

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2061013	(X3) Date Survey Completed 12/17/2025
Name of Provider or Supplier Wellstar Urgent Care Crabapple	Street Address, City, State 12460 Crabapple Road, Suite 901, Alpharetta, 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 December 17, 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:
D5807	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on interview, document review, and laboratory policy review, the laboratory failed to ensure reference ranges for creatinine on a chemistry profile patient report were in agreement with the laboratory policy and/or manufacturer's instructions for use (IFU) for 6 (Patients #1 - #6) of 6 patient reports reviewed. Findings included: The manufacturer's IFU for the "iSTAT CHEM8+ Cartridge" revised 10/15/2021, indicated "Expected Values The reference range for whole blood are similar to reference ranges derived from serum or plasma measurements with standard laboratory methods." Per the manufacturer's IFU, "Crea [creatinine] reference range 0.6 - 1.3 [milligram per deciliter (mg/dL)]." A laboratory policy titled, "Abbott iSTAT 1 System Chem8+ (Non-Waived)," published 07/16/2025, revealed, "Analytic Measurement Range, Notification Values and Reference Intervals: Crea [creatinine] Female: 0.5 - 0.9 [mg/dL] Male: 0.7 - 1.2 [mg/dL]." Patients #1 - #6's chemistry profile revealed the reference range for creatinine as 0.44 - 1.03 mg/dL. During an interview on 12/17/2025 at 11:30 AM, the Laboratory Director confirmed the discrepant creatinine reference range values between the patients' chemistry profiles,</p>

the laboratory policy, and the manufacturer's IFU for the Chem8+ test cartridge and was unable to explain the source of the creatinine reference range values as listed in the laboratory policy or on the patients' chemistry profiles provided and reviewed.