

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 66D0675993	(X3) Date Survey Completed 07/23/2025
Name of Provider or Supplier Commonwealth Health Center - Respiratory	Street Address, City, State 1178 Hinemlu' St Garapan, Saipan Mariana Islands, 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, the following standard level deficiency was cited:
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: I. Based on review of manufacturer's instructions, laboratory environmental records, and interview with the laboratory manager, the laboratory failed to define, monitor and document the room humidity level where 2 of 2 Siemens Rapid Point 500e analyzers were in use as evidenced by: 1. In review of the manufacturer's instructions in Appendix E: Specification for the Siemens Rapid Point 500e analyzers states, "Ambient operating relative humidity 5-85% noncondensing." 2. In review of the laboratory environmental records, the laboratory could not provide documentation that they recording and documenting the manufacturer's requirement of humidity for the two Rapid point 500e Analyzers used in the laboratory. 3. In interview with the laboratory manager at 1535 he confirmed that they didn't record and document the humidity. II. Based on direct observation, laboratory temperature charts, and interview with the laboratory manager, the laboratory failed to define room temperature ranges</p>

consistent with the manufacturer's instructions for one of one reagent stored in the laboratory as evidenced by: 1. In direct observation at 1525 the following reagent was stored in the laboratory at room temperature with storage requirements of 4-25 degrees C. a. 1 case of Multicap-S pH blood gas 175ul Lot #2811234N expiration date of 2026-11-30 2. In review of the laboratory's temperature chart called "Daily Temperature Check," their temperature range was set at 20-30 degree C. 3. In an interview at 1526 with the laboratory manager, he confirmed that the temperature ranges differ from the manufacturer's instructions and that they would not have take corrective action above 25 degrees C.