Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0471917	01/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Schafer Medical Center	800 Isabel Sw, Ardmore, 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 findings were reviewed with 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, and interview with testing person #1 and testing person #2, the laboratory failed to perform the manufacturers' required maintenance procedures on analyzers used for patient testing. Findings include: ENVOY 500 CHEMISTRY ANALYZER (1) At the beginning of the survey, testing person #1 stated to the surveyor the laboratory performed Chemistry testing (i.e., Albumin, Cl (Chloride), CO2 (Carbon Dioxide), Glucose, K (Potassium), Na (Sodium), Total Cholesterol, Direct Bilirubin, etc.) using the Envoy 500 chemistry analyzer; (2) The surveyor reviewed records from 08/01/16 through 12/31/17 and identified the maintenance procedures required by the manufacturer, as recorded on the maintenance log: (a) Weekly: (i) Clean Sample Needles w/alcohol swab (ii) Perform EXTRA WASH CUVETTES (iii) View Levey-Jennings Charts (iv) Perform Shutdown of Operating System (b) Monthly: (i) Print Levey-Jennings charts for review by Director QC (Quality Control) (ii) Backup QC Data (if no LIS) (iii) Purge Patient Archive (suggested) (iv) Check mouse/keyboard batteries (v) Replace Bypass /GND Tubing (c) Quarterly: (i) Replace ISE Tubing Set (ii) Replace K Electrode (iii) Replace Cl- Electrode (iv) Replace CO2 Electrode (3) From the review, the surveyor identified maintenance procedures which had not been documented as having been performed. The specific findings follow: (a) Weekly - Had not been documented as having been performed: (i) Between 10/24/16 and 11/07/16 (ii) Between 11/21/16 and

	12/04/16 (iii) Between 03/13/17 and 03/27/17 (b) Monthly - During 3 of the 16 months reviewed, the following procedures had not been documented as having been performed: (i) September 2016: (aa) Print Levey-Jennings charts for review by Director QC (bb) Backup QC Data (cc) Purge Patient Archive (dd) Check mouse /keyboard batteries (ii) October 2016: (aa) Print Levey-Jennings charts for review by Director QC (bb) Backup QC Data (cc) Purge Patient Archive (ee) Check mouse /keyboard batteries (ff) Replace Bypass/GND Tubing (iii) November 2016: (aa) Print Levey-Jennings charts for review by Director QC (bb) Backup QC Data (cc) Purge Patient Archive (dd) Check mouse/keyboard batteries (c) Quarterly - During 1 quarter (4th quarter 2017) of the 5 quarters reviewed, the required maintenance procedure had not been documented as having been performed. (4) The surveyor reviewed the findings with testing person #1 and testing person #2 and asked if additional documentation was available which proved the required maintenance procedures listed above had been performed. Testing person #1 and testing person #2 could not locate additional information which proved the maintenance procedures listed above had been performed. SYSMEX XP-300 HEMATOLOGY ANALYZER (1) At the beginning of the survey, testing person #1 stated to the surveyor the laboratory performed CBC (Complete Blood Count) testing (i.e., WBC-White Blood Count; RBC-Red Blood Count; Hemoglobin, Hematocrit, Platelet Count, etc.) using the Sysmex XP-300 hematology analyzer; (2) The surveyor reviewed records from 08/01 /16 through 12/31/17 and identified the manufacturer required the following weekly maintenance procedure, as recorded on the maintenance log: (a) Clean SRV (Sample rotor valve) tray (3) From the review, the surveyor identified the required weekly maintenance procedure had not been documented as having been performed: (a) Between 01/09/17 and 02/06/17 (b) Between 07/17/17 and 08/07/17 (c) Between 11/01 /17 and 11/13/17 (4) The surveyor reviewed the findings with testing person #1 and testing person #2 and asked if additional documentation was available which proved the weekly maintenance procedure had been performed as required. Testing person #1 and testing person #2 could not locate additional information which proved the maintenance procedure listed above had been performed.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of records, and interview with testing person #1 and testing person #2, the laboratory failed to provide reference intervals appropriate for the patient population serviced by the laboratory. Findings include: (1) At the beginning of the survey, testing person #1 stated to the surveyor the laboratory performed CBC (Complete Blood Count) (i.e., RBC-Red Blood Count, Hgb-Hemoglobin, Hct-Hematocrit, etc.) testing using the Sysmex XP-300 hematology analyzer; (2) The surveyor reviewed four patient CBC reports as follows: (a) Patient #1: Adult male. Testing performed on 10/31/16 (b) Patient #2: Adult female. Testing performed on 10 /31/16 (c) Patient #3: Adult female. Testing performed 11/29/17 (d) Patient #4: Adult male. Testing performed on 11/30/17 (3) The four test reports included the same reference intervals for the following CBC analytes: (a) RBC: 4.20 - 6.30 (b) Hgb: 12.0 - 18.0 (c) Hct: 37.0 - 51.0 (4) The surveyor reviewed the findings with testing person #1 and testing person #2 and asked if the laboratory had gender specific CBC

	reference intervals. Testing person #1 and testing person #2 verified the laboratory did not have gender specific reference intervals for the CBC analytes listed above. NOTE: Routinely, female reference intervals for analytes RBC, Hemoglobin, and Hematocrit are lower than male reference intervals.