Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D2051527	(X3) Date Survey Completed 03/29/2021
Name of Provider or Supplier St Louis Cardiovascular Institute	**Street Address, City, State** 1028 South Kirkwood Rd Suite A, St. Louis, 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
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control records (QC) / patient records for 2021 and interview with technical consultant #1, the laboratory failed to detect immediate external QC errors and monitor over time the accuracy of test performance for the activated clotting time (ACT) test procedure performed on the Hemochron ACT instrument. Findings: 1. Review of QC records revealed the laboratory obtained an unacceptable external normal control (lot # H9DNA012) value of 81 seconds on January 26, 2021 The normal external QC range observed on the QC log and manufacturer's assay sheet showed an acceptable range of 126-224 seconds for lot # H9DNA012. The QC logs did not show repeat QC testing on January 26, 2021. The laboratory did not have a mechanism to detect immediate QC errors and monitor test system/operator performance. 2. Patient records provided by technical consultant #1 showed the laboratory tested 10 patients from January 26, 2021 through the next scheduled external QC date of February 2, 2021. 3. Interview with technical

	consultant #1 on March 29, 2021 at 11:00 AM confirmed, the laboratory failed to obtain an acceptable external normal QC value on January 26, 2021 and detect immediate errors due to test system failure or operator performance.