Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1031654	05/02/2019
Name of Provider or Supplier	**Street Address, City, State**	
Russell Center For Vein & Vascular Care, The	120 Frank Martin Rd Ste 101, Shelbyville, TN	

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
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the laboratory director's failure to monitor pre-analytic written orders (D5303); failure to effectively maintain analytic systems (D5400, D5401, D5411, and D5545);and failure to monitor post-analytic patient test reports (D5805) resulting in Immediate Jeopardy.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a lack of personnel records and a procedure manual and an interview with the Laboratory Director, the laboratory failed to assess the competencies on two of two testing persons performing moderate complexity testing (MCT) on the Activated

	Clotting Time (ACT) (Refer to D5209); the laboratory failed to document a quality assurance plan to ensure testing persons were qualified to perform MCT in coagulation (refer to D5293) resulting in Immediate Jeopardy.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on the lack of a laboratory procedure manual and employee personnel records for 2018-2019, and interview with the laboratory director, the laboratory failed to have a procedure to include all six criteria for assessing personnel competency resulting in Immediate Jeopardy. The findings include: 1) There was no laboratory procedure manual or procedure for the following six criteria to be included in the procedure and competency documentation: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills. 2) There were no 2018-19 employee personnel records available for documentation of competency assessment for the six required criteria. 3) Interview on May 2, 2019 at 3:00 p.m. with the laboratory director, the laboratory did not have a testing personnel competency procedure that included the six criteria for testing personnel competency assessment required by the Centers for Medicare and Medicaid Services (CMS).
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory 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 general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on the lack of the Laboratory's procedure manual and on interview with the Laborator Director, the laboratory failed to establish procedures for Quality Assessment to include: Patient Test Management Assessment, Quality Control Assessment, Proficiency Testing Assessment, Comparison of Test Results, Relationship of Patient Information to Patient Test Results, Personnel Assessment, Communications, Complaint Investigations, Quality Assurance Review with Staff, and Quality Assurance Records (lab records retention) resulting in Immediate Jeopardy. The findings include: 1. There was no laboratory procedure manual revealing written policies to monitor, assess and correct problems identified in the

	laboratory. 2. Upon interview at approximatley 1:30pm on May 2, 2019, with the Laboratory Director confirmed there was no Quality Assessment Policy or monitors in place for 2018-19.
D5303	TEST REQUEST CFR(s): 493.1241(b) The laboratory may accept oral requests for laboratory tests if it solicits a written or electronic authorization within 30 days of the oral request and maintains the authorization or documentation of its efforts to obtain the authorization. This STANDARD is not met as evidenced by: Based on observation of patient records and interview with the Laboratory Director, the laboratory failed to document any written or electronic orders for patient testing of the Activated Clotting Time (ACT) from 2018-19 resulting in Immediate Jeopardy. Findings include: 1. The patient records did not reveal any written or electronic orders for the ACT from 9/20/2018-5/2/2019. 2. In an interview at 2:00pm on May 2, 2019, the laboratory director revealed only oral orders were issued for the ACT patient testing from 9/20/2018-5/2/2019.
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 a lack of a procedure manual (D5401); laboratory failed to follow the manufacturer's instructions (D5411); laboratory failed to perform verification and performance specifications for the Actalyke Electronic Clotting Tube (XL-ECT) and the laboratory failed to run two external controls for the ACT for moderate complexity testing (Refer to D5545); resulting in Immediate Jeopardy.
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 lack of a laboratory procedure manual and upon interview with the Laboratory Director determined the laboratory failed to include procedures and policies for the Activated Clotting Time (ACT) patient testing in 2018-19. The findings include: 1. There was no laboratory procedure manual available for review

	for 2018-19. 2. An interview at approximately 2:30pm on May 2, 2019, with the Laboratory Director, confirmed there was no procedure manual available for ACT testing for 2018-19.
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 a review of manufacturer's instructions for Activated Clotting Time (ACT) testing, lack of complete laboratory quality control records for 2018-19 and an interview with the laboratory director, determined that documentation was not available for the lab performing two levels of controls once per shift as specified in the manufacturer's instructions for the Actalyke Electronic Clotting Tube (XL-ECT) for ACT patient testing resulting in Immediate Jeopardy. The findings include: 1. Review of the manufacturer's instructions for ACT testing indicates: "2 levels of quality controls once per shift on any shift in which an XL-ECT is to be used". 2. Review of the incomplete quality controls (QC) for the XL-ECT ACT test revealed QC only performed weekly. 3. An interview with the laboratory director at 2:45pm on May 2, 2019, revealed the laboratory only performing weekly QC for the ACT patient testing not in accordance with the manufacturer's instructions.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the 2018-19 quality control (QC) records, patient testing logs, manufacturer's QC instructions, and an interview with the laboratory director, determined that the laboratory failed to perform and document at least two levels of QC materials daily with patient testing for the Activated Clotting Time (ACT) testing, resulting in Immediate Jeopardy. The findings include: 1. A lack of QC records for the ACT test revealed the laboratory failed to perform two levels of QC (testing only weekly) prior to testing and reporting patient results on the patient testing logs from 9 /20/2018-5/2/2019. 2. A review of the manufacturer's QC instructions stated: "The XL-ECT should be run at two levels once per shift on any shift in which the Actalyke Instrument is to be used". 3. Interview on May 2, 2019, at 2:35pm, with the Laboratory Director confirmed laboratory failed to perform two levels of QC (testing only weekly) prior to testing and reporting patient results on the patient testing logs from 9/20/2018-5/2/2019.
D5805	TEST REPORT CFR(s): 493.1291(c)

	The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a lack of any ACT patient test reports, patient test logs and an interview with the laboratory director, the laboratory failed to provide any ACT test reports with the laboratory's name, address, test results, units, or patient ranges from 9/20/2018-5/2/2019. The findings include: 1) There were no ACT patient test reports for the 70 ACT patients from the test logs available to review for 2018-19. 2) Interview on May 2, 2019 at :300 p.m. with the laboratory director confirmed no ACT patient test reports were available for review from 9/20/2018-5/2/2019.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on not meeting the experience qualifications of a moderate complexity testing (MCT) lab director (LD) the laboratory failed to have a qualified laboratory director (D6003) resulting in Immediate Jeopardy.
D6003	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1405 AND 493.1406 The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the Laboratory is located; and (b)(2)(ii) Have had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or (b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or (b)(2)(ii)(C) Laboratory

training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and (b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing; (b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; (b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under 493.1406; or (b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located. Laboratory director qualifications on or before February 28, 1992 The laboratory director must be qualified to manage and direct the laboratory personnel and test performance. (a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (b)(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification; (b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (b)(4)(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or (b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either: (b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-

	time laboratory experience; (b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications. This STANDARD is not met as evidenced by: Based on a review of employee records for credentials, review of state agency documentation and an interview with the Laboratory Director, the laboratory failed to have a qualified laboratory director in 2018-19, resulting in Immediate Jeopardy. Findings include: 1. A review of the employee records revealed a Medical Doctor's License and Diploma for the current new lab director. 2. A review of the laboratory director's application to the state agency revealed misleading information about the current lab director's experience with directing moderate complexity testing (MCT) laboratories for the Hematology specialty in the past years. 3. In an interview, on May 2, 2019, at 1:30pm, the laboratory director confirmed he had no past laboratory experience as a director or supervisor in the past years.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on not meeting the experience qualifications of a moderate complexity testing (MCT) technical consultant (TC) the laboratory failed to have a qualified TC (D6035) resulting in Immediate Jeopardy.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State

	in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of employee records, credentials and an interview with the Laboratory Director, the laboratory failed to have a qualified technical consultant (TC) in 2018-19, resulting in Immediate Jeopardy. Findings include: 1. A review of the employee records revealed a Medical Doctor's License and Diploma for the current new TC. 2. The TC credentials were not able to verify one year experience or training for the Hematology specialty. 3. In an interview, on May 2, 2019, at 1:30pm, the laboratory director confirmed he had no past laboratory experience as a director or technical consultant in the past years.