

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2050413	(X3) Date Survey Completed 01/12/2023
Name of Provider or Supplier Cook Hospital Tower Lab	Street Address, City, State 415 North 2nd Street Suite #2, Tower, MN	
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 observation, document review, and interview with laboratory personnel, the laboratory failed to ensure function checks for a Chemistry analyzer were performed and documented as required in 2022. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 1:15 p.m. on 01/12/23. 2. An Abbott i-STAT analyzer was observed as present and available for use during the tour. The laboratory used the CHEM8+ cartridge on the i-STAT analyzer for a Basic Metabolic Panel test with eight analytes. 3. Twice annual verification of the i-STAT thermal probe was required as established in the i-STAT CHEM8+ procedure found in the i-STAT manual. 4. Thermal probe verification was performed in November 2021 and December 2022 as indicated in laboratory records. 5. Thermal probe verification documentation from mid-2022 was not found in laboratory records. The laboratory was unable to provide this documentation upon request. 6. In an interview at 4:35 p.m. on 01/12/23, the LD confirmed the above finding. .</p>