

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2176291	(X3) Date Survey Completed 09/03/2020
Name of Provider or Supplier Thomasville Regional Medical Center	Street Address, City, State 300 Medical Park Drive, Thomasville, AL	
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
D0000	An unannounced Complaint Survey (Intake #AL00039721) was conducted simultaneously with an Initial Survey for Thomasville Regional Medical Center on 9/2 and 9/3/2020. None of the complaint allegations were substantiated. The two deficiencies cited were related to non-compliance issues discovered during the Initial Survey reviews. .
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 a review of Blood Bank policies and procedures, an interview with the General Supervisor, and a lack of documentation for periodic alarm checks of the Blood Bank refrigerator (where blood products are routinely stored), the surveyor determined the laboratory failed to perform procedures to ensure the refrigerator would emit an audible alarm if temperatures were too low for safe storage of the blood products therein. This affected one of one refrigerators, used for storage of blood and blood products. The findings include: 1. A review of the Blood Bank procedures, "Equipment QC [Quality Control] Protocol" and "Blood Bank Refrigerator Maintenance", revealed checks of the Blood Bank refrigerator alarm should be performed monthly. 2. During an interview on 9/3/2020 at 11:20 AM, the surveyor asked for documentation of the monthly alarm checks. The General Supervisor explained the laboratory had routinely performed checks of the high temperature alarm by leaving the refrigerator door open. However, the laboratory had</p>

not checked the low temperature alarm (by placing the temperature probe in ice water, as per procedure) since the hospital began patient testing in March 2020. .

D6045

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(7)

(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:
Based on a review of personnel records, and an interview with the Laboratory Supervisor, the surveyor determined the Technical Consultant (also the Laboratory Director) failed to ensure training documentation was complete for four out of eight Testing Personnel performing moderate-complexity testing. The findings include: 1. A review of Testing Personnel (TP) training records revealed incomplete documentation as follows: A) TP #3: Sysmex CS-2500-Not signed by the Laboratory Supervisor Access 2, DxH, and DxC-700-No Trainer initials specified B) TP #5: DxH-No training dates or trainer initials specified DxC-700 Access 2-No training dates specified C) TP #6: DxC and some Access 2 training initialed by TP #5 (whose own training was not properly documented) D) TP #9: DxH-No trainer initials specified Access 2-No training dates or trainer initials specified 2. During an interview on 9/2 /2020 at 2:30 PM with the Laboratory Supervisor, the surveyor reviewed and confirmed the above noted findings. SURVEYOR ID #32558 Licensure and Certification Surveyor