

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0465446	(X3) Date Survey Completed 12/02/2021
Name of Provider or Supplier Bradley County Medical Center	Street Address, City, State 404 South Bradley Street, Warren, AR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5431	<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: Through review of maintenance and background count records for the Sysmex XN 1000 analyzers serial numbers 30598 and 30523 and interview with laboratory staff members it was determined that the laboratory did not follow the protocol for daily maintenance and background counts as prescribed to ensure the accuracy of complete blood cell counts (CBC) in one of one month reviewed. Findings follow: A) Review of the maintenance and background count records for the Sysmex XN 1000 analyzers, serial numbers 30598 and 30523, conducted on December 2, 2021 at 10:00 AM revealed that daily maintenance and background counts were recorded for both analyzers for the dates of 12/1/21, 12/2/21, 12/3/21, 12/4/21, 12/5/21 and 12/6/21. B) In an interview on 12/2/21 at 10:00 AM the laboratory staff member, identified as number thirteen on the CMS 209 form, when asked what the current date was replied December 2nd, and that they have no idea why maintenance and background counts were recorded for the dates of 12/3/21 through 12/6/21.</p>
D5555	<p>IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f)</p> <p>(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the</p>

alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Through review of Bradley County Medical Center records of continuous temperature monitoring system, back-up thermometer temperatures recorded every four hour by laboratory personnel and interview with laboratory staff, it was determined that the blood bank freezer, used for the storage of fresh frozen plasma (FFP), failed to maintain the required temperature of equal to or below -18 degrees C. on one of one month reviewed. Findings follow: A) Review of the Bradley County Medical Center records of continuous temperature monitoring system for the month of November 2020 revealed that the upper limit was defined as -14 Degrees C. and the temperature was recorded as warmer than -18 degrees C. on 111 occasions. B) Review of the back-up thermometer temperature records monitored every four hours by laboratory personnel for the blood bank FFP freezer revealed that temperatures were recorded as greater then - 18 degrees C. on 77 of 210 documented recordings in November 2020. C) In an interview on 12/2/21 at 01:00 PM the laboratory staff member, identified as number thirteen on the CMS 209 form, stated that the laboratory did not participate in the determination of acceptable ranges set in the automated temperature and humidity monitoring system, that the acceptable ranges for some parameters measured by the system were incorrect, that it was not known if the automated system was monitored and if policies and procedures required that laboratory personnel be notified if acceptable ranges were exceeded and that temperature in the blood bank freezer exceeded acceptable limits on the occasions identified above.