Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0939682	03/27/2019
Name of Provider or Supplier	**Street Address, City, State**	
Hennepin Healthcare - Emergency Ambulance Service	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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed ensure 2 of 4 personnel who routinely performed Chemistry and Hematology testing on patient samples participated in proficiency testing (PT) in 2017 and 2018. Findings are as follows: 1. The laboratory performed Chemistry and Hematology testing as confirmed by Technical Consultant 3 (TC3) during the entrance interview on 03/27/19 at 1:05 p.m. 2. The laboratory performed PT using the American Proficiency Testing Institute (API) proficiency provider. 3. Testing Personnel 1 (TP1) did not participate in 6 of 6 API PT events completed by the laboratory in 2017. Testing Personnel 3 (TP3) did not participate in 6 of 6 API PT events completed by the laboratory in 2018. 4. In an interview on 03/27/19 at 1:45 p.m., TC3 indicated TP1 and TP3 routinely performed testing on patient samples and confirmed neither participated in PT as indicated above.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity.

	(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to document storage temperatures for Chemistry and Hematology test cartridges and quality control material from 08/10/17 to date of survey, 03/27/19. Findings are as follows:: 1. The laboratory performed Chemistry and Hematology testing as confirmed by Technical Consultant 3 (TC3) during the entrance interview on 03/27/19 at 1:05 p.m. 2. Control materials and testing cartridges were observed in the refrigerator during a tour of the storage area. A Fischer Scientific Min/Max digital thermometer with serial number 101848968 and calibration expiration date 08/20/17 was observed as in use - See D5435. 3. Storage temperature documentation was not found in laboratory records for the timeframe reviewed, 08/10/17 through 03/27/19. The laboratory was unable to provide the missing records upon request. 4. During an interview on 03/27/19 at 1:17 p.m., TC3 confirmed the storage temperatures had not been documented.
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 Min/Max digital thermometers from 08/20/17 to date of survey, 03/27/19. Findings are as follows: 1. The laboratory performed Chemistry and Hematology testing as confirmed by Technical Consultant 3 (TC3) during the entrance interview on 03/27/19 at 1:05 p.m. 2. A Fischer Scientific Min/Max digital thermometer with serial number 101848968 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 calibration due date, 08/20/17, was indicated on the back of the Min /Max digital thermometer. The laboratory was unable to provide calibration records for the thermometer from the timeframe reviewed, 08/10/17 through 03/27/19, upon request. 4. During an interview on 03/27/19 at 3:05 p.m., TC3 confirmed the Min/Max digital thermometer calibration was overdue and indicated the facility maintenance department had not performed calibrations on this piece of equipment.