

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0471800	(X3) Date Survey Completed 01/25/2018
Name of Provider or Supplier Dycus-Camp Clinic	Street Address, City, State 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 findings were reviewed with testing person #1 at the conclusion of the survey.
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with testing person #1, the laboratory failed to have a written function check protocol to ensure the centrifuge functioned properly. Findings include: (1) At the beginning of the survey, testing person #1 stated to the surveyor the laboratory performed microscopic urinalysis and patient urine specimens were centrifuged at a speed of 1750 RPM (Revolutions Per Minute) at a time of 5 minutes in the Model 614V centrifuge; (2) The surveyor reviewed the annual function check (speed and timer check) records from 2017 and 2018 for the centrifuge and identified the following information: (a) 02/05/17: (i) The speed was checked at 1500 RPM; (ii) The result of the check was 1550 RPM; (iii) There was no acceptable limits included on the form. (b) 01/22/18: (i) The speed was checked at 1500 RPM; (ii) The result of the check was 1540 RPM; (iii) There was no acceptable limits included on the form. (3) The surveyor observed the stickers on the centrifuge from the function checks listed above. A speed of 1500 RPM was checked instead of 1750 RPM, the speed used by the laboratory for centrifuging urine samples. In addition, the stickers not did include the acceptable</p>

limits for the speed function check result; (4) The surveyor then reviewed the laboratory policy and procedure manual but could not locate a policy/procedure for performing centrifuge function checks. The surveyor asked testing person #1 how the acceptability of the function checks was determined. Testing person #1 explained the technician who performed the checks would document on the record if the results were unacceptable; (5) The surveyor asked testing person #1 if the laboratory had a written function check protocol for the urine centrifuge, which included the speed to be checked and included acceptable limits for the speed and timer function checks. Testing person #1 explained a function check protocol had been written but could not be located.