

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 10D2076677	<b>(X3) Date Survey Completed</b> 11/23/2021
<b>Name of Provider or Supplier</b> Cardiovascular Institute Of Central Florida	<b>Street Address, City, State</b> 2105 Sw 20th Pl, Ocala, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An initial certification survey was performed on 11/23/21 at Cardiovascular Institute of Central Florida, a clinical laboratory located in Ocala, Florida. Cardiovascular Institute of Central Florida was found NOT in compliance with the 42 CFR Part 493, Requirements for Laboratories. .
<b>D5421</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory was unable to provide documentation of validations of the Abbott i-Stat and Medtronic ACT Plus instruments. Findings include: Review of the laboratory's quality control documentation showed the laboratory did not have documentation at the time of the survey for the validations on the Abbott i-Stat and Medtronic ACT Plus instruments. The laboratory performs Activated Clotting Time (ACT) testing. During an interview on 11/23/21 at 10:45am, the Office Manager stated he did not know where the validation documentation of the i-Stat and Medtronic instruments was located.</p>