Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 44D0701686	**(X3) Date Survey Completed** 06/16/2023
Name of Provider or Supplier Primary Care Center Of Newport, The	**Street Address, City, State** 434 Fourth Street, Suite 310, Newport, TN	
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**
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 observation of the laboratory, review of manufacturers' instructions, lack of documentation, and interview with the lead testing person, determined the laboratory failed to monitor and document room temperature and humidity in the area where the Abbott Cell Dyn instrument was in use for Complete Blood Count (CBC) patient testing from January 2022 through the survey date of 06.16.2023. Findings include: 1. Observation of the laboratory at approximately 10:00 a.m. on 06.16.2023 revealed an Abbott Cell Dyn instrument on the laboratory counter in use for performing CBC patient testing. No devices for monitoring temperature or humidity were noted in the laboratory. 2. Review of the laboratory's Abbott Cell Dyn System Operational Specifications stated, "Laboratory Temperature: 18-30 degrees Celsius (C) (64-86 degrees Fahrenheit (F)). Relative humidity: 10%-85%, RHNC" 3. Interview with the lead testing person at approximately 11:00 a.m. on 06.16.2023 confirmed the laboratory failed to monitor and document room temperature and humidity in the area where the Abbott Cell Dyn instrument was in use for Complete Blood Count (CBC) patient testing since January 2022 through the survey date of 06.16.2023.