

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 43D0406780	<b>(X3) Date Survey Completed</b> 05/10/2022
<b>Name of Provider or Supplier</b> Brookings Health System	<b>Street Address, City, State</b> 300 22nd Avenue, Brookings, 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 5/10/22. The Brookings Health System 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 record review and interview, the laboratory failed to calibrate one of one centrifuges (blood bank serofuge) to ensure proper centrifugation and accurate interpretation of the ABO and Rh blood typing test methods. Findings include: 1. Review of the immunohematology maintenance records revealed no documentation the blood bank serofuge had been calibrated to determine the combination of speed and timing to ensure an optimum blood cell dot formation in 2021 or to date in 2022. That test method had been used as part of the ABO and RH blood typing procedures used to determine a patient's blood type. Review of the laboratory's Calibration of Blood Bank Serofuge standard operating procedure, last signed by the laboratory director on 5/2/21 revealed: *Purpose: The duration of centrifugation will affect agglutination. An inadequate time may result in insufficient packing and false negative results. Excessive centrifugation may cause the red cells to be packed so tightly that pseudoagglutination results or resuspension may be so difficult that weak</p>

reactions are dispersed." \*"Interpretation; The optimal time of centrifugation is that at which the strongest reaction is obtained with positive cells, a clear cut negative reaction is obtained with negative cells..." Review of the annual test volume survey form revealed 973 ABO and 961 Rh blood typing had been performed on patient specimens during 2021. Interview with the laboratory supervisor on 5/10/22 at 1:40 p. m. revealed: \*She confirmed the serofuge had been used for centrifuging patient ABO and Rh blood typing specimens. \*She confirmed the serofuge had last been calibrated in 2013 when it was first placed into use. \*She was unaware the serofuge needed to be calibrated on an annual basis.