Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2213082	04/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
Vascular Institute Texas	7515 S Main St, Suite 100, Houston, TX	

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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2093	ROUTINE CHEMISTRY CFR(s): 493.841(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's American Proficiency Institute (API) proficiency testing records for 2021, and staff interview, it was revealed that the laboratory failed to return its proficiency testing results to API within the time frame specified by the program for one of one testing event in 2021. Findings include: 1. A review of the laboratory's policy titled 'Proficiency Testing' revealed the following: "Once test results are obtained, the results must be submitted to the proficiency agency within the allotted time." 2. A review of the laboratory's API proficiency testing records revealed the laboratory received an unsatisfactory score of 0% for 2021 Chemistry- Core third event. 3. Further review of the laboratory's API

	records for the 2021 Chemistry- Core third event revealed the following notation: "Results were not submitted prior to deadline." 4. An interview with the Clinical Administrator on 4/12/22 at 9:30 a.m. in the conference room, after review of the records, confirmed the above findings.
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 a review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, it was revealed that the laboratory failed to have documentation of a competency assessment for one of one technical consultant in 2021. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 4/8/22) revealed the laboratory identified 1 technical consultant. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of a competency assessment for the technical consultant in 2021. 3. An interview with the Clinical Administrator on 4/12/22 at 10: 20 a.m. in the conference room, after review of the records, confirmed the above findings.
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 a review of the laboratory's policies, the laboratory's American Proficiency Institute (API) proficiency testing records for 2021, and staff interview, it was revealed the laboratory failed to follow its policy for performing corrective action when the laboratory scored less than 100% for the ACT (Activated Clotting Time) analyte for one of one Hematology testing event in 2021. Findings include: 1. A review of the laboratory's policy titled 'Proficiency Testing' revealed the following: "The laboratory will receive a performance report, comparing your test results to other laboratories testing the dame sample using the same methodology. A score of 100% or 80% is passing, however any score less than 100% should prompt the lab to take appropriate action to identify the problem." 2. A review of the laboratory's API proficiency testing records for 2021 revealed the laboratory received an 50% for the analyte ACT in the 2021 Hematology/Coagulation third event. 3. Further review of the testing records for the 2021 Hematology/Coagulation third event revealed the following notation: "ACT- unable to retest. May have been a mixing problem. To be mindful of careful mixing next event." 4. The Clinical Administrator was asked if any further corrective action was taken to identify the problem per the laboratory's policy.

	No further documentation was provided. 5. An interview with the Clinical Administrator on 4/12/22 at 9:30 a.m. in the conference room, after review of the records, confirmed the above findings.
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 a review of the laboratory's verification records, the laboratory's reference ranges for analytes tested on the Abbott i-STAT analyzer, and staff interview, it was revealed that the laboratory failed to have documentation of verifying its patient normal ranges for 12 of 12 analytes tested on the Abbott i-STAT analyzer. Findings include: 1. A review of the laboratory's verification records for the Abbott i-STAT analyzer (Serial number 401771) revealed verification studies were approved by the laboratory director in March 2021. 2. The laboratory was asked to provide documentation of verifying the following patient normal ranges for the 12 analytes tested on the Abbott i-STAT analyzer. No documentation was provided. Chem 8+ cartridge: Sodium (Na) 138 - 146 Potassium (K) 3.5 - 4.9 Chloride (Cl) 98 - 109 Ionized Calcium (iCa) 1.12 - 1.32 Glucose (Gluc) 70 - 105 Blood Urea Nitrogen (BUN) 8 - 26 Total Carbon Dioxide (TCO2) 23 - 27 Creatinine (Crea) 0.6 - 1.3 Hematocrit (Hct) 38 - 51 Hemoglobin (Hgb) 12.0 - 17.0 Anion Gap 10.0 - 20.0 ACT cartridge: ACT >250 3. An interview with the Clinical Administrator on 4/12/22 at 10: 25 a.m. in the conference room, after review of the records, confirmed the above findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Individualized Quality Control Plan (IQCP), the laboratory's quality control records, the laboratory's submitted CMS 116 form, and staff interview, it was revealed that the laboratory's IQCP failed to have documentation to support the modification in quality control testing for two of two cartridges (Chem 8+ and ACT) run on the Abbott i-STAT analyzer. Findings include:

	1. A review of the laboratory's IQCP for the Abbott i-STAT analyzer revealed the laboratory modified the frequency of quality control testing for the Chem 8+ and ACT cartridges to the following: - with each shipment - with each new lot - every 30 days 2. A review of the laboratory's quality control records from March 2021 to March 2022 for the Abbott i-STAT analyzer revealed the frequency of quality control testing for the 2 cartridges: Chem 8+: 3/23/21 4/23/21 elapsed time between QC runs: 32 days 5/20/21 elapsed time between QC runs: 28 days 7/13/21 elapsed time between QC runs: 55 days 8/9/21 elapsed time between QC runs: 28 days 8/25/21 elapsed time between QC runs: 16 days 9/15/21 elapsed time between QC runs: 21 days 11/2/21 elapsed time between QC runs: 49 days 12/22/21 elapsed time between QC runs: 51 days 3/16/22 elapsed time between QC runs: 85 days ACT: 3/24/21 4/23/21 elapsed time between QC runs: 31 days 5/20/21 elapsed time between QC runs: 28 days 7/14 /21 elapsed time between QC runs: 54 days 8/9/21 elapsed time between QC runs: 27 days 8/25/21 elapsed time between QC runs: 16 days 3/29/22 elapsed time between QC runs: 217 days 3. Further review of the laboratory's IQCP revealed the laboratory failed to have documentation of performing a QC study that includes testing quality control materials each day for at least the length of the modification. 4. A review of the laboratory's submitted CMS 116 form revealed the laboratory estimated performing 225 Chem 8+ and 100 ACT tests annually. 5. An interview with the Clinical Administrator on 4/12/22 at 10:55 a.m. in the conference room, after review of the records, confirmed the above findings. Key: QC = Quality Control ACT = Activated Clotting Time
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 random review of patient's test reports from October 2021 to January 2022, and staff interview, it was revealed that the laboratory failed to include the testing facility's address on five of five patient's test reports reviewed from 2021 and 2022. Findings include: 1. A random review of patient's test reports from October 2021 to January 2022 revealed the laboratory failed to include the testing facility's address on the following 5 patient's test reports: Patient ID: 9963 Tested on 10/13/21 Patient ID: 9963 Tested on 10/19/21 Patient ID: 9998 Tested on 11/30/21 Patient ID: 10281 Tested on 1/5/22 Patient ID: 10557 Tested on 1/19/22 2. An interview with the Clinical Administrator on 4/12/22 at 11:35 a.m. in the conference room, after review of the records, confirmed the above findings.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing results from 2021 and staff interview, it was revealed the laboratory director failed to ensure proficiency testing results were returned within the required timeframe (refer to D2093).
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 a review of the laboratory's quality control records and staff interview, it was revealed that the laboratory director failed to ensure a quality control program was established and maintained for the testing that the laboratory performs. (Refer to D5445)