

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 26D0705327	<b>(X3) Date Survey Completed</b> 05/05/2026
<b>Name of Provider or Supplier</b> General John J Pershing Memorial Hospital	<b>Street Address, City, State</b> 130 E Lockling, Brookfield, MO	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5445</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(1)(2)(g)</p> <p>(d) 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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:</p> <p>This STANDARD is not met as evidenced by: Based on review of individualized quality control plan (IQCP) for the iSTAT 1 chemistry analyzer, December 2024 to date May 5, 2026 iSTAT quality control (QC), patient results and interview with the general supervisor (GS), the laboratory failed to ensure that the IQCP for the iSTAT 1 chemistry analyzer was followed for 1 of 18 months. Findings: 1. Review of Pershing Health System Laboratory IQCP for iSTAT 1 chemistry analyzer stated "Two levels of external control will be used once per new lot or shipment of test materials or MONTHLY or when recommended by manufacturer due to maintenance or repair". 2. Review of iSTAT 1 chemistry analyzer QC showed no QC was performed in March 2025. 3. Review of iSTAT 1 chemistry patient results showed 24 patient results in 2025. 4. Interview with the GS on May 5, 2026 at 10:00 AM confirmed the laboratory failed to ensure iSTAT 1 chemistry analyzer IQCP was followed.</p>
<b>D5535</b>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.1267(a)(d)</p>

(a) Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer.

This STANDARD is not met as evidenced by:

Based on review of Gem 5000 blood gas procedure, review of 2024/2025/2026 blood gas PVP calibrations, review of patient results, and interview with testing personnel #7, the laboratory failed to follow manufacturer's requirements for one of five PVP calibrations. findings: 1. Review of "Respiratory Care Services" procedure states "PVP samples are run every 6 months (December and June)". 2. Review of PVP calibrations showed only one calibration in 2025 for the analytes PCO<sub>2</sub>, pH and PO<sub>2</sub>. 3. Review of blood gas patient results for 2025 revealed 300 blood gas patients results reported. 4. Interview with testing personnel #7 on May 5, 2026 at 11:30 AM confirmed the laboratory failed to follow manufacturer's requirements for PVP calibrations in 2025.

**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, prothrombin time (PT) patient results, and interview with the general supervisor (GS), the laboratory failed to verify the correct International Sensitivity Index (ISI) value was being used for calculating the international normalized ratio (INR) value from May 2025 to date May 5, 2026. Findings: 1. Review of the current Siemens Dade Innovin package insert lot #564696 expiration September 30, 2028 showed the ISI value as 1.01 for the Sysmex CA-600 analyzer. 2. Review of the Sysmex CA-600 coagulation analyzer showed the Siemens Dade Innovin lot# 564667 onboard the analyzer with an ISI value as 1.04. The laboratory was unable to provide when lot #564667 was no longer in use, if other lot numbers were also used, and the date lot #564696 was put in use. 3. Review of PT patient results for 2025 showed 951 patients results reported. 3. Interview with the GS on May 5, 2026 at 11:30 AM confirmed the laboratory failed to verify the correct ISI value was being used for calculating the INR value.

**D5775**

**COMPARISON OF TEST RESULTS**

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

This STANDARD is not met as evidenced by:

Based on observation of laboratory analyzers, review of instrument comparisons for 2024, 2025 and to date 2026, review of Centers for Medicare and Medicaid Services Form 116 (CMS-116) annual test volumes and interview with the general supervisor (GS), the laboratory failed to have a system that twice a year evaluates and defines the

relationship between test results using different instruments in 2024. Findings: 1. Observation of the laboratory analyzers showed an iStat analyzer and Ortho Clinical Vitros 5600 chemistry analyzer, both analyzers perform chloride, creatinine, glucose, potassium, sodium, carbon dioxide, and blood urea nitrogen testing. 2. Observation of the laboratory analyzers showed a Sysmex XN-550 hematology analyzer and Sysmex XP-300 hematology analyzer, both analyzers perform white blood cell count, red blood cell count, hemoglobin, hematocrit, mean corpuscular volume, mean corpuscular hemoglobin concentration, platelet, mean platelet volume, percent lymphocyte, percent neutrophil, and red blood cell distribution width testing. 3. Observation of the laboratory analyzers showed a Triage analyzer and Ortho Clinical Vitros 5600 chemistry analyzer, both analyzers perform troponin and creatinine kinase myocardial band testing. 4. Review of instrument comparisons showed the laboratory had no documentation to evaluate and define the relationship between the iStat analyzer and Ortho Clinical Vitros 5600 chemistry analyzer, the Sysmex XN-550 hematology analyzer and the Sysmex XP-300 hematology analyzer and the Triage analyzer and Ortho Clinical Vitros 5600 chemistry analyzer in 2024. 5. Review of CMS-116 test volumes showed the lab performs approximately 46,200 hematology patient tests and 101,136 chemistry patient tests annually. 4. Interview with the GS on May 5, 2026 at 11:00 AM, confirmed the laboratory failed to have a system that twice a year evaluates and defines the relationship between test results using different instruments.

**D6086**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(3)(ii)

(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

This STANDARD is not met as evidenced by:  
Based on review of Gem 5000 blood gas analyzer verification procedures, review of patient results and interview with the testing personnel #7, the laboratory director failed to ensure the verification procedure for the Gem 5000 blood gas analyzer was performed after the analyzer was put back in service from an extended time out of service. Findings: 1. Review of the Gem 5000 blood gas analyzer verification procedure showed no accuracy, precision, and other pertinent performance characteristics performed for the analytes pH, PCO2, and PO2 after the analyzer was put back in service from an extended time out of service. The Gem 5000 was out of service from November 12, 2024 to February 19, 2025. 2. Review of blood gas patient results for 2025 revealed 300 blood gas patient results reported. 2. Interview with the testing personnel #7 on May 5, 2026 at 11:00 AM confirmed the laboratory director failed to ensure the verification procedure was performed on the Gem 5000 blood gas analyzer after analyzer was out of service for an extended time.

**D6102**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(12)

(e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

This STANDARD is not met as evidenced by:

Based on review of competencies and patient results and interview with the general supervisor (GS), the laboratory director failed to ensure initial and semi-annual training was performed on one of two new respiratory therapy testing personnel (TP) prior to testing patient specimens. Findings: 1. Review of competencies showed no initial training in August 2024 for TP #8. 2. Review of competencies showed no semi-annual training between August 2024 and August 2025 for TP #8. 3. Review of patient results showed the respiratory therapy department performed approximately 300 blood gas tests annually. 3. Interview with GS on May 5, 2026 at 12::00 PM confirmed the laboratory director failed to ensure initial and semi-annual training was performed on TP #8 prior to testing patient specimens.