

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0651950	(X3) Date Survey Completed 04/08/2021
Name of Provider or Supplier Perry County General Hospital Lab	Street Address, City, State 206 Bay Avenue, Richton, MS	
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
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by:</p> <ol style="list-style-type: none"> 1. Based on review of quality control (QC) records for the Beckman Coulter Access 2 immunoassay system from 1/1/21 through 2/28/21 and manufacturer's acceptable ranges for MAS CardioImmune XL controls, Lot #CXL21121A and Lot #CXL21123A, the laboratory failed to document, as performed, the establishment of statistical parameters for acceptable ranges for myoglobin testing with the MAS CardioImmune XL controls. Findings include: Review of QC records for the Beckman Coulter Access 2 immunoassay system from 1/1/21 through 2/28/21 revealed MAS CardioImmune XL controls were in use for myoglobin testing during this time frame. Review of the manufacturer's acceptable ranges for MAS CardioImmune Controls, Level 1 Lot #CXL21121A and Level 3 Lot #CXL21123A, revealed no acceptable range for myoglobin testing on the Beckman Coulter Access 2 immunoassay system. On the day of the survey, 4/7/21, there was no documentation of the establishment of statistical parameters for the myoglobin ranges listed on the

Access 2 QC records. 2. Based on review of QC records for the Beckman Coulter AU480 chemistry system from 1/1/21 through 2/28/21 and manufacturer's acceptable ranges for BioRad Liquid Assayed Multiquel Premium controls, Level 1 Lot #86921, Level 2 Lot #86922, and Level 3 Lot #86923, the laboratory failed to document, as performed, the establishment of statistical parameters for acceptable ranges for prealbumin testing with the BioRad Liquid Assayed Multiquel Premium controls. Findings include: Review of QC records for the Beckman Coulter AU480 chemistry system from 1/1/21 through 2/28/21 revealed BioRad Liquid Assayed Multiquel Premium controls were in use for prealbumin testing during this time frame. Review of the manufacturer's acceptable ranges for BioRad Liquid Assayed Multiquel Premium controls, Level 1 Lot #86921, Level 2 Lot #86922, and Level 3 Lot #86923, revealed no acceptable range for prealbumin testing on the Beckman Coulter AU480 chemistry system. On the day of the survey, 4/7/21, there was no documentation of the establishment of statistical parameters for the prealbumin ranges listed on the AU480 chemistry system QC records. THIS IS A REPEAT DEFICIENCY.

D5555

IMMUNOHEMATOLOGY
CFR(s): 493.1271(c)(f)

(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.

This STANDARD is not met as evidenced by:
Based on review of blood bank refrigerator continuous-monitoring temperature recorder graphs, blood bank refrigerator temperature logs, and blood bank transfusion records from 9/10/18 through 3/31/21, the laboratory failed to ensure blood for transfusion was stored under appropriate conditions for sixty-five weeks during this time frame, when the blood bank refrigerator temperature was not recorded on the graphs. Findings include: Review of blood bank refrigerator continuous-monitoring temperature recorder graphs from 9/10/18 through 3/31/21 revealed the blood bank refrigerator temperature was not recorded on the blank graphs for the following weeks: 2019 March 11 & 18; May 13 & 20; June 3, 17, & 24; July 2, 16, 23, & 30; August 1, 8, 15, & 22; November 12, 19, & 26. 2020 February 5 through March 18; April 1 through May 27; June 24 through August 12; September 9, 16, 30; October 7 & 28; November 4, 18, & 25; December 2, 9, & 23. 2021 January 6 through February 24; March 3, 17, 24, & 31. Review of the blood bank refrigerator temperature logs from 9/8/18 through 3/31/21 revealed the temperature of the blood bank refrigerator was manually recorded on the logs only once per day, which does not ensure continuous storage under appropriate conditions.

D6123

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on review of blood bank refrigerator continuous-monitoring temperature recorder graphs, blood bank refrigerator temperature logs, and blood bank transfusion records from 9/10/18 through 3/31/21, the technical supervisor failed to detect the lack of temperature recording on the blank graphs for sixty-five weeks during this time frame. Findings include: Review of blood bank refrigerator continuous-monitoring temperature recorder graphs, blood bank refrigerator temperature logs, and blood bank transfusion records from 9/10/18 through 3/31/21 revealed the technical supervisor documented review of the weekly temperature recorder graphs from 9/10/18 through 3/31/21, along with blood bank maintenance records, but failed to detect the lack of temperature recording on the blank graphs for sixty-five weeks during this time frame. Refer to D5555 (Failure to ensure blood for transfusion was stored under appropriate conditions).