyor, the laboratory performed CBC (Complete Blood Count) testing using the Sysmex XS-1000i analyzer; (2) On the third day of the survey, the surveyor identified the manufacturer's required weekly maintenance procedure as documented on the manufacturer's maintenance log, which was "power down the IPU (Internal Processor Unit);" (3) The surveyor then reviewed the maintenance records from 21 months (July 2017 through March 2019) and identified during 4 of the 21 months reviewed, the weekly maintenance had not been documented as performed: (a) Between 08/22/17 and 09/05/17 (b) Between 05/22/18 and 06/05/18 (4) The surveyor reviewed the findings with the laboratory manager and the technical consultant, who stated to the surveyor the weekly maintenance had not been documented as performed, as listed above. DIMENSION EXL (1) On the first day of the survey, the laboratory manager stated to the surveyor the laboratory performed the following testing on the Dimension EXL 200 analyzer: (a) CMP*,

	Amylase, CK (Creatinine Kinase), CK-Isoenzyme, Direct Bilirubin, High Density Lipoprotein, Magnesium, Total Cholesterol, Triglycerides, Troponin I, and Uric Acid (b) Therapeutic Drug testing: Acetaminophen, Alcohol, Digoxin, Dilantin, Salicylate, Valproic Acid, and Vancomycin (c) Immunoassay testing: TSH (Thyroid Stimulating Hormone), PSA (Prostate Specific Antigen), Serum Quantitative pregnancy, and Free T4 (2) On the second day of the survey, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The manufacturer required the follow procedures be performed on a monthly basis: (a) Replace IMT Pump Tubing (b) Clean IMT System (c) Replace/Clean Air Filters (d) Stylette HM Wash Probes (e) Replace HM Pump Heads (f) Clean R2 Drain (3) The surveyor then reviewed maintenance records for the analyzer from January 2018 through March 2019. The surveyor identified during the 15 months reviewed, the laboratory failed to perform the Replace IMT Pump Tubing, Clean IMT System, Replace/Clean Air Filters, Stylette HM Wash Probes, and Replace HM Pump Heads procedures between 05/31/18 and 07/03/18; (4) The surveyor reviewed the records with the laboratory manager and the technical consultant who stated to the surveyor the above required maintenance procedures had not been documented as being performed as listed above. ID-MTS DILUENT DISPENSER (1) On the first day of the survey, the laboratory manager stated to the surveyor the laboratory performed Compatibility (i.e. ABO/Rh Type, Antibody Screen, Crossmatch) testing on units of Packed Red Blood Cells for transfusion purposes. In addition, the laboratory manager stated the testing was performed using the ID-Micro Typing System; (2) The surveyor reviewed the manufacturer's instructions for the test system and identified the manufacturer required the ID-MTS diluent dispenser (used to aliquot the MTS Diluent 2Plus during the testing), be cleaned on a weekly basis; (3) The surveyor then reviewed the maintenance records from 6 months (January, March, July, and December 2018; and January and March 2019). There was no documentation the weekly cleaning had been performed as required between 03/03/18 and 03/14/18; (4) The surveyor reviewed the findings with the laboratory manager and the technical consultant, who stated to the surveyor, there was no documentation which proved the required weekly cleaning of the MTS diluent dispenser had been performed as listed above. *CMP: BUN (Blood Urea Nitrogen), Calcium, Creatinine, Glucose, Chloride, CO2, Potassium, Sodium, Albumin, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Alkaline Phosphatase, Total Bilirubin, and Total Protein NOTE: D5429 had been cited at the previous recertification survey performed 06/20/17- 06/21/17.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of records, policy and procedure, and interview with the laboratory manager, the laboratory failed to ensure that blood products were stored under appropriate conditions. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor units of Packed Red Blood Cells to be used

	for patient transfusions were stored in the blood bank refrigerator; (2) The surveyor reviewed the blood bank alarm check policy and procedure. The policy stated the warm temperature of activation should cause the alarm to sound at 5.8 degrees C (Centigrade). (Note: units of packed cells must be stored between 1-6 degrees C, therefore, the low temperature of activation should be no lower than 1 degree C and the high temperature of activation should be no higher than 6 degrees C): (3) The surveyor then reviewed quarterly alarm check records from October 2017 through March 2019. The surveyor identified that, although the alarm checks had been performed quarterly, 1 of the 7 high temperature activation alarm checks performed during the time period reviewed was unacceptable: (a) 03/05/19: The warm temperature alarm sounded at 6.4 C, which was warmer than the acceptable limit. (4) The surveyor reviewed the records with the laboratory manager and the technical consultant and explained the high temperature of activation must be 6.0 C or less to ensure units of packed red blood cells were stored at the appropriate temperature; (5) The laboratory manager stated to the surveyor the records showed the laboratory did not ensure the blood bank refrigerator alarm sounded before the refrigerator reached an unacceptable temperature for storage of units of packed red blood cells.