

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0391679	(X3) Date Survey Completed 04/19/2018
Name of Provider or Supplier Reproductive Medicine Center	Street Address, City, State W129 N7055 Northfield Dr, Menomonee Falls, WI	
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 surveyor review of procedures and maintenance documents, and interview with the technical supervisor, annual microscope maintenance was not performed in 2016 as required by the laboratory's procedures. Findings include: 1. Review of the laboratory's Quality Control Policies and Procedures shows microscope maintenance by an outside vendor is required annually. 2. Review of microscope maintenance records from 2015 through 2017 showed no record of annual maintenance for 2016. 3. Interview with the technical supervisor, staff A, on April 19, 2018 confirmed annual microscope maintenance was not performed in 2016.</p>