Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0669076	12/06/2018
Name of Provider or Supplier	**Street Address, City, State**	
Saint Joseph Health System Inc D/B/A	701 Bob-O-Link Drive, Suite 100, Lexington, KY	

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
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on interview and record review of Chemistry proficiency testing results, the laboratory failed to attain a satisfactory score of a least eighty percent (80 %) on the Creatinine certified analyte. Findings include: 1. Record review on 12/06/18 at 10:35 AM, of Chemistry Proficiency Testing Results, revealed the laboratory scored a sixty percent (60 %) in the second testing event of 2017, and all five (5) analytes for that survey were below the peer group mean, suggesting a calibration problem. The Calibration was not part of the corrective action, and the survey samples were not repeated to verify if the error could be duplicated. The corrective action for the proficiency failure did not identify the cause of the failure. 2. Interview with staff on 12/06/18 at 1:30 PM, revealed the laboratory did not identify a source of error that would explain the failure, and the laboratory did not have a resource to investigate the problem any further.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a

	procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on staff interview and record on 12/06/2018, the laboratory failed to ensure that laboratory procedures were signed and dated prior to patient testing.(See D5401). The laboratory failed to record the humidity each day of testing. (See D5413) The laboratory failed to perform annual microscope maintenance. (See D5429) The laboratory failed to calibrate when the quality control was showing an upward trend. (See D5437)
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on staff interview, and review of the policy and procedure manual, on 12/06/18 at 1:30 PM, the laboratory failed to to ensure the policies and procedures used in the laboratory procedure manual were signed and dated by the Laboratory Director prior to patient testing. Findings include: 1. Review of the Saint Joseph Health System policy and procedure manual, revealed the Laboratory Director failed to sign nineteen (19) out of nineteen (19) procedures prior to placing the procedures in place. Several procedures had revisions or modifications to the procedure that were not signed or dated. In addition, the Quality Assurance Checklist included policy and procedure review; however, the Laboratory Director was not signing to indicate he had reviewed the monthly review. 2. Interview with staff on 12/06/18 at 1:00 PM, revealed the Laboratory Director did not have a system in place to ensure all policies and procedures were signed, and dated prior to patient testing and reporting. In addition, staff revealed the Laboratory Director did not have a system in place to ensure all modified procedures were signed and dated prior to patient testing and reporting.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on staff interview and record review of policy and procedure review on 12/06 /2018, the laboratory failed to include, Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection, Microscopic examination, including the detection of inadequately prepared slides. Control procedures. Reference intervals (normal values). Imminently life-threatening test results, or panic or alert values. The findings include: 1. Policy review conducted on 12/06/2018 at 10:00 AM revealed the laboratory did not have all the necessary procedural requirements for the procedure "Manual Differential and Slide Review". 2. Interview with the laboratory staff on 12/6 /2018 at 1:30 PM confirmed that the laboratory did not have a system in place to ensure that the policies and procedures contained all the necessary information needed to perform and report the test procedure.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper 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 staff interview and record review, on 12/06/18, the laboratory failed to monitor and document the humidity in the laboratory where the testing was performed from 12/15/16 through 12/05/18. Findings include: 1. Record review revealed the Manufacturer's Operations Manual for the Sysmex XS-1000 Analyzer lists an operating range for humidity for the Analyzer between thirty percent (30%) and eighty-five percent (85%). 2. Record review revealed the Manufacturer's Operations Manual for the Alpha Wassermann Analyzer, lists an operating range for humidity for the analyzer between thirty percent (20%) and eighty-five percent (85%). 3. Review of the Maintenance Log, revealed no documented evidence the humidity had been monitored and recorded from 12/15/16 through 12/05/18. 4. Testing personnel acknowledged in an interview on 12/06/18 at 11:05 AM, the Laboratory Director failed to have a system in place to ensure the humidity was monitored and documented daily.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory

	must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on staff interview and record review on 12/06/18, the laboratory failed to perform and document annual microscope maintenance from 12/15/16 through 12/05 /18. Finding include: 1. Record review on 12/06/18 at 9:18 AM, revealed there was no documented evidence of annual microscope maintenance. 2. Interview with the General Supervisor, on 12/06/18 at 1:30 PM, revealed the laboratory did not have a system in place from 12/15/16 through 12/5/18 to ensure microscope maintenance was performed and documented as required.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on staff interview, record review, and review of the Procedure Manual for the Sysmex XS-1000 Hematology Analyzer, the laboratory failed to perform and document calibration procedures in accordance with Manufacturer's Instructions. Findings include: 1. Review of the Operators Manual for the Sysmex XS 1000, revealed calibration was not required on a six (6) month interval, but was required if controls indicated an unusual trend or were outside of acceptable limits and could not be corrected by maintenance. The Peer Review Data for the Sysmex XS-1000, revealed a positive bias for all three (3) levels of controls for platelet counts from 02 /22/17 through 06/01/17. However, record review revealed calibration was not performed between 02/22/17 through 06/01/17. 2. Testing personnel acknowledged in an interview on 12/06/18 at 1:30 PM, the Laboratory Director failed to have a system in place to ensure the Sysmex XS-1000 Hematology Analyzer was calibrated when shifts or trends were observed in the quality control data that would suggest a positive or negative bias in the hematology results from 02/22/17 through 06/01/18.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on staff interview and record review of the Quality Assurance Checklist on 12 /06/18, the Laboratory Director failed to sign the monthly Quality Assurance Checklist from 12/15/16 through 12/05/18. Findings include: 1. Record review on 12 /06/18 at 12:05 PM, revealed a monthly Quality Assurance Checklist was completed and signed by the General Supervisor, but the Laboratory Director did not document his review of the Checklist from 12/15/16 through 12/05/18. 2. Staff acknowledged in an interview on 12/6/18 at 1:30 PM, the Laboratory Director did not have a system in place to document monthly Quality Assurance activities.
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 staff interview and record review on 12/06/18, the Technical Supervisor failed to perform annual performance evaluations (Annual Laboratory Competencies) using the six (6) required methods of assessments for testing personnel from 12/15/16 through 12/05/18 for three (3) of three (3) employees reviewed. Findings include: 1. Record review of the Annual Laboratory Competencies, revealed the Laboratory failed to perform competency assessments using all six (6) required methods of assessments for testing personnel. The required methods of assessment include: monitoring the recording and reporting of test results, review of worksheets, review of quality control results, review of proficiency test results, review of maintenance records, assessment of testing external proficiency testing samples, and assessing the skills for solving problems. 2. There was no documentation of Annual Laboratory Competencies for personnel listed as a General Supervisor from 12/15/16 through 12 /05/18. Record review revealed Personnel #1 was evaluated using zero (0) out of six (6) methods of assessment on 04/26/18 and 11/29/18. The review did not include any assessment for General Supervisor responsibilities. Record review revealed Personnel #2 was evaluated using two (2) out of six (6) methods of assessment on 10/31/17 and 11/30/18. The review did not include any assessment for General Supervisor responsibilities. Record review revealed Personnel #3 was evaluated on 12/01/17 using zero (0) out of six (6) methods of assessment, and 12/05/18 using two (2) out of six (6) methods of assessment. The review did not include any assessment for General Supervisor responsibilities. 3. Interview with the General Supervisor, on 12/06/18 at 09:43 AM, revealed the Laboratory Director failed to have a system in place to ensure annual evaluations were performed and documented using the six (6) methods of assessment for testing personnel and General supervisors.