Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D2105436	01/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
St Louis Specialty Surgical Center	1028 S Kirkwood Rd Suite B, Kirkwood, 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	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 review of coagulation procedure and interview with testing personnel (TP) #5, the laboratory failed to follow procedure for performing activated clotting time (ACT) quality control (QC). Findings: 1. Review of the coagulation procedure "Quality Control Program for Activate Clotting Time (ACT+) Blood Testing with Hemochron Signature Elite" states "Testing the external normal and abnormal controls once a week". 2. Review of ACT QC for Hemochron coagulation analyzer #1 showed no QC preformed the week of June 14, 2021, July 5, 2021, August 16, 2021, August 30, 2021, October 11, 2021, October 25, 2021, November 1, 2021, November 8, 2021, November 22, 2021, November 29, 2021, December 6, 2021, December 13, 2021 and December 20, 2021. 3. Review of ACT QC for the Hemochron coagulation analyzer #2 showed no QC performed the week October 11, 2021, October 25, 2021, November 1, 2021, November 8, 2021, November 22, 2021, November 29, 2021, December 6, 2021, December 13, 2021 and December 20, 2021. 4. Interview on January 5, 2022 at 9:15 AM with TP #5 confirmed the laboratory failed to follow procedure for performing ACT QC.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it

	can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the performance verification procedures for the Hemochron coagulation analyzer and interview with the testing personnel (TP) #5, the laboratory failed to demonstrate accuracy, precision, reportable range and to verify manufacturer's reference intervals (normal values) for activated clotting time (ACT) before reporting patient results. Findings: 1. Review of the verification procedures for the Hemochron coagulation analyzer for ACT showed no accuracy, precision, reportable range and no verification of normal values. 2. Interview with the TP #5 on January 5, 2022 at 9:15 AM confirmed the laboratory failed to ensure the verification procedures for Hemochron coagulation analyzer were demonstrated before reporting patient results.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of personnel records revealed and interview with the testing personnel #5 confirmed, the laboratory failed to have academic credentials required to qualify one of thirteen testing personnel for the speciality of hematology for moderate complexity testing (refer to tag #6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the testing personnel (TP) #5, the laboratory failed to have documentation of academic credentials to qualify one of thirteen testing personnel for moderate complexity testing. Findings: 1. Review of

	the personnel records for TP #12 for the speciality of hematology revealed the laboratory failed to have academic credentials to qualify this individual. 2. Interview with the TP #5 on January 5, 2022 at 10:00 AM confirmed, the laboratory failed to have the required documentation to qualify the individual serving as TP #12 of moderate complexity hematology testing.