Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0469661	10/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Ssm Health St Anthony Healthplex El Reno	3333 Territory Lane, El Reno, 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 on 10/24,25,26/18. The laboratory was found to be in compliance with standard-level deficiencies cited. The findings were reviewed with the vice president Mercy laboratory west, laboratory director, regional laboratory director, laboratory manager, and testing person #3 during an exit conference performed at the conclusion of the survey.
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: Based on on review of records and interview with the laboratory manager and regional laboratory director, the laboratory failed to follow the manufacturer's instructions for coagulation reagent lot changes. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor PT/INR (Prothrombin Time/International Normalized Ratio) testing was performed using the Stago STA Satellite analyzer; (2) On the second day of the survey, the surveyor observed the coagulation reagents, currently in use, in the laboratory refrigerator. The laboratory manager stated to the surveyor the following reagents were put into use on 02/28/18: (a) STA-Neoplastine C1 Plus lot #251800 (b) STA-Coag Control Normal lot #250559 (c) STA-Coag Control Abnormal lot #252114 (3) The surveyor reviewed the manufacturer's instructions for reagent lot changes which stated the following: (a) "Current Lot vs. New Lot Correlation: Collect 40 patient samples across the reportable range; 20 normal samples (minimum) 15 therapeutic (INR 1.5-4.0)" (b) "Total Precisions: Use control materials that will be used for the assay Run each level six (6) times per day over five (5) days Data will be used to create 'site specific'

	quality control range Total 30 data points per analyte is recommended for routine assays. This is to verify that the new reagent is working within the manufacturer's specifications. It is acceptable to use the assigned control range for a short period of time (30 days) while the control data is being collected". (4) The surveyor reviewed the records for the lot changes with the following identified: (a) For the Current Lot vs. New Lot Correlation, the laboratory tested only 8 samples within the therapeutic INR range of 1.5-4.0 instead of 15 as required by the manufacturer; (b) For the Total Precisions using the Normal control, the laboratory chose to utilize the manufacturer assigned control range of 11.5-15.5, however, the range was used beyond the 30 day timeframe allowed by the manufacturer. The manufacturer assigned control range had been used from 03/01/18 through 09/30/18. (5) The surveyor reviewed the records with the laboratory manager and regional laboratory director. Both stated the manufacturer's instructions had not been followed as indicated above.
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 regional laboratory director, the laboratory failed to perform maintenance procedures as required by the manufacturers. Findings include: SYSMEX XS-1000i ANALYZER (1) On the first day of the survey, the laboratory manager stated to the surveyor CBC (Complete Blood Count) testing was performed on the Sysmex XS-1000i analyzer; (2) On the second day of the survey, the surveyor reviewed the manufacturer's maintenance instructions for the analyzer which were: (a) Weekly (i) Power Down IPU (3) Maintenance records were reviewed by the surveyor for 14 months (August 2017 through September 2018). The weekly maintenance had not been documented as performed between: (a) 10/24/17 and 11/07/17 (b) 04/24/18 and 05/08/18 (c) 07/03/18 and 07/17/18 (d) 08/23/18 and 09/05/18 (4) The surveyor reviewed the records with the laboratory manager and regional laboratory director. Both stated there was no evidence the above maintenance had been performed as required. ROCHE COBAS C311 ANALYZER (1) On the first day of the survey, the laboratory manager stated to the surveyor CMP*, Lipid Profile*, Ammonia, Amylase, Direct Bilirubin, CK (Creatine Kinase), Hemoglobin A1c, Lactic Acid, Lipase, Magnesium, Phosphorus, Acetaminophen, Alcohol, Digoxin, Dilantin, and Vancomycin testing were performed on the Roche Cobas c311 analyzer; (2) On the second day of the survey, the surveyor reviewed the manufacturer's maintenance instructions for the analyzer which were: (a) Weekly (i) Clean Cell Covers (ii) Clean Rinse Stations (iii) Power off/on Analyzer (iv) Perform Wash Reaction Parts (v) Perform Cell Blank (3) The surveyor then reviewed maintenance records for 14 months (August 2017 through September 2018). There was no evidence the weekly maintenance had been performed between: (a) 10/24/17 and 11/07/17 (b) 04/24/18 and 05/08/18 (c) 07/03/18 and 07/17/18 (d) 08/23/18 and 09/05/18 (4) The surveyor reviewed the records with the laboratory manager, who stated there was no evidence the maintenance, as indicated above, had been performed as required. *CMP (Comprehensive Metabolic Panel) - BUN, Calcium, Creatinine, Glucose, Chloride,

	CO2, Potassium, Sodium, Albumin, ALT, AST, Alkaline Phosphatase, Total Bilirubin, and Total Protein *Lipid Profile - Cholesterol, HDL Cholesterol, Triglyceride
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, policies and procedures, and interview with the laboratory manager and regional laboratory director, 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, which were stored in the Sanyo blood bank refrigerator, were used for patient transfusions; (2) The surveyor reviewed blood bank policies and procedures. The refrigerator alarm check policy required that temperature checks (for low and high temperatures of activation) be performed on a quarterly basis (Note: units of packed cells must be stored between 1-6 degrees Centigrade (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 reviewed alarm check records for 2017 and 2018 to date, and identified the alarm checks had not been performed on a quarterly basis (every 3 months) as follows: (a) 2017 - Two alarm checks had been performed (05/16/17 and 11/03/17), therefore, alarm checks had not been performed during the first and third quarters; (b) 2018 - Two alarm checks had been performed to date (05/11/18 and 10/18/18), therefore, alarm checks had not been performed during the first and third quarters. (4) The surveyor reviewed the records with the laboratory manager and regional laboratory director. Both stated the alarm checks had not been performed on a quarterly basis as indicated above.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the

	laboratory failed to ensure corrective action taken for a failed calibration verification was complete. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor Sodium and Potassium testing were performed using the Roche Cobas c311 analyzer; (2) On the third day of the survey, the surveyor reviewed calibration verification records for the analyzer (calibration verification was performed using 5 levels of materials which ranged in values across the reportable range for each analyte) and identified unacceptable Sodium and Potassium values for the calibration verification performed on 06/21/17: (a) Sodium - Level 1 target value was 94.89 and the laboratory obtained a value of 119.33 with a difference of 24.44 flagged as unacceptable on the report. A note at the bottom of the report stated, "Order new kit to repeat"; (b) Potassium - Level 1 target value was 2.173 and the laboratory obtained a value of 2.600 with a difference of 0.427 flagged as unacceptable on the report. A note at the bottom of the report stated, "Order new kit to repeat". (3) The surveyor reviewed the records with the laboratory manager asked if the testing had been repeated on the new kit. The laboratory manger stated a new kit had been ordered and tested, with acceptable results attained, however, the records could not be located; (4) The surveyor determined the corrective action was not complete since there was no documentation to support an acceptable calibration verification had been performed with a new kit.