Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0471917	01/05/2024
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 recertification survey was performed on 01/05/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director and testing person #1 during an exit conference performed at the conclusion of the survey.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the laboratory director and testing person #1, the laboratory failed to follow their written policy for establishing the means for new lot numbers of control materials prior to implementation for 12 of 12 lot numbers used during the review period of 01/04/2023 through 11/30/2023. Findings include: (1) On 01/04/2024 at 9:50 am, testing person #1 stated the following: (a) The laboratory performed CBC (Complete Blood Count) testing using the Sysmex XP-300 hematology analyzer; (b) Three levels of EIGHTCHECK-3WP X-TRA QC (Quality Control) materials were tested each day of patient testing; (c) Laboratory established means and historic SD's (standard deviations) were used to determine acceptability of quality control results. (2) A review of the procedure manual titled, "Sysmex XP-300" under the section "Setting mean and standard deviation procedure" stated the following: (a) "1. The stated values correspond to the method and instrument used by the laboratory, by running parelle runs with new lot for five days- twice a day for 5 days. 2. The means obtained after 10 runs reflects the manufacturer stated assay range for temporary mean.3. Calculate at two standard deviation range with minium 3 months runs incorporated this SD range

	around new temporary mean. 4. The controls will be run 20 times to establish new mean and will be monitor throughout the date of the control." (3) A review of records for 12 control lot numbers used from 01/04/2023 through 11/30/2023 identified the laboratory did not follow their policy as follows: (a) Lot #23620710, 23620711, and 23620712 used from 01/04/2023 through 03/29/2023 - The controls had been tested nine times over six days as follows: (i) Twice on 01/04/2023 (ii) Once on 01/05/2023 (iii) Once on 01/06/2023 (iv) Once on 01/09/2023 (iv) Once on 01/10/2023 (iiv) Three times on 01/11/2023 (b) Lot #30810710, 30810711, and 30810712 used from 03 /22/2023 through 05/31/2023 - The controls had been tested ten times over six days as follows: (i) Once on 03/22/2023 (ii) Twice on 03/23/2023 (iii) Twice on 03/24/2023 (iv) Once on 03/27/2023 (iv) Twice on 03/28/2023 (iiv) Twice on 03/29/2023 (c) Lot #31650710, 31650711, and 31650712 used from 06/15/2023 through 09/28/2023 - The controls had been tested ten times over three days as follows: (i) Twice on 09/15 /2023 (ii) Twice on 09/16/2023 (iii) six times on 09/19/2023 (d) Lot #32490710, 32490711, and 32490712 used from 10/02/2023 through 11/30/2023 - The controls had been tested nine times over four days as follows: (i) Once on 09/07/2023 (ii) Once on 09/11/2023 (iii) Twice on 09/12/2023 (iv) Five times on 09/13/2023 (4) The findings were reviewed with the laboratory director and testing person #1 who stated on 01/04/2024 at 12:00 pm, the laboratory did not follow their written policy.
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 testing person #1, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures for one of two analyzers reviewed from January through December 2023. Findings include: (1) On 01/05/2024 at 09:50 am, testing person #1 stated Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), BUN, Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, Sodium, Total Bilirubin. Total Protein, Total Cholesterol, HDL Cholesterol, and Triglyceride testing were performed using the Envoy 500 analyzer; (2) A review of the manufacturer's maintenance log showed the following required weekly maintenance procedures: (a) "Clean Sample Needles with Alcohol Swab" (b) "Perform EXTRA WASH CUVETTES" (c) Perform Shutdown of Operating Systems" (3) A review of maintenance logs from January 2023 through December 2023 identified no documentation weekly maintenance had been performed between: (a) 05/22/2023 and 06/05/2023 (b) 10/23/2023 and 11/06/2023 (4) The records were reviewed with testing person #1 who stated on 01/05/2024 at 12:00 pm, the weekly maintenance had not been documented as performed as shown above.