Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D2131355	11/16/2021
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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the Laboratory Test List and Annual Volume form, proficiency testing records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1:10 pm on 11/16/2021, the laboratory failed to enroll in an approved proficiency testing (PT) program for the analytes, sodium, potassium, chloride, calcium, glucose, blood urea nitrogen, carbon dioxide, creatinine, and hematocrit, for two out of two years from 2020-2021. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not enroll in PT for the analytes, sodium, potassium, chloride, calcium, glucose, blood urea nitrogen, carbon dioxide, creatinine, and hematocrit in 2020 and 2021.
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 #2 (refer to the Laboratory Personnel Report) at approximately 2: 45 pm on 11/16/2021, the laboratory failed to verify the performance specifications of accuracy, precision, and reportable range for the Abbott iStat test system. The findings include: 1. The laboratory began using the Abbott iStat test system to perform activated clotting time (ACT) testing in October 2021. 2. At the time of the survey, the laboratory did not have performance specification records for the Abbott iStat test system.