

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0442259	(X3) Date Survey Completed 01/16/2025
Name of Provider or Supplier Pemiscot Memorial Health Systems	Street Address, City, State 946 E Reed St, Hayti, MO	
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>(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(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. (d)(10)(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. (d)(10)(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Dimension EXL 200 chemistry analyzer quality control (QC) records, review of assayed QC for 2 of 51 analytes on the Dimension EXL 200 chemistry analyzer, and interview with the general supervisor (GS) #2, the laboratory failed to document how criteria was established for acceptability of control materials providing quantitative results. Findings: 1. Review of the Dimension EXL 200 QC records showed the laboratory used assayed Thermo Scientific MAS ChemTrak and Thermo Scientific Omni-cardio QC. The laboratory could not show how they established, documented, and defined statistical parameter criteria (mean and standard deviations) for acceptability of quantitative chemistry QC when they had to change the ranges from the manufacturer's established ranges. 2. Review of assayed QC on the Dimension EXL 200 analyzer showed alkaline phosphatase level 1 QC standard deviation of 4.21 U/L. Thermo Scientific MAS ChemTrak manufacturer's package insert level 1 for alkaline phosphatase revealed a standard deviation of 3.9 U/L. The laboratory could not provide documentation for how alkaline phosphatase QC range was established. 3. Review of assayed QC on the Dimension EXL 200 analyzer showed troponin level 1 QC standard deviation of 2.46 pg/ml. Thermo Scientific</p>

MAS Omni-cardio manufacturer's package insert level 1 for troponin revealed a standard deviation of 1.44 pg/ml. The laboratory could not provide documentation for how troponin QC range was established. 4. Interview with the GS #2 on January 16, 2025 at 10:00 AM confirmed the laboratory failed to establish criteria for acceptability of control materials providing quantitative results.

D5545

HEMATOLOGY
CFR(s): 493.1269(b)(d)

(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed.

This STANDARD is not met as evidenced by:
Based on review of the Siemens Dade Innovin package insert, Sysmex CA-600 coagulation analyzer, and interview with the general supervisor (GS) #2, the laboratory failed to verify the correct International Sensitivity Index (ISI) value was being used for calculating the INR value. Findings: 1. Review of the Siemens Dade Innovin package insert lot #564631 expiration September 22, 2025 showed the ISI value as 1.05 for the Sysmex CA-600 analyzer. 2. Review of the Sysmex CA-600 coagulation analyzer showed the Siemens Dade Innovin lot# 564631 currently in use onboard the analyzer with an ISI value as 1.07. The laboratory was unable to provide documentation of when Siemens Dade Innovin lot# 564631 was put into use. 3. Interview with the general supervisor #2 on January 16, 2025, at 9:00 AM confirmed the laboratory failed to verify the correct ISI value was being used for calculating the INR value.