

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0939682	(X3) Date Survey Completed 08/21/2025
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
D0000	<p>. The Hennepin Healthcare - Emergency Ambulance Service laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey performed on August 20, 2025. The following standard-level deficiency was cited: 493.1281 Comparison of test results .</p>
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to evaluate the relationship between one of one Hematology test results obtained from identical testing devices at least twice annually 2023 and 2024. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Technical Consultant 1 (TC1) during a tour of the laboratory office at 10:10 a.m. on 08/20/25. 2. Four Abbott i-STAT devices were observed as present and available for use during the tour. The fourth device, 440427, was implemented in March 2024. The laboratory used the i-STAT PT/INR cartridge for PT/INR testing on these devices. 3. Comparison of test results obtained from duplicate instruments was required twice annually as established in the Quality Control Plan - Point of Care procedure found in the MediaLab document management system. 4. Comparison of PT /INR test results obtained from the three i-STAT devices in use in 2023 was completed on 05/04/23 as indicated on the i-STAT Instrument to Instrument Comparison spreadsheet. A second 2023 comparison was not found in laboratory</p>

records. Comparison of PT/INR test results obtained from the four i-STAT devices in use in 2024 were completed as indicated on the i-STAT Instrument to Instrument Comparison spreadsheet as follows: i-STAT's compared Date of comparison 334879 and 374827 6/26/24 374839 and 440427 12/13/24 The laboratory was unable to provide the missing test comparisons from 2023 and 2024 upon request. 5. In an interview at 1:20 p.m. on 08/20/25, TC1 confirmed the above finding. 6. In an email received at 8:42 a.m. on 08/21/25, TC1 indicated 226 PT/INR tests were performed between 08/21/23 and 12/31/23 and 681 PT/INR tests were performed in 2024. .