

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0443032	(X3) Date Survey Completed 06/17/2021
Name of Provider or Supplier Liberty Clinic, The	Street Address, City, State 2609 Glenn Hendren Dr, Liberty, MO	
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
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 observation of the urinalysis centrifuge, review of 2019/2020/2021 function check records, and interview with the technical consultant (TC) #2, the laboratory failed to define a protocol to verify the urine centrifuge was operating at the appropriate speed for obtaining urine sediment for microscopic examination. Findings: 1. Observation of the urinalysis centrifuge showed the centrifuge was operating at a speed of 2500 RPMs. 2. Review of function check records showed no documentation to show the laboratory verified the urine centrifuge speed of 2500 RPMs. 3. Interview with TC #2 on June 16, 2021 at 10:00 AM confirmed the laboratory failed to define a protocol to verify the RPMs required for obtaining urine sediment.</p>
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently</p>

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on review of the 2019/2020/2021 proficiency testing (PT) records and interview with the technical consultant (TC) #2, the laboratory director failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: 1. Review of the hematology/coagulation PT records for the third PT testing event of 2020 showed the laboratory obtained a "not graded" result for urine sediment, sample US-06. The laboratory could not provide documentation to show appropriate staff evaluated the "not graded" results to identify any problems that may require corrective action. 2. Interview with TC #2 on June 16, 2021 at 10:00 AM confirmed, the laboratory director failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.