

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D1045334	(X3) Date Survey Completed 10/12/2018
Name of Provider or Supplier Urology Central, Pc	Street Address, City, State 50 Memorial Dr Ste 108, Leominster, MA	
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	A CLIA recertification survey was conducted for the Urology Central laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
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 record review and interview, the laboratory failed to maintain documentation to verify that maintenance protocols were followed to ensure equipment performance is reliable for accurate test results as evidenced by the following: a) The office manager stated in an interview that microscope maintenance would take place annually. b) Quality control record review for calendar years 2017 and 2018 revealed no documentation available for the two years reviewed to confirm that the microscope was serviced in accordance with laboratory protocol. c) The office manager confirmed in an interview on 10/12/18 at 10:05 AM that the microscope had been been serviced for the last two years but did not maintain documentation to verify this fact..</p>