Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0656628	03/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Seiling Municipal Hospital	809 Ne Hwy 60, Seiling, 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 03/13,14/2023. The laboratory was found in compliance with a standard-level deficiency cited. The findings were reviewed with the technical consultant, laboratory manager, and chief executive officer during an exit conference performed at the conclusion of the survey.
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, policies and procedures, and interview with the technical consultant and laboratory manager, the laboratory failed to define a written function check protocol to ensure the urine centrifuge was functioning properly for three of three function checks performed from December 2021 through November 2022. Findings include: (1) On 03/13/2023 at 10:55 am, the laboratory manager stated the following: (a) The laboratory performed urine microscopic testing; (b) The urine specimens were processed at a speed of 1500 rpm (revolutions per minute) for 5 minutes using the Select Medical Product PSS 602 centrifuge. (2) A function check protocol that defined the frequency of the urine centrifuge speed and timer checks and the acceptable limits for the checks could not be located; (3) During an interview on 03/14/2023 01:20 pm, the laboratory manager stated the laboratory did not have a written function check protocol but the centrifuge was checked by an outside

	biomedical company at least annually; (4) A review of the centrifuge maintenance records from December 2021 through November 2022 identified the following for three of three function checks: (a) 12/21/2021 - Although the timer had been checked, there was no documentation of the actual time obtained and the documenation stated, "pass"; (b) 05/06/2022 - There was no documentation the timer had been checked for accuracy; (c) 11/04/2022 - Although the timer had been checked, there was no documentation of the actual time obtained and the documenation stated, "acceptable". (5) The findings were reviewed with the technical consultant and laboratory manager. Both stated on 03/13/2023 at 01:50 pm, the laboratory did not have a written function check protocol for the urine centrifuge and the laboratory did not ensure the urine centrifuge was functioning properly as shown above.