Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2115814	01/31/2018
Name of Provider or Supplier	**Street Address, City, State**	
Genesis Vascular	1000 Towne Center Blvd, Bld 400 Godley Station Bld, Pooler, GA	

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	An Initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on January31, 2018. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on staff interview, the laboratory failed to rotate performance of proficiency testing samples among all personnel who test patient samples. Findings include: 1. Interview with the technical supervisor and testing personnel # 2 (see CMS 209) on January 31, 2018 at 12 pm revealed all proficiency testing samples were performed by testing personnel # 2. 2. No signed attestation statements or raw data showing testing personnel's identification were available for review.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by:

	Based on review of 2016 and 2017 proficiency testing (PT) records and staff interview, the testing personnel (TP) and laboratory director (LD) failed to sign attestation statements, attesting that PT samples were tested in the same manner as patient specimens. Findings include: 1. Review of 2016 and 2017 PT records revealed no signed attestation statements. 2. Interview with the technical supervisor and TP # 2 (see CMS 209) on January 31, 2018 at 12 pm confirmed attestation statements are not signed by the TP and LD.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of 2016 and 2017 proficiency testing (PT) records, lack of records to review and staff interview, the laboratory failed to document each step of the testing process and failed to maintain a copy of all testing records. Finding include: 1. Review of PT records revealed no test records , raw data or documentation showing each step of the testing process including how specimens were tested, who tested the specimens, how many times specimens were tested and instrument printouts showing values obtained. 2. Interview with the technical supervisor and testing personnel # 2 (see CMS 209) on January 31, 2018 at 12 pm confirmed records are not available at the time of the survey.
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 laboratory records and staff interview, the laboratory failed to meet the requirements for testing in the speciality of Hematology for testing Prothrombin time and activated clotting time. Findings include: Refer to: D 5211, D 5291, D 5403, D 5421, D 5463, D 5545,& D 5787
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

	This STANDARD is not met as evidenced by: Based on review to Proficiency testing (PT) records and staff interview, the laboratory failed to document review of PT scores. Findings include: 1. Review of PT records showing the laboratory's scores revealed no documentation of review by the laboratory staff or laboratory director. 2. Interview with the technical supervisor and testing personnel # 2 (see CMS 209) on January 31, 2018 at 12 pm confirmed PT scores are not signed indicating they were reviewed.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's on-line Quality Assurance (QA) policy and procedure, review of laboratory records and staff interview, the laboratory failed to follow their written QA plan. Findings include: 1. Review of on-line policy and procedures revealed a written QA policy and procedure as well as forms designed for use in the QA process. 2. Review of laboratory records revealed no evidence of QA activity. 3. Interview with the technical supervisor on January 31, 2018 at approximately 3 pm confirmed the laboratory has a QA policy but no documentation of QA activity is available.
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 manuals and staff interview, the

	laboratory failed to have a procedure for performing Prothrombin time which included the required information. Findings include: 1. Review of the laboratory's printed procedure manual revealed no procedure for performing Prothrombin time. 2. The technical supervisor searched the electronic version of the procedure manual during the survey but was unable to locate a procedure. 3. Interview with the technical supervisor on January 31, 2018 at 1 pm confirmed a procedure for Prothrombin time was not available.
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 laboratory records, lack of records to review, and staff interview, the laboratory failed to verify performance specifications prior to reporting patient results for Prothrombin time (PT) and activated clotting time ACT) using the I-Stat analyzer. Findings Include: 1. Review of laboratory records revealed no documentation of performance specification verification for PT and ACT testing performed on the I-Stat analyzer. 2. Interview with the technical supervisor and testing personnel # 2 (see CMS 209) on January 31, 2018 at 1:30 pm confirmed no documentation of performance specification verification for PT and ACT is available.
D5463	CONTROL PROCEDURES CFR(s): 493.1256(d)(7)(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--Over time, rotate control material testing among all operators who perform the test. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of 2016 and 2017 quality control (QC) records and staff interview, the laboratory failed to rotate over time, testing of control material among all testing personnel (TP) who perform patient testing. Findings include: 1. Review of 2016 and 2017 QC logs revealed no QC was performed by testing personnel #1. 2. Interview with the technical supervisor and testing personnel # 2 (see CMS 209) on January 31, 2018 at 12:30 pm confirmed all QC in 2016 and 2017 was performed by TP # 2.
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 2016, 2017 and 2018 quality control (QC) records, review of the laboratory's procedure for performing activated clotting time, and staff interview, the laboratory failed to perform two levels of controls daily, every 8 hours and each time a lot number of reagents was changed (new cartridges) for Prothrombin time (PT) and activated clotting time (ACT) and failed to perform the External Simulator check each day of patient testing on the I-Stat analyzer. Findings include: 1. Review of QC records revealed documentation of the following QC performed for PT: 01/04/16 two levels 03/04/16 two levels 05/02/16 one level 06/12/16 one level 10/5/16 one level No other documentation of daily QC is available for PT testing. 2. Review of records of QC performed on receipt of new lots numbers of reagents (new cartridges) for PT testing revealed the following documentation: 10/24/16 one level 01/02/18 one level 01/12/18 one level No other documentation of QC performed upon receipt of new cartridges is available. 3. Review of QC records for ACT revealed the following: 01/04 /16 two levels 01/22/16 two levels 03/04/16 two levels 03/16/16 one level 05/02/16 one level 06/02/16 one level No other documentation of daily QC is available for ACT testing. 4. Review of records of QC performed on receipt of new lots numbers of reagents (new cartridges) for ACT testing revealed the following documentation: 03 /16/16 two levels 05/04/16 one level 08/25/16 one level 10/05/16 one level 10/24/16 one level 11/04/16 one level 11/29/17 two levels 01/04/18 one level 01/18/18 two levels No other documentation of QC performed upon receipt of new cartridges is available. 5. Review of the laboratory's procedure for for performing QC on ACT testing revealed liquid controls and the External Simulator should be performed daily. No procedure was available for PT testing. 6. Review of QC records for performing the External Simulator revealed it is only performed after a software update is needed. 7. Interview with the technical supervisor and testing personnel # 2 (see CMS 209) on January 31, 2018 at 1:30 pm confirmed two levels of liquid controls are not run each day and every 8 hours of patient testing, new cartridges are not checked prior to use by running two levels of liquid controls and the external simulator is not checked daily. Both personnel also confirmed the laboratory began testing patient samples when the facility opened in January 2016.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of patient test records and staff interview, the laboratory failed to record the identity of the personnel who performed testing for Prothrombin time (PT) and Activated clotting time (ACT) on the I-Stat analyzer. Findings include: 1. Review of 2 of 2 patient test records revealed no documentation showing the identity of the

	person performing the test. 2. Interview with the technical supervisor and testing personnel #2 (see CMS 209) confirmed the identity of the testing personnel is not included in the patient test record.
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 review of laboratory records, lack of records to review and staff interview, the laboratory failed to provide overall management and direction for operating the laboratory. Findings include: Refer to D 6013, D 6016, D 6020, D 6021, D 6030, D 6031
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on lack of records to review and staff interview, the laboratory director failed to ensue performance specifications for Prothrombin time and activated clotting time detection using the I-Stat analyzer were preformed and acceptable. Findings include: Refer to D 5421
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and staff interview, the laboratory director failed to ensure proficiency testing was performed and records maintained as required: Findings include: Refer to D 2007, D 2009, D2015 and D 5211

D6020	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 the quality control program is 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 quality control records and staff interview, the laboratory director failed to ensure the quality control program was established and maintained. Findings include: Refer to D 5545
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 on-line quality assurance (QA)policy, lack of records to review and staff interview, the laboratory director failed to ensure the QA program was maintained. Findings include: Refer to D 5291
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 laboratory records, lack of records to review and staff interview, the laboratory director failed to ensure policies and procedures for determining and monitoring personnel competency are established and followed. Findings include: 1. Review of laboratory records revealed no policy for competency assessment and no records that competency assessment was performed. 2. Interview with the technical

	supervisor and testing personnel # 2 (see CMS 209) at approximately 3 pm on January 31, 2018 confirmed not policy or records are available.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of laboratory documents, review of the laboratory's procedure manual, the inability of the testing personnel to access a procedure for performing Prothrombin time and staff interview, the laboratory director failed to document approval of the procedure manual and failed to ensure procedures for all aspects of testing are available to testing personnel. Findings include: 1. Review of laboratory records revealed no documentation that the procedure manual is approved by the laboratory director. Also refer to D 5403