

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0934854	(X3) Date Survey Completed 06/20/2019
Name of Provider or Supplier Advanced Reproductive Medicine	Street Address, City, State 10777 Nall Avenue, Suite 200, Overland Park, KS	
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: Review of 2018 and 2019 thermometers records, and interview with laboratory director on June 20, 2019 at 1130 reveals that the laboratory fails to define a function check protocol for the thermometers used for temperature monitoring. The director stated that she had no records of function check for the thermometers used in the laboratory for the past two years.</p>