

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0705327	(X3) Date Survey Completed 02/15/2018
Name of Provider or Supplier General John J Pershing Memorial Hospital	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of the blood bank procedure manual and interview with the general supervisor on February 15, 2018 at 3:00 PM confirmed, the procedure manual failed to include a step by step procedure for performing immediate spin crossmatch testing.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper</p>

storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on review of manufacturer's instructions, lack of documentation and interview with the general supervisor, the laboratory failed to define criteria consistent with manufacturer's instructions and document core laboratory temperature and humidity conditions for 2016, 2017 and to date 2018. Findings: 1. The manufacturer's instructions for the hematology analyzer reveals operating environment requirements for temperature must be between fifteen and thirty degrees Celsius and the relative humidity must be equal to or less than eighty percent. 2. No documentation was available to show the laboratory defined criteria consistent with the manufacturer's instructions for temperature and humidity conditions in the core lab. No documentation was available to show the laboratory monitored and documented temperature and humidity conditions. 3. Interview with the general supervisor on February 15, 2018 at 3:00 PM confirmed the laboratory failed to define criteria for temperature and humidity consistent with manufacturer's instructions and document those conditions.

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. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
Based on review on instrument comparison activities, lack of documentation and interview with the general supervisor, the laboratory failed to evaluate and define a relationship twice a year between analyzers performing comprehensive metabolic panel (CMP) and troponin testing for 2016 and 2017. Findings: 1. Review of instrument comparison activities revealed no documentation the laboratory evaluated and defined a relationship twice a year between the two Vitros 350 chemistry analyzers performing CMP testing and did not evaluate and define a relationship twice a year between the Architect and Biosite analyzers performing troponin testing. 2. Interview with the general supervisor on February 15, 2018 at 3:00 PM confirmed, the laboratory failed to evaluate, define relationship and document comparisons between the two instruments performing CMP and the two instruments performing troponin testing.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical

phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on review of personnel competency procedures and interview with the general supervisor on February 15, 2018 at 3:00 PM confirmed, the laboratory director failed to establish a procedure/method to assess eleven of eleven testing personnel for consistency who perform microscopic procedures for manual differentials and urine sediment examinations.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview with the general supervisor on February 15, 2018 at 3:00 PM confirmed, the technical supervisor failed to evaluate and document the performance/competency for one of eleven (testing person #1) testing personnel at least annually for 2017.