Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0712303	04/09/2026
Name of Provider or Supplier	**Street Address, City, State**	
Cape Cod Hospital	27 Park St, Hyannis, MA	

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 onsite validation survey was conducted on 04/09/2026. The laboratory was found to be in compliance with condition-level deficiencies. The following standard-level deficiencies were 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: I. Based on laboratory observation, review of Blood Gas Laboratory room temperature logs, review of manufacturer package inserts, and interview with the Technical Consultant (TC), the laboratory failed to define an acceptable room temperature range based on the manufacturer's requirements for 13 of 13 months from April 2025 to April 2026. Findings: 1. During a tour of the Blood Gas Laboratory (Room 3-09-500) on 04/19/2026 at 12:30 PM, the following items were observed stored on open shelves: a. ABL90 Flex Solution Pack - SP90, Lot # RS-26, Quantity 7 boxes b. Qualicheck5+, Levels 1(Lot # RO233), Level 2 (Lot # RO237) and Level 3 (Lot # RO225) 2. A review of the Blood Gas Laboratory room temperature logs from April 2025 to April 2026 showed an acceptable room temperature range of 15-32C. 3. A review of the ABL90 Flex Solution package insert revealed room temperature requirements for storage was 2-25C. 4. A review of the Qualicheck5+, Levels 1-3, package insert revealed the following storage requirement, "24 months at 2-25C, with

	up to 14 days up to 32C. Ampoules must be stored at a constant temperature between 18C to 32C for 5 hours before use." 5. In an interview on 04/09/2026 at 12:45 PM, the TC confirmed the findings stated above. II. Based on Emergency Room and Blood Gas Laboratory observations, review of room temperature records, review of instrument operator's manual, and interview with the TC, the laboratory failed to define an acceptable room humidity range based on the instrument manufacturer's requirements for 13 of 13 months from April 2025 to April 2026. Findings: 1. During a tour of the Emergency Room on 04/09/2026 at 12:00 PM, the following Blood Gas Instrument was observed for patient sample testing: Radiometer ABL 90 Flex Plus #1 Serial Number: 092RO586NO15 2. During a tour of the Blood Gas Laboratory (Room # 3-09-500) on 04/19/2026 at 12:30 PM, the following Blood Gas Instruments were observed for patient sample testing: Radiometer ABL 90 Flex Plus #2 Serial Number: 092RO586NO14 Radiometer ABL 90 Flex Plus #3 Serial Number: 092RO586NO16 3. A review of the Emergency Room Department Temperature/Barometric Pressure log and the Blood Gas Laboratory Room and Refrigerator Temperature log revealed no defined acceptable range for room humidity and no record of room humidity readings from April 2025 to April 2026. 4. A review of the Radiometer ABL 90 Flex Plus Operator's manual revealed the manufacturer's room humidity requirement for operation was 20% to 80%. 5. In an interview on 04/09/2026 at 12:45 PM, the TC confirmed the findings stated above.