

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0389833	(X3) Date Survey Completed 01/31/2019
Name of Provider or Supplier West Suburban Center For Arthritis	Street Address, City, State 601 N Barker Rd Ste 110, Brookfield, 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
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the "Verification Report and Data" reports for the QUANTA Lyser automated processor and interview with the technical supervisor, the laboratory did not perform and document the function checks required by the manufacturer after the verification performed on May 14, 2018 expired on September 29, 2018. Findings include: 1. Review of the QUANTA Lyser "Verification Report and Data" reports showed the most recent record available was from testing performed on May 14, 2018. The report shows the results expired on September 29, 2018. 2. Interview with the technical supervisor on January 31, 2019 at 12:30 PM confirmed no records were available showing the laboratory completed the manufacturer's required function checks for the QUANTA Lyser processor since May 14, 2018.</p>