

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D2131355	(X3) Date Survey Completed 08/16/2019
Name of Provider or Supplier Vascular Institute Of The Midwest	Street Address, City, State 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 9:45 am on 8/16/2019, the laboratory director and testing personnel failed to attest to the routine integration of PT samples into the patient workload by signing PT attestation statements for two out of five proficiency testing events (2019 events 1 and 2) from 01/01/2018 - 8/16/2019. The findings include: 1. For 2019 testing event 1, the laboratory director and testing personnel did not sign the PT attestation statements for the arterial blood gas, activated clotting time and Prothrombin time PT modules. 2. For 2019 testing event 2, the laboratory director did not sign the PT attestation statement for the Prothrombin time PT module.</p>
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the i-STAT operator's guide and confirmed by laboratory personnel identifier #3 (refer to Laboratory Personnel Report) at approximately 10:30 am on 08/16/2019, the laboratory failed to perform and document function checks of the thermal probe every six months for three out of three time periods from 01/01/2018 - 8/16/2019. The findings include: 1. The i-STAT operator's manual states that a thermal probe check must be performed on the i-STAT analyzer every six months. 2. At the time of the survey, the laboratory did not have records indicating the thermal probe had been checked from 01/01/2018 - 08/16/2019. 3. Laboratory personnel identifier #3 confirmed that the laboratory did not know the thermal probe needed to be checked every six months, and that the laboratory had not performed the thermal probe check from 01/01/2018 - 8/16/2019.