

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0919612	(X3) Date Survey Completed 07/22/2026
Name of Provider or Supplier Point Of Care Laboratory Union Memorial Hosp	Street Address, City, State 201 East University Parkway, Baltimore, MD	
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	An on-site validation survey was performed on July 22, 2026 with the following standard level deficiencies cited.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 direct observation, TempTrak temperature settings, review of manufacturer's instructions, laboratory's written policies and procedures, and interview with the Technical Consultant (TC) #1 and #2, according to the Form Centers for Medicare and Medicaid Services (CMS) 209, the laboratory failed to define temperature ranges consistent with the manufacturer's instructions for 2 of 2 years (2024 and 2025). Findings Included: 1) During a laboratory tour on 7/22/2026, the following refrigerators were observed in the facility with RNA Medical Quality Control (QC) reagents, used for the AVOXimeter, stored: a. 5 East (CCU) Med Refrigerator, Sensor ID: 084007/2, TempTrak Temperature alarm range 2.2 to 7.8 degrees Celsius b. 5 West (CCU) Med Refrigerator, Sensor ID: 084068/2, TempTrak Temperature alarm range 2.2 to 7.8 degrees Celsius c. Cath Lab 1 Med Refrigerator, Sensor ID: 084025 /2, TempTrak Temperature alarm range 2.2 to 7.8 degrees Celsius d. Cath Lab 2 Med Refrigerator, Sensor ID: 084026/2, TempTrak Temperature alarm range 2.2 to 7.8 degrees Celsius e. Cath Lab 3 Med Refrigerator, Sensor ID: 084044/2, TempTrak

Temperature alarm range 2.2 to 7.8 degrees Celsius f. Cath Lab 4 Med Refrigerator, Sensor ID: 084027/2, TempTrak Temperature alarm range 2.2 to 7.8 degrees Celsius g. Cath Lab 5 (CVI) Med Refrigerator, Sensor ID: 184054/2, TempTrak Temperature alarm range 2.2 to 7.8 degrees Celsius h. Cath Lab 7 (EP) Med Refrigerator, Sensor ID: 083252/2, TempTrak Temperature alarm range 2.2 to 7.8 degrees Celsius i. CCRU-A Med Refrigerator, Sensor ID: 084002/2, TempTrak Temperature alarm range 2.2 to 7.8 degrees Celsius j. CCRU-B Med Refrigerator, Sensor ID: 084004/2, TempTrak Temperature alarm range 2.2 to 7.8 degrees Celsius k. Walk-In Refrigerator, Sensor ID: 205114/2, TempTrak alarm range 1.7 to 7.8 degrees Celsius

2) Review of the manufacturer's instructions for RNA Medical QC reagents (Lot Numbers QC 1: 54882, QC2: 254979, QC3: 55076, Multi-Level: 548296) storage temperature requirements stated 2-8 degrees C. 3) Review of the laboratory's policy titled 'MedStar Health POCT-MOD.421 Oximetry-AVOXimeter1000E MUMH' stated the following on page 2 of 12: "Quality control materials are stored at 3 to 5 degrees Celsius. Material should NOT be pre-warmed prior to testing". 4) In an interview on 7/22/26 at 11:30 AM, TC #1 and #2 confirmed the QC reagents were stored in any refrigerators mentioned above, and storage temperature ranges for the QC reagents in the laboratory's written policy as well as the temperature alarm range for Walk-In Refrigerator Sensor ID:205114/2 were not defined in accordance with manufacturer's instructions.