

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0045936	(X3) Date Survey Completed 11/19/2019
Name of Provider or Supplier University Of Central Missouri Health Care Center	Street Address, City, State 600 South College Street, Warrensburg, 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
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on microscope maintenance and interview with the technical consultant the laboratory failed to establish maintenance protocol for the microscope. Findings: 1. Review of microscope showed no documentation of maintenance for 2018 to date November 19, 2019. 2. Interview with the technical consultant on November 19, 2019 at 11:00 AM confirmed the laboratory failed to establish maintenance protocol for the microscope.</p>
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of quality control (QC) procedures and interview with the technical consultant, the laboratory failed to perform a positive and negative control each day of testing for moderately complex human chorionic gonadotropin(HCG) kit testing. Findings: 1. Review of QC procedures for HCG kit testing showed the laboratory allowed usage of serum or urine for HCG. This changed the kits from waived complexity to moderate complexity. Review of the QC documentation revealed the laboratory failed to perform a positive and negative external control each day of testing. 2. Interview with the technical consultant on November 19, 2019 at 11:00 AM confirmed, the laboratory did not test a positive and negative control each day of serum HCG testing.