

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2051885	(X3) Date Survey Completed 10/15/2025
Name of Provider or Supplier Wellstar Urgent Care Atlanta	Street Address, City, State 3730 Carnia Drive, Sw, Suite 110, Atlanta, GA	
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 Clinical Laboratory Improvement Amendments (CLIA) initial survey was completed on October, 15, 2025 - October, 15, 2025. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were 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: Based on facility policy review, a review of a chemistry analyzer user manual, facility document review, observation, and interview, the laboratory failed to maintain acceptable room temperatures according to manufacturer guidelines for 2 (March 2025 and June 2025) of 12 months reviewed for chemistry testing. Findings included: A facility policy titled, "[The Facility's Management Group Abbreviation] Quality Control and Quality Assurance," dated 07/22/2024, specified, "6. Daily temperature checks of refrigerators used for reagent storage are performed by individual testing departments. The departments are responsible for monitoring temperature and humidity log sheets. Log sheets are kept at the location site and are readily available for inspection." The facility's chemistry analyzer manufacturer's user manual for an I-Stat analyzer, revised 10/18/2021, included a policy titled, "Quality Control," which specified, "Ensure that cartridges are not exposed to temperatures exceeding 30 C</p>

[degrees Celsius] (86 F [degrees Fahrenheit])." Facility documents titled, "[The Facility's Management Group Abbreviation] Temperature and Humidity Log," for the timeframe from October 2024 through October 2025, revealed the following dates the room temperature was documented outside the acceptable parameters according to the I-Stat analyzer user manual: - 03/20/2025- The room temperature was documented as 33 degrees Celsius. - 06/20/2025- The room temperature was documented as 38 degrees Celsius. - 06/27/2025- The room temperature was documented as 33 degrees Celsius. An observation of the laboratory on 10/15/2025 at 10:50 AM revealed the laboratory utilized an I-STAT chemistry analyzer and had an I-Stat test cartridge (Labeled with lot number H25163C, expiration date of 12/09/2025, refrigerator storage range of 2-8 degrees Celsius) unrefrigerated on the laboratory counter. During an interview on 10/15/2025 at 2:15 PM, Testing Personnel #1 stated that the temperature and humidity documentation logs corresponded to the room where the I-Stat test cartridge was observed on the counter for testing. During an interview on 10/15/2025 at 11:05 AM, Testing Personnel #1 confirmed that the I-Stat test cartridges were "routinely taken out of the refrigerator and left on the laboratory counter for testing."