Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 24D0939682	**(X3) Date Survey Completed** 06/18/2021
Name of Provider or Supplier Hennepin Healthcare - Emergency Ambulance Service	**Street Address, City, State** 701 Park Avenue P4 Lab, Minneapolis, 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**
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: . Based on observation and interview with laboratory personnel, the laboratory failed to perform and document function checks (calibration) for 1 of 1 digital thermister unit from 02/18/20 to 08/25/120. Findings are as follows: 1. The laboratory performed Chemistry and Hematology testing as confirmed by Technical Consultant 3 (TC3) during the entrance interview on 06/18/21, at 9:05 a.m. 2. A VersaTrak digital themister unit with serial number (S/N) 17985 was observed as in use in the laboratory refrigerator during a tour of the storage area. Control materials and testing cartridges were observed in the refrigerator. 3. The manufacturer's original calibration date (08/25/20) and expiration date (8/25/22) was indicated on the Certificate of Accuracy for the currently installed unit. A review of the installed thermister unit records revealed that the previously installed unit (S/N 11721) had a manufacturer's original calibration date (02/18/18) and expiration date (2/18/20.) 4. During an interview on 06/18/21, at 12:05 p.m., and in a subsequent email received 6/21/21, TC3 confirmed that the installed VersaTrak digital themister units had a 6 month, 1 week gap in certified accuracy calibration, and indicated the facility maintenance department had not replaced the themister unit on time. .