

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0722040	(X3) Date Survey Completed 11/07/2018
Name of Provider or Supplier Saint Francis Laboratory Poplar Bluff	Street Address, City, State 225 Physicians' Park Drive Suite 104, Poplar Bluff, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of Alere D-dimer procedure, D-dimer quality control (QC) logs and interview with the technical supervisor the laboratory failed to follow procedure and perform D-dimer QC one month in the last twelve months. Findings: 1. Review of Alere D-dimer procedure states "external QC is ran once every 30 days or with each new lot". 2. Review of D-dimer QC showed no QC was performed in the month of October 2018. 3. Interview with the technical supervisor on November 7, 2018 at 10:30 AM confirms the laboratory failed to follow D-dimer procedure.</p>
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p>

This STANDARD is not met as evidenced by:
 Based on observation of the blood bank multi-setting pipettor, lack of function check documentation and interview with the technical supervisor, the laboratory failed to define a function check protocol to ensure accurate performance of the pipettor.
 Findings: 1. Observation of the multi-setting blood bank pipettor showed it delivers 12.5, 25 and 50 microliters of fluid volume. The laboratory did not have documentation to show the laboratory verified the pipettor delivered the appropriate volumes. The laboratory did not have a written function check protocol to verify acceptable performance of the multi-setting blood bank pipettor. 2. Interview with the technical supervisor on November 7, 2018 at 11:30 AM confirmed the laboratory failed to verify accurate performance of the blood bank pipettor.

D5477

CONTROL PROCEDURES
 CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
 Based on review of quality control (QC) documents for bacteriology and interview with the technical supervisor the laboratory failed to check each batch of blood agar, MacConkey agar, chocolate agar and blood culture media for its ability to support growth and as appropriate, select or inhibit specific organisms for 2017 to date.
 Findings: 1. Review of QC logs showed the laboratory failed to check each batch of blood agar, MacConkey agar, chocolate agar and blood culture media for its ability to support growth and as appropriate, select or inhibit specific organisms. 2. Interview with the technical supervisor on November 7, 2018 at 10:30 AM confirmed the laboratory failed to check each batch of blood agar, MacConkey agar, chocolate agar and blood culture media for its ability to support growth and as appropriate, select or inhibit specific organisms.

D5481

CONTROL PROCEDURES
 CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
 Based on review of quality control (QC) and patient records for 2018, QC procedures and interview with the technical supervisor, the laboratory failed to ensure results of control materials meet the laboratory's limits of acceptability before reporting patient results. QC records for the ALT analyte showed level three QC material failed to meet acceptable criteria for 35 of 39 test runs during October / November 2018. Findings: 1. Review of QC records showed the laboratory established acceptable limits for ALT

of 192-251 U/L for lot number 45773 and entered the acceptable limits into the chemistry analyzer QC files. Instrument printouts from the chemistry analyzer revealed the QC for ALT level three, lot number 45773 failed to meet the laboratory's criteria for acceptability for 35 QC runs from October 2, 2018 through November 7, 2018. The printouts revealed the failed QC results obtained were less than 192 U/L (minimal acceptable value) and flagged as out of range for the 35 QC runs. 2. Review of QC procedures revealed the laboratory did not review, accept or reject QC results directly from the analyzer. The QC data is transmitted from the analyzer to the laboratory information system (LIS) for review by testing personnel and periodic review by the technical supervisor. The laboratory accepts or rejects all QC results from the LIS. Review of the QC graphs from the LIS showed acceptable limits stated in the LIS for QC level three lot number 45773 differed from those established by the laboratory. The QC limits (164-280 U/L) stated in the LIS exceeded those established by the laboratory and did not flag the QC results as unacceptable or "out of range." 3. Patient records retrieved by the technical supervisor showed the laboratory reported 1720 patient ALT results from October 2, 2018 through November 7, 2018. 4. Interview on November 4, 2018 at 11:30 AM, the technical supervisor said the QC ALT limits for lot number 45773 stated in the LIS differed from those established by the laboratory and were incorrect. Interview confirmed the results of QC level three for the ALT analyte failed to meet the laboratory's criteria for acceptability before reporting patient results

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on review of patient test reports, approved laboratory procedure manual and interview with the technical supervisor, the laboratory failed to ensure pertinent patient normal were available for interpretation. Findings: 1. The differences between normal values on patient test reports and those included in the approved procedure manual are as follows: Normal values included on patient test reports: Triglyceride (0-150 mg/dl) Iron (50-170 ug/dl) Ferritin (15-200 ng/ml) Creatine Kinase (26-192 U/L) CK-MB (0.-3.6 ng/ml) Troponin I (0.00-0.06 ng/ml) Vitamin D (10.8-54.7 ng/ml) Normal values included in the procedure manuals approved by the laboratory director: Triglyceride (0.0-200.0 mg/dl) Iron (65.0-175 ug/dl) Ferritin (22.0-415.0 ng/dl) Creatine Kinase (39-308 U/L) CK-MB (0.5-3.6 ng/ml) Troponin I (0.02-0.10) Vitamin D (10.8-54.8 ng/ml) 2. Interview with the technical supervisor on November 7, 2018 at 11:30 AM confirmed the normal values stated in the approved laboratory procedure manual differed from those included on the test reports.