

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2289909	(X3) Date Survey Completed 08/14/2024
Name of Provider or Supplier Cardiac & Vascular Consultants Of	Street Address, City, State 3865 W Front Street Suites 4 & 5, Traverse City, MI	
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
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interivew, the laboratory failed to follow its quality control procedure for the Hemachron Signature Elite for Activated Clotting Time (ACT) testing (refer to D5445).</p>
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager (OM), the laboratory</p>

failed to follow its established procedures for quality control for the Hemachron Signature Elite for 5 (#1-5) of 5 patients tested on January 29, 2024 and January 30, 2024. Findings include: 1. Record review of the laboratory's quality control for the Hemachron (Microcoagulation Analyzer) for Activated Clotting Time (ACT) testing showed that controls were not run for 2 days in January 2024 for 5 of 5 patients: a. Quality Control was not run for 2 patients on 1/29/2024 (Patient #1 and Patient #2) b. Quality Control was not run for 3 patients on 1/30/2024 (Patient #3, Patient #4 and Patient #5). 2. Record review of the of laboratory's Individualized Quality Control Plan (IQCP) revealed in "Conclusion summary" in section labeled "External controls (Minimum of 2 levels) will be assayed...every 30 days after the lot/shipment is in use...". 3. Record review of the laboratory 's quality control (QC) for the the Hemachron (Microcoagulation Analyzer) for Activated Clotting Time (ACT) testing revealed QC was run on 12/28/2023 and 2/1/2024 thereafter. 4. An interview with the Office Manager (OM) on 8/14/2024 at 11:58 am confirmed that QC was not done every 30 days per the IQCP.