Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D2131355	03/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Vascular Institute Of The Midwest	3385 Dexter Court Pavillion 3, Suite 100, Davenport, IA	

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
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on lack of written or electronic test requests and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 2: 40 pm on 03/08/2018, the laboratory failed to have a written or electronic test request for two out of two patients (patient identifiers A and B) having activated clotting time (ACT) testing performed in January and February 2018. The findings include: 1. Patient identifier A had two ACT tests performed on 02/07/2018. 2. Patient identifier B had an ACT test performed on 01/16/2018. 3. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not have a written or electronic test request for ACT testing performed on patient identifiers A and B.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in

	493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 4: 30 pm on 03/08/2018, the laboratory failed to have the following written procedures: the laboratory's system for interpreting and entering results in the patient record and the course of action to take when a test system becomes inoperable.
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 lack of performance specification records and confirmed by laboratory personnel identifier #5 (refer to the Laboratory Personnel Report) at approximately 4: 00 pm on 03/08/2018, the laboratory failed to perform the performance specifications of accuracy, precision, reportable range, and verification of the manufacturer's reference ranges for the Abbott i- Stat test system (activated clotting time [ACT], prothrombin time [PT], pH, partial pressure of carbon dioxide [PCO2], and partial pressure of oxygen [PO2]), prior to testing and reporting patient test results. The findings include: 1. The laboratory began using the Abbott i-Stat test system in November 2017. 2. At the time of the survey, personnel identifier #5 confirmed that the laboratory did not have performance specification records for the test system.
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 review of patient test reports and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 2:40 pm on 03/08/2018, the laboratory failed to include, as part of the test report, the test performed, the test results, and units of measure for two out of two test reports (patient identifiers A and B). The findings include: 1. Patient identifier A had an activated clotting time (ACT) test performed at 12:22 pm on 02/07/2018 with a result of 375 seconds. Patient identifier A had a second ACT test performed at 12:41 pm on 02/07/2018 with a result of 164 seconds. 3. Patient identifier B had an ACT test performed at 10:30 am on 01/16/2018 with a result of 318 seconds. 4. At the time of the survey, personnel identifier #2 confirmed that the test performed, the test results, and units of measure were not included on the test reports.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 4: 30 pm on 03/08/2018, the laboratory director failed to ensure that the laboratory established and maintained a quality assessment program that included the four quality systems: general laboratory, pre-analytical, analytical, and post analytical.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 4: 30 pm on 03/08/2018, the laboratory director fails to ensure that the laboratory establishes written training and competency assessment policies (both semiannual and annual) and procedures for testing personnel performing moderate complexity testing.