Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0471800	01/07/2020
Name of Provider or Supplier	**Street Address, City, State**	
Dycus-Camp Clinic	320 N Service Rd, Moore, 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 01/07/20 The findings were reviewed with the testing person at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the testing person, the laboratory failed to ensure blood collection tubes were stored as required by the manufacturer for 1 of 5 months. Findings include: (1) At the beginning of the survey, the testing person stated the following to the surveyor: (a) Routine CBC (Complete Blood Count) testing was performed using the Abbott Cell-Dyn 1800 analyzer; (b) Blood collection tubes were used for the following: (i) Patient testing on the Abbott Cell-Dyn 1800 analyzer (2) Later during the survey, the surveyor reviewed the manufacturer's environmental requirements for: (a) Blood collection tubes - required a room temperature 4-25 degrees C (Celsius) (i) BD Vaccutainer K2 EDTA (100 tubes of lot# 9260500) (3) The surveyor reviewed temperature records for 5 months (August 2019 through December 2019). It was identified that documented temperatures were warmer than 25 degrees C for 1 of 5 months as follows: (a) August 2019 - 3 of 31 temperatures were documented as warmer than 25 degrees C (Days 13,19,20); (4) The surveyor reviewed the records

	with the testing person who stated the materials had not been stored according to manufacturer's instruction.
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 testing person, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for 1 of 5 months. Findings include: (1) At the beginning of the survey, the testing person stated to the surveyor that CBC (Complete Blood Count) testing was performed on the Abbott Cell-Dyn 1800 analyzer; (2) Later during the survey, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The requirements for weekly maintenance were as follows: (a) Auto Clean (b) Clean Aspiration Probe Exterior (3) The surveyor then reviewed maintenance records for 5 months (August 2019 through December 2019). There was no evidence the weekly maintenance had been performed: (a) Between 01/02/19 and 11/06/19 (4) The surveyor reviewed the records with the testing person, who stated the maintenance had been performed but not documented as required.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, policy, and interview with the testing person, the laboratory failed to ensure the urine centrifuge was functioning properly for 1 of 2 years Findings include: (1) At the beginning of the survey, the testing person stated to the surveyor urine sedimentation testing was performed in the laboratory. The specimens were processed in the Druker Centrifuge Model 614V centrifuge at a speed of 1750 rpm (revolutions per minute) for 5 minutes; (2) The surveyor reviewed the centrifuge function check policy which required annual speed checks be performed on the centrifuge; (3) The surveyor reviewed the centrifuge maintenance records for 2018 and 2019. The speed had not been checked at the speed the urine specimens were processed, to ensure the centrifuge was functioning properly at that speed, for 1 of 2 checks performed as follows: (i) 07/01/19 - The speed had been checked at 1500 rpm and 2000 rpm. (4) The surveyor reviewed the findings with the testing person. The testing person stated the centrifuge speed had not been checked at the speed used to

	process urine specimens as indicated above. D5435 was cited on the recertification survey performed on 01/25/18.