

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 47D0090944	(X3) Date Survey Completed 11/16/2023
Name of Provider or Supplier Grace Cottage Hospital	Street Address, City, State 185 Grafton Rd, Townshend, VT	
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
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on observations, record review, and staff interview, the laboratory failed to meet analytic systems requirements for Immunohematology in 2023. Refer to D5555.</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 alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and staff interview the laboratory (lab) failed to ensure red blood products were stored with an adequate temperature alarm system in 2023. Findings include: 1. Review on 11/16/2023 of the lab's policy titled "Blood Bank: Protocol for the Blood Bank Alarm System" last revised 6/27/23 revealed the</p>

blood bank refrigerator (BB Frig) will alarm when the temperature falls outside 1.5 - 5.5 degrees Celsius. 2. Observation on 11/16/2023 at 9:00 a.m. of the BB Frig revealed it is used to store red blood cell products and the switch was not turned to the on position for the audible alarm. Further observation during a test of the alarm system on 11/16/23 at 9:00 a.m. revealed no alarm was activated outside the lab after the simulated temperature rose above 5.5 degrees Celsius. Another temperature probe was selected for a simulated temperature alarm test at 9:05 a.m.; this probe is used for the hospital's electronic temperature recording system (Sensoscientific). 3. Review on 11/16/2023 of the Sensoscientific temperature log for the BB Frig revealed temperatures were recorded every 15 minutes. The temperature after the alarm test for the BB Frig was not recorded until 9:12 a.m. and displayed a warning and indication that the alarm was delayed for 10 minutes before initiating notification. Further review of this log revealed the temperature would not alarm unless the recorded temperature fell outside 1-6 degrees Celsius. With the temperature logged every 15 minutes and a 10 minute delay, blood products could be stored outside the acceptable temperature for 25 minutes before the alarm is activated and notification has taken place. 4. Observations on 11/16/2023 revealed notification by phone from the hospital registration desk was first received by the lab at 9:24 a.m. and a page for the temperature alarm was first received on the lab's pager at 9:54 a.m. 5. Review of alarm checks for the BB Frig revealed it was last checked and passed the check on 6 /21/2023. 6. Interview on 11/16/2023 at 11:30 a.m. with the General Supervisor confirmed the above findings. The GS revealed the lab was not aware the primary alarm bell was taken out of service during renovation after the last alarm check.