Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1038043	12/22/2020
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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 a review of the laboratory's IQCP (Individualized Quality Control Plan) for the Abbott i-STAT, a review of quality control records for the ACT (activated clotting time) cartridges from 2019 and 2020, a random review of patient reports, and staff interview, it was revealed that the laboratory failed to provide documentation of

	following its own IQCP 2 of 2 times in 2020 to perform quality control testing every 30 days when the same lot of cartridges is in use. Findings include: 1. A review of the laboratory's IQCP for the Abbott i-STAT (signed by the laboratory director on 3/1/19) revealed the following: "Liquid Quality Control Solutions Frequency: 2 levels with each new shipment or lot 2 levels each 30 days lot is in use" 2. A review of the liquid quality control records for the ACT cartridges run on the Abbott i-STAT (serial number 365339) from 2019 and 2020, revealed the following 2 times when the 30 day time frame was exceeded for testing the quality control (QC) material per the laboratory's IQCP: a) ACT cartridge lot number R19319 Date Run: 1/14/20 Next Run: 2/25/20 42 days between QC runs b) ACT Cartridge lot number R20162 Date Run: 8 /19/20 Next Run: 9/28/20 40 days between QC runs 3. A review of patient reports revealed the following patients were tested with the Abbott i-STAT ACT cartridges when the quality control had not been performed within the laboratory's 30 day quality control time frame: Patient: 10718 Date: 2/18/20 ACT Result: 213 seconds Patient: 10985 Date: 2/25/20 ACT Result: 345 Seconds Patient: 9522 Date: 9/22/20 ACT Result: 307 seconds 4. An interview with the technical consultant (as indicated on the CMS 209 form, signed by the laboratory director on 12/21/20) on 12/22/20 at 10:45 a.m. in the office, after review of the records, confirmed the above findings.
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 a review of the Avoximeter 1000E Whole Blood Oximeter Operator's Manual, a review of the Avoximeter Daily Quality Control Logs from 2019 and 2020, a random review of patient test records, and staff interview, it was revealed the laboratory failed to ensure the optical quality controls were acceptable for 5 of 5 times in 2019 and 2020 prior to reporting patient's oxygen saturation results on the Avoximeter 1000E. Findings include: 1. A review of the Avoximeter 1000E Whole Blood Oximeter Operator's Manual (2015) revealed the following: "Quality control testing of the Avoximeter 1000E consists of the following operations: - Daily optical quality control The yellow and orange optical filters supplied with the Avoximeter 1000E provide a convenient means of verifying that the optics are not obscured by blood or debris and that the instrument is properly calibrated. Verify that the results for each filter are within the expected ranges listed below: Yellow Optical Filter % HbO2 Expected Range 93.5 - 96.5% Orange Optical Filter %HbO2 Expected Range 37.2 - 40.8%" 2. A review of the Avoximeter Daily Quality Control Logs from 2019 and 2020 revealed the following 5 days when the optical filters were documented outside of the acceptable range for %HbO2: Date: 3/21/19 Yellow Filter Reading: 96.6% Date: 4/1/19 Yellow Filter Reading: 96.8% Date: 2/7/20 Yellow Filter Reading: 96.6% Date: 5/26/20 Yellow Filter Reading: 97.0% Date: 12/16/20 Yellow Filter Reading: 98.9% 3. A random review of the laboratory's patient test records from 2019 and 2020 revealed the laboratory resulted the following 6 patient's oxygen saturation (O2 SAT) results when the optical filters for the Avoximeter 1000E were documented outside of the acceptable range: Patient: 9817 Date: 3/21/19 O2 SAT = 68.0% Patient: 10363 Date: 4/1/19 O2 SAT = 43.5% Patient: 9211 Date: 4/1/19 O2 SAT = 57.7% Patient: 10877 Date: 2/7/20 O2 SAT = 72.0% Patient: 7828 Date: 5/26 /20 O2 SAT = 90% Patient: 11461 Date: 12/16/20 O2 SAT = 61.9% 4. An interview

	with the technical consultant (as indicated on the CMS 209 form, signed by the laboratory director on 12/21/20) on 12/22/20 at 12:00 p.m. in the office, after review of the records, confirmed the above findings. Key: %HbO2 = Oxygen saturations of hemoglobin
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of laboratory policies, quality control records, patient's results, and confirmed by staff interview, it was revealed that the laboratory's quality assurance program failed to detect problems in analytic systems Findings include: 1. The laboratory's quality assurance program failed to detect that quality control was not run every 30 days on the Abbott i-STAT when the same lot number of cartridges was in use (Refer to D5445). 2. The laboratory's quality assurance program failed to detect the optical quality controls were unacceptable prior to reporting patient's oxygen saturation results on the Avoximeter 1000E (Refer to D5481).