

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  07D2060101	<b>(X3) Date Survey Completed</b>  10/15/2019
<b>Name of Provider or Supplier</b>  Bioreference Laboratories, Inc	<b>Street Address, City, State</b>  1 Perryridge Rd, Greenwich, CT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5431</b>	<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 record review and staff interview, the laboratory failed to document centrifuge function checks every 6 months to ensure platelet poor plasma (PPP) is obtained. Findings include: 1. Record review on 10/15/19 of the laboratory's procedure manual revealed PPP procedure must be performed semi-annually and recorded in the centrifuge maintenance binder. 2. Record review on 10/15/19 of the laboratory's centrifuge maintenance records revealed: a. The above procedure is not followed and documentation for semi-annual PPP is not available for the 'special coagulation' centrifuge with serial number: 610814-16. b. The last documented PPP function check was performed for the above centrifuge in September 2017. 3. Staff interview with the technical consultant (TC) on 10/15/19 at 10:20 AM, confirmed the above findings. 4. Staff interview with the phlebotomist on 10/15/19 at 10:20 AM confirmed the above centrifuge is used to spin special coagulation samples on a weekly basis.</p>