

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 43D0407466	<b>(X3) Date Survey Completed</b> 08/14/2018
<b>Name of Provider or Supplier</b> Sanford Chamberlain	<b>Street Address, City, State</b> 300 South Byron Boulevard, Chamberlain, SD	
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>D0000</b>	A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 8/13/18 through 8/14/18. The Sanford Chamberlain laboratory was found not in compliance with the following requirement: D5435.
<b>D5435</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> 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: Based on review of the immunohematology maintenance records, annual test volume survey form, and interview with the laboratory supervisor, the laboratory failed to calibrate the bloodbank centrifuge to ensure proper centrifugation and accurate interpretation of the ABO Rh typing and immediate spin crossmatch test methods. Findings include: 1. Review of the immunohematology maintenance records revealed the bloodbank centrifuge had been calibrated 7/21/16 to determine the combination of speed and timing of the bloodbank centrifuge to ensure an optimum blood cell dot formation had been formed. That test method had been used as part of the ABO RH typing and immediate spin crossmatch procedure for determining patient blood type and compatibility with donor blood units. There was no documentation the centrifuge had been calibrated since that date. Review of the annual test volume survey form revealed 214 ABO Rh blood typings and 150 immediate spin crossmatches had been performed on patient specimens during 2017. Interview with the laboratory supervisor</p>

at 8:20 a.m. on 8/14/18 revealed the centrifuge calibration to determine optimum timing and speed was normally completed in August of each year. He was not sure why there was no documentation for the August 2017 calibration. The calibration had not yet been performed for 2018.