

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 43D0407393	<b>(X3) Date Survey Completed</b> 07/13/2021
<b>Name of Provider or Supplier</b> Sanford Hospital Webster	<b>Street Address, City, State</b> 1401 West 1st Street, Webster, 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 7/13/21. The Sanford Hospital Webster 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 observation, record review and interview the laboratory failed to retain the results of the daily background checks on the Abbott Cell Dyn Ruby analyzer for eight of twenty four months (7/13/19 through 3/6/20) to ensure critical operating characteristics that affected the stability of the analyzer met specific criteria defined by the manufacturer. Findings include: 1. Observation on 7/13//21 at 11:10 a.m. of the Abbott Cell Dyn Ruby hematology analyzer's electronic files revealed: *Laboratory personnel A was able to pull up a record of the analyzer's electronic files. *The oldest retained daily background check was dated 3/7/20. * Daily background counts prior to 3/7/20 were unavailable. *There was no way to verify if the background counts prior to 3/7/20 had been acceptable. *Increased background counts could lead to inaccurate patient specimen test results. Interview with the laboratory personnel A on 7/13/21 at 11:10 a.m. revealed: *She verified daily background counts had not been printed out or maintained. *She was unaware the Abbott Cell Dyn Ruby hematology analyzer's</p>

memory was not sufficient to maintain the required 2 years of background counts.  
\*No other log or spreadsheet was available to document the daily background test results.