

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0981537	(X3) Date Survey Completed 10/04/2022
Name of Provider or Supplier Birmingham Heart Clinic	Street Address, City, State 100 Pilot Medical Drive Suite 300, Birmingham, AL	
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
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: Based on a review of the ISTAT internal Electronic Simulator records, a review of the ISTAT procedure manual, and an interview with the Director of Diagnostics (DOD), the Laboratory failed to ensure the internal Electronic Simulator check met the manufacturer's acceptable criteria before patient testing began. This was noted for one day of nine months reviewed in 2022. The findings include: 1. A review of the ISTAT records revealed the internal Electronic Simulator check failed on May 18, 2022. Three patient Hematology Activating Clotting Time (ACT) tests were run on this date. 2. A review of the ISTAT Procedure Manual on page 15 revealed, "...if FAIL is displayed... rerun the cartridge..... or repeat the procedure with a different external Electronic Simulator." There was no documentation the laboratory had repeated the external Electronic Simulator check as per procedure. 3. During an interview on October 4, 2022, at 11:00 AM, the Director of Diagnostics confirmed, "failed internal Electronic Simulator's need to be repeated."</p>