Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1038043	11/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
St Lukes Diagnostic Cath Lab Lp	6620 Main Street Suite 1520, Houston, TX	

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
D0000	The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by:

	Based on review of proficiency testing records and interview of facility personnel, the laboratory failed to successfully participate in a proficiency testing program for the specialty of routine hematology for the analyte Hemoglobin. Refer to D2130
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a review of 2016 - 2018 American Proficiency Institute (API) proficiency testing (PT) records and interview of facility personnel it was revealed that the laboratory failed to participate in the 2nd hematology testing event of 2018. Findings were: 1. A review of the CMS national proficiency testing database revealed a score of "0" on the 2nd hematology event of 2018 for this facility. 2. A review of American Proficiency Institute (API) PT records revealed the laboratory received a 0% for the 2018-2 Hematology PT for "Failure to Participate." The PT summary was rated by the provider as unsatisfactory performance for all analytes for testing event 2018-2 Hematology. 3. An interview of the technical consultant on 1005 hours in the laboratory confirmed the above findings. She confirmed the laboratory had failed to submit results to the proficiency testing company and that the laboratory had not performed a self-evaluation. key: CMS - Center for Medicare and Medicaid services
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) records from 2018, and confirmed in interview, the laboratory failed to attain a satisfactory performance (score of at least 80 %) for 2 of 3 consecutive events for the analyte Hemoglobin in Hematology. Findings were: 1. Review of the 2018 API proficiency testing records revealed 2 of 3 consecutive events when the laboratory failed to attain at least an 80% score for the analyte hemoglobin. cross refer to D2130 2018 1st event Hemoglobin (0%) BLX-01 50 (acceptable range 13.9 - 16.1) BLX-02 89.4 (acceptable range 16.5 - 19.0) BLX-03 67.9 (acceptable range 11.1 - 12.9) BLX-04 58.9 (acceptable range 12.5 - 14.5) BLX-05 78.7 (acceptable range 9.6 - 11.2) 2018 2nd event Hemoglobin (0%) 2. An interview with the technical consultant on 11 /7/18 at 1030 hours in the laboratory confirmed the above findings.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: A review of the laboratory's American Proficiency Institute proficiency testing from 2017 and 2018 and confirmed in interview, the laboratory quality assessment policies and procedures failed to identify, monitor and correct problems in the general laboratory systems. Refer to D2123, 2130
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 review of the laboratory records, quality control records, and confirmed in interview, the laboratory failed to have an effective mechanism by which to monitor & evaluate the overall quality of the analytic systems, to identify & correct problems for testing performed by the laboratory in the following areas: Test systems, equipment, instruments & supplies (refer to D5411, D5413); and Control procedures (refer to D5445, D5469).
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory records, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions and document the verification performance of the i-STAT system using the external electronic simulator every 24 hours of use. Findings were: 1. Review of the Procedure Manual for the i-STAT System (Art: 714446-00V, 09/22/16) revealed "Verify the performance of each analyzer on site using the Electronic Simulator (external or internal) once a day on the days the analyzers are in use." 2. Review of the laboratory records revealed no documentation of the external electronic simulator every day of patient testing. 3. Random review of the final patient reports from August 2018 to October 2018 revealed the laboratory performed patient ACT testing with no

	documentation of the external simulator the day of testing. Date Sample ID 10/24/18 10097 10/24/18 10081 10/25/18 10109 9/12/18 10028 9/10/18 10019 10/23/18 10082 9/12/18 10021 9/17/18 9947 9/21/18 2964 9/18/18 9955 8/28/18 9944 10/9/18 9958 4. An interview with the primary testing person on 11/7/18 at 1125 hours in the office confirmed the above findings. She stated that the laboratory does perform the external simulator each day but she acknowledged that it is not documented or monitored. key: ACT - activated clotting time
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 review of the manufacturer's instructions, laboratory policies, laboratory records, patient records, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions to ensure the ACT i-STAT cartridges are stored at room temperature (18 - 30 C) prior to analysis. Findings were: 1. Review of the Procedure Manual for the i-STAT System (Art: 714446-00V, 09/22/16) revealed "verify that room temperature has not exceeded 30C. If the measured room temperature has exceeded 30C for any period time: Quarantine the cartridges; Notify the iSTAT system Coordinator immediately; Do not use the cartridges; record the out of control event in the i-STAT QC [quality control] log and the action taken" 2. Review of the laboratory policy i-STAT System (Abbott Diagnostics) - Laboratory Services, effective August 2018 revealed under Reagent (Material) Stability and Storage revealed "cartridges may be stored at room temperature (18-30 C) for up to 14 days or as specified by manufacturer. Cartridges must be at room temperature when used for testing." 3. Review of the laboratory records available revealed no documentation of the laboratory monitoring the room temperature where the ACT iSTAT testing is performed. 4. Random review of the final patient reports from August 2018 to October 2018 revealed the laboratory performed patient ACT testing with no documentation of the laboratory monitoring the room temperature. Date Sample ID 10/24/18 10097 10/24/18 10081 10/25/18 10109 9/12/18 10028 9/10/18 10019 10/23/18 10082 9/12/18 10021 9/17/18 9947 9/21/18 2964 9/18/18 9955 8/28 /18 9944 10/9/18 9958 5. An interview with the primary testing person on 11/7/18 at 1040 hours in the office confirmed the above findings. She was unaware the laboratory needed to monitor the temperature for iSTAT testing. key: ACT - activated clotting time
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control records, patient test records, and confirmed in interview, the laboratory failed to provide documentation of performing an IQCP (Individualized Quality Control Plan) to modify the frequency of quality control testing and failed to provide documentation of performing quality control each day of patient testing for the THgb and HbO2 patient testing on the Avoximeter 1000E whole blood oximeter. Findings were: 1. Review of the laboratory quality control records from January 2018 to October 2018 for the Avoximeter 1000E revealed the laboratory performed external quality control for THgb and HbO2 weekly. Level 1 lot #64855, exp 6/2018 Level 3 lot # 65046, exp 6/2018 01/02/18, 01/09/18, 1/16/18, 1/30/18, 2/6/18, 2/13/18, 2/20/18, 2/27/18, 3/6/18, 3/13/18, 3/20/18, 3/27/18 5/1/18, 5/8/18, 5/15/18, 5/22/18, 5/29/18, 6/5/18, 6/12/18, 6/19/18 Level 1 lot #84857, exp 6/2019 Level 3 lot #75048, exp 05/2019 6/26/18, 7/3/18, 7/10/18, 7/17/18, 7/24/18, 7/31/18, 8/7/18, 8/14/18, 8/21/18, 8/28/18, 9/4/18, 9/11/18, 9/18/18, 9/25/18, 10/2/18, 10/9/18, 10/16/18, 10/23/18, 10/30/18 2. Random review of patient test records from 05/2018 to 10/2018 revealed 11 of 12 patient test results for THgb and HbO2 when the laboratory failed to provide documentation of performing external quality control testing on the following dates when patient tests were performed. Date Patient ID 10/22/18 1384 10/10/18 6929 09/07/18 6161 09/07/18 9993 08/03/18 9936 08/03/18 9923 07/20/18 9913 07/16/18 9881 06/15/18 8757 05/11/18 9763 05/09/18 9778 3. Review of the laboratory quality control records revealed no documentation of an IQCP study to modify the frequency of controls for the Avoximeter 1000E whole blood oximeter. 4. An interview with the primary testing person on 11/7/18 at 1240 hours confirmed the above findings. She was unaware the laboratory should perform daily external quality control unless they performed an IQCP. key: THb - Total Hemoglobin HbO2 - O2 saturation
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) 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--Establish or verify the criteria for acceptability of all control materials. (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. (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. (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory quality control records, patient test results, and confirmed in interview, the laboratory failed to establish its

	own acceptable quality control ranges for the analyte THb and HbO2 for tesing on the Avoximeter 1000E blood oximeter per the manufacturer. Findings were: 1. Review of the package insert for the Full Rang Co-oximeter control revealed "the expected values are provided as a guide in evaluating analyzer performance. Since instrument design and operating conditions may vary, each laboratory should establish its own expected values and control limits." 2. Review of the package insert for the Full Rang Co-oximeter control Level 1 (84857, exp 09/19); level 3 (75048, exp 05/19) revealed documentation the laboratory used the manufacturer's expected values for the Avoximeter 1000E for THb and HbO2. Level 1 lot #84857, exp 6/2019 THb 7.0 - 8.4 g/dL HbO2 89.8 - 98.8 % Level 3 lot #75048, exp 05/2019 THb 14.2 - 16.8 g/dL HbO2 49.7 - 58.3 % 3. Review of the laboratory quality control records from June 2018 to October 2018 revealed no documentation of the laboratory establishing its own acceptable quality control ranges for the Avoximeter 1000E. 4. Random review of patient test records from 05/2018 to 10/2018 revealed 11 patient test results for THgb and HbO2. Date Patient ID 10/22/18 1384 10/10/18 6929 09/07/18 6161 09/07 /18 9993 08/03/18 9936 08/03/18 9923 07/20/18 9913 07/16/18 9881 06/15/18 8757 05/11/18 9763 05/09/18 9778 5. An interview with the primary testing person on 11/7 /18 at 1245 hours in the office confirmed the above findings. She was unaware the laboratory had to establish its own ranges. key: THb - Total Hemoglobin HbO2 - O2 saturation
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 review of the laboratory records, quality control records, and confirmed in interview, the laboratory quality assessment policies and procedures failed to to monitor & evaluate the overall quality of the analytic systems, to identify & correct problems for testing performed by the laboratory in the following areas: Test systems, equipment, instruments & supplies (refer to D5411, D5413); and Control procedures (refer to D5445, D5469).
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records from 2017 and 2018, and staff interview, the laboratory director failed to ensure proficiency test results were returned on time (refer to D2123).

D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory quality control records, patient test records, and confirmed in interview, the laboratory director failed to ensure the quality control program was established and maintained to assure the quality of laboratory services provided as evidenced by: 1. The laboratory failed to provide documentation of performing an IQCP (Individualized Quality Control Plan) to modify the frequency of quality control testing for the Avoximeter 1000E blood oximeter (refer to D5445). 2. The laboratory failed to establish its own acceptable quality control ranges for the Avoximeter 1000E blood oximeter per the manufacturer (refer to D5469).
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the CMS form 209, personnel records and verified by interview, the Technical Consultant failed to perform the competency evaluations for 8 of 9 testing personnel for the moderately complex testing for ACT on the iSTAT analyzer and THb and HbO2 on the Avoximeter 1000E. Findings were: 1. A review of the facility's personnel files revealed 8 of 9 testing personnel (TP #1, TP# 3, TP#4, TP#5, TP#6, TP#7, TP#8, and TP #9) had an annual 2018 competency assessment for ACT on the iSTAT analyzer and THb and HbO2 on the Avoximeter 1000E performed by TP #2, who does not qualify as the technical consultant. TP#2 has a high school diploma and a bachelor's degree in Marketing. 2. An interview with the technical consultant on 11/7/18 at 1005 hours in the office confirmed the above findings. She was unaware the technical consultant required a bachelor's degree in a life sciences. key: CMS - Centers for Medicaid and Medicare Services ACT - activated clotting time THb - Total Hemoglobin HbO2 - O2 saturation
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

	This STANDARD is not met as evidenced by: Based on review of the laboratory policies, laboratory personnel files, and confirmed in interview, the technical consultant failed to perform semi-annual competency for 2 of 2 testing person (TP) during the first year of testing patient specimens for the moderately complex testing for ACT on the iSTAT analyzer and THb and HbO2 on the Avoximeter 1000E performed in the laboratory. (TP#3, 6) Findings were: 1. Review of the laboratory policy Competency Assessment - Laboratory Services revealed "Evaluating and documenting competency of personnel responsible for testing classified as moderately complexity is required at least semiannually during the first year the individual tests patient specimens." 2. A review of the facility's personnel files revealed no documentation of the semi-annual competency for 2 of 2 testing personnel (TP#3 hire date 1/2017; TP #6 hire date 01/2017) for the ACT on the iSTAT analyzer and THb and HbO2 on the Avoximeter 1000E. TP#3, initial competency performed 4/7/17 TP#6, initial competency performed 5/5/17 3. An interview with the technical consultant on 11/7/18 at 1040 hours in the office confirmed the above findings. She was unaware the 2nd competency was not performed. key: ACT - activated clotting time THb - Total Hemoglobin HbO2 - O2 saturation