

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  43D0407349	<b>(X3) Date Survey Completed</b>  05/17/2022
<b>Name of Provider or Supplier</b>  Sanford Deuel County Medical Center	<b>Street Address, City, State</b>  701 3rd Avenue South, Clear Lake, 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 5/17/22. The Sanford Deuel County Medical Center laboratory was found not in compliance with the following requirements: D5481 and D6028.
<b>D5481</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure quality control (QC) results met established acceptability criteria before reporting patient test results for 11 of 30 days (4/14/22 through 4/25/22) reviewed. Findings include: 1. Review on 5/17/22 of the laboratory's daily QC records for the month of April 2022, revealed: *The laboratory used the Abbott Cell-Dyn Emerald analyzer for the testing of patient hematology specimens. *Three levels of control (low, normal, and high) had been run each day of patient testing to ensure the accuracy of patient specimen results prior to reporting. *Hematology control results had been printed after each run. QC values outside the acceptable were printed in bold with a comment code ( L-below the acceptable range and H-above the acceptable range). *Abbott Cell-Dyn Systems Hematology control Lot number 2038, expiring 5/27/22, had been the controls in use. *The laboratory had accepted the manufacturer's stated package insert ranges for acceptability. *The Abbott Cell Dyn Hematology Control manufacturer's package insert acceptable ranges had been: -Low control red blood cell (RBC) count 2.0-2.8 million per cubic milliliter (/cml). -Normal control white blood cell (WBC) count 7.5-9.5 thousand/cml. -Normal control RBC count 4.05-4.55 million/cml. -High control WBC count 15.5-20.5 thousand/cml. -High control RBC count 4.98-5.58 million/cml.</p>

\*There had been 12 consecutive days when QC was out of acceptable range. \*On 4/14/22 the control reports revealed: -The normal control had been analyzed 4 times. --RBC results had been 4.83, 4.77, and 4.74 million/cml. -The high control had been analyzed 3 times. --RBC results had been 4.88, 4.89, and 4.89 million/cml. -There had been no corrective action documented. \* On 4/15/22 the control reports revealed: -The high control had been analyzed 3 times. --RBC results had been 4.83, 4.77, and 4.74 million/cml. -Corrective action documentation included "new sample" after the first unsuccessful run and "bleach clean" after the second unsuccessful run. There had been no corrective action documentation after the third run. \*On 4/16/22 the control reports revealed: -The high control had been analyzed once. --RBC result had been 4.91 million/cml. -There had been no documentation of corrective action taken. \*On 4/17/22 the control reports revealed: -The normal control had been analyzed twice. --RBC results had been 4.00 and 3.92 million/cml. -The high control had been analyzed twice. --RBC results had been 4.88 and 4.90 million/cml. -There had been no documentation of corrective action taken. \*On 4/18/22 the control reports revealed: -The normal control had been analyzed once. --RBC result had been 3.87 million/cml. -The high control had been analyzed once. --RBC result had been 4.88 million/cml. -There had been no documentation of corrective actions taken. \*On 4/19/22 the control reports revealed: -The low control had been analyzed once. --RBC result had been 1.94 million/cml. -The normal control had been analyzed four times. --RBC results had been 3.77, 3.79, 3.76, and 3.80 million/cml. -The high control had been analyzed twice. --RBC results had been 4.63 and 4.79 million/cml. -There had been no documentation of corrective actions taken. \*On 4/20/22 the control reports revealed: -The normal control had been analyzed once. --WBC result had been 7.4 thousand/cml. --RBC result had been 3.94 million/cml. -The high control had been analyzed once. --RBC result had been 4.79 million/cml. -There had been no documentation of corrective actions taken. \*On 4/21/22 the control reports revealed: -The low control had been analyzed once. --RBC result had been 2.00 million/cml. -The normal control had been analyzed twice. --RBC results had been 3.86 and 3.81 million/cml. -The high control had been analyzed twice. --RBC results had been 4.93 and 4.74 million/cml. -Corrective action documentation had been "after bleach clean" after the second unsuccessful run. There had been no other corrective action documented. \*On 4/22/22 the control reports revealed: -The high control had been analyzed once. --RBC result had been 4.92 million/cml. -There was no documentation of corrective actions taken. \*On 4/23/22 the control reports revealed: -The low control had been analyzed once. --WBC result had been 1.9 thousand/cml. -The normal control had been analyzed once. --WBC result had been 7.2 thousand/cml. --RBC result had been 3.88 million/cml. -The high control had been analyzed once. --WBC result had been 15.3 thousand/cml. --RBC result had been 4.84 million/cml. -There had been no documentation of corrective actions taken. \*On 4/24/22 the control reports revealed: -The normal control had been analyzed once. --RBC result had been 3.98 million/cml. \*On 4/25/22 the control reports revealed: -The low control had been analyzed once. --WBC result had been 1.9 thousand/cml. --RBC result had been 3.94 million/cml. -The normal control had been analyzed once. --WBC result had been 7.1 thousand/cml. --RBC result had been 4.90 million/cml. -The high control had been analyzed twice. --WBC results had been 15.4 and 15.4 thousand/cml. --RBC results had been 4.88 and 4.90 million/cml. \*The Abbott Cell-Dyn Emerald analyzer had been calibrated on 4/25/22. The QC results after the calibration had been within acceptable ranges. Review on 5/17/22 of the laboratory's Hematology-Emerald-Clear Lake policy, last revised on 3/2/22, revealed: \*"Control Procedures: Controls are used to determine whether an instrument is operating with accuracy and precision. Run a minimum of three levels of control at the beginning of each day of operation prior to running patient samples. Quality Control (QC) procedures are performed at a frequency needed to monitor

system results trueness. Quality Control procedures, both internal and external, allow the operator to verify the performance of the analytical systems. Evaluation of results from commercial and patient controls facilitates the interpretation of laboratory data to determine the acceptability of patient results." \*The modified Westgard Rules available on the Cell-Dyn Emerald system are: Rule 1: Value outside 3 SD [standard deviations]: A control result exceeded the mean  $\pm$ 3 SD. Rule 2: Two consecutive values outside the same 2 SD: Two consecutive results fell outside 2 SD on the same side of the mean. Rule 3: Two consecutive values outside opposite 2 SD: One result was greater than 2 SD above the mean and the next result was greater than 2 SD below the mean; consequently, the range between the results is greater than 4 SD. Rule 4: Two of three consecutive values outside the same 2 SD: on the same side of the mean. Rule 5: Four consecutive values outside the same 2 SD: Four consecutive results fell outside 2 SD on the same side of the mean." \*Since three levels of control are typically used to monitor a hematology analyzer, it is reasonable to consider all three runs at the same time. In other words, check for the rule violations across the three levels, not just within a particular level. If the same rule is violated at more than one level, determine whether the violation indicates a loss of precision or a loss of accuracy, and troubleshooting accordingly. Document troubleshooting and do not run patient specimens before controls are running within range." Interview on 5/17/22 at 11:15 with laboratory personnel A revealed: \*She confirmed the WBC and RBC QC had been outside of the acceptable control ranges from 4/14/22 through 4/25/22. \*She confirmed she had been aware the QC had been outside the acceptable ranges. She had been "Watching it". \*She had been aware the appropriate corrective actions had not been taken or documented for the out of acceptable range QC values. \*She confirmed patient WBC and RBC specimens had been reported to providers on the days QC was outside of the acceptable range. \*She had not notified the providers if QC had been out of range. \*She stated the laboratory normally had a calibrator available for use in case it was necessary to recalibrate the analyzer. \*There had not been a calibrator available in the laboratory. \*She had ordered a new calibrator for the Cell- Dyn Emerald. It had taken approximately 4 days to receive the new calibrator. \*The Cell- Dyn Emerald had been recalibrated once the new calibrator had arrived.

**D6028**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(10)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

This STANDARD is not met as evidenced by:  
Based on record review and interview, the laboratory director failed to ensure competency evaluations for one of six laboratory staff (A) were completed by qualified personnel (their credentials had not been reviewed to determine if they had been qualified to serve as a technical consultant) for the nonwaived test methods they had performed under the laboratory's Clinical Laboratory Improvement Amendments (CLIA) certificate. 1. Review of the personnel file for laboratory staff A revealed her competency assessments were completed on 7/23/19, 7/27/20 and 9/30/21 by

laboratory staff B. There was no indication the laboratory director was involved in the competency assessment process. Review of the Center for Medicare and Medicaid Services 209 Laboratory Personnel Report Form signed by the laboratory director on 5/16/22 revealed that laboratory staff A and C were listed as technical consultants. Laboratory staff B was listed only as testing personnel and not a technical consultant. Interview on 5/17/22 at 10:40 a.m. with laboratory staff A revealed: \*She confirmed that laboratory staff B had completed her competency assessments. \*She was aware laboratory staff B had not been qualified under CLIA regulations as a technical consultant and therefore should not have performed the employee competency assessments. \*She revealed the laboratory competency assessment policy was in development, but had not been signed by the laboratory director. The laboratory director was unavailable for interview at the time of the survey.