Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 66D2059411	**(X3) Date Survey Completed** 07/25/2025
Name of Provider or Supplier Commonwealth Healthcare Corp - Rota Health Center	**Street Address, City, State** Songsong Village, Rota, Rota, MP	
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	A federal surveyor from the Centers for Medicare & Medicaid Services (CMS) Survey Branch conducted a recertification survey on 7/25/2025, the following standard level deficiency was 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, review of laboratory freezer temperature charts, and interview with the laboratory manager, the laboratory failed to define freezer temperature ranges (freezer RHF112) consistent with the manufacturer's instructions for two of two Biofire reagents stored in the laboratory's freezer as evidenced by: 1. In direct observation at 1010, the laboratory stored the following reagents in the freezer: a. 1- Biofire Rp2/RP2 1 Plus lot #619 Apr 25 expiration date" 2027-12-31 The manufacturer's requirement specified on the box stated, "store at -25 to -15 degrees C." b. 1- Biofire Film array Panel lot #D18DCC24 expiration date: 2028-08-31 The manufacturer's requirement specified on the box stated, "Store at -25 to -15 degrees C." 2. In review of the laboratory's freezer chart for July 2025, the laboratory temperature range for the freezer was set at -20 degree or colder. The laboratory indicated the temperature of the freezer from 7-09-2025 to 7-25-2025 was -30 degree

	C. 3. In interview with the laboratory manager at 1125, confirmed that the freezer temperature's range wasn't within the manufactuer's storage requirements for biofire reagents.