

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2063316	(X3) Date Survey Completed 08/28/2020
Name of Provider or Supplier Spiriplex, Inc	Street Address, City, State 100 Tri State International, Ste 100, Lincolnshire, IL	
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 direct observation, record review and an interview with the testing personnel (TP) and Owner, the laboratory failed to establish a maintenance protocol to check the accuracy of all equipment used in General Immunology testing. Findings: 1. On 08/28 /20 at 10:20 AM during a tour of the laboratory, the surveyor observed a 2 table top centrifuges: S/N-1931501462 and S/N-216765, used by the TP. 2. The laboratory's procedures' manual and maintenance logs were reviewed. 3. The procedures' manual failed to include in it's maintenance policy the servicing and calibrating of the 2 (two) centrifuges. 4. The maintenance logs showed the 2 centrifuges had not been serviced or calibrated for accuracy during the years of 2018 through 2020. 5. On a recertification survey conducted 08/28/20 at 1:00 PM, the TP and Owner confirmed the above findings.</p>