Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2029146	05/13/2025
Name of Provider or Supplier	**Street Address, City, State**	
Compass Urgent Care, Llc	9985 Airport Blvd, Mobile, AL	

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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on the laboratory tour, review of the i-STAT User Guide, and interviews with the Clinic Director (CD) and the Laboratory Manager (LM), the laboratory failed to follow manufacturer's specifications on acceptable anti-coagulant for the collection of Chem8+ specimen performed on the ABBOTT i-STAT analyzer. The surveyor noted the vacutainers for Chem8+ specimen collection had the incorrect anti-coagulant from the date of the last survey, 12-22-2022 to the date of the current survey, 05-13-2025. The findings include: 1. During the laboratory tour on 5-13-2025 at approximately 8: 09 AM the surveyor observed vacutainers for the collection of Chem 8+ testing that contained the Sodium Heparin as anticoagulant. 2. A review of the ABBOTT i-STAT User Guide for blood collection revealed on page three, the following instructions. Other Chemistry and Blood Gas Cartridges (including Chem8+) can use: Venous: Plain Syringe, heparinized syringe (for ionized calcium, use balance heparin syringes) or whole blood collected in evacuated tubes containing Lithium Heparin, as long as the ... 3. Interviews with the CD and LM on 5-13-2025 at 8:16 AM revealed the Testing Personnel responsible for ordering supplies was not aware of the manufacturer's specifications for the Lithium Heparin anticoagulant and had ordered the Sodium Heparin vacutainers.
D5431	MAINTENANCE AND FUNCTION CHECKS

	CFR(s): 493.1254(a)(2) (a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following: This STANDARD is not met as evidenced by: Based on reviews of i-STAT maintenance logs, the ABBOTT i-STAT System Manual and an interview with the Clinic Director (CD) and the Laboratory Manager (LM), the laboratory failed to document function checks required by the manufacturer on the i-STAT analyzer from the previous survey on 12-22-2022 to the current survey on 5-13-2025. The findings include: 1. A review of the i-STAT maintenance logs revealed no documentation of the manufacturer's required function checks for the Thermal Probe. 2. A review of the i-STAT System Manual on page 14-17 revealed the following: "... Thermal Probe Check: Check the thermal probes on the i-STAT 1 Analyzer as follows: ...4. Interpretation of the thermal probe check value: Acceptable: a value from -0.1 to +0.1, inclusive... Documentation of Results: ... use the form included in this section of the manual to record the results." 3. The laboratory was unable to provide documentation of the thermal probes checks during the survey. 4. During the exit conference on 5-13-2025 at 1:30 PM, the CD and LM stated they were not aware of the requirement to document the thermal probe check.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on reviews of the Policy and Procedure manual for the Chem8+ testing on the ABBOTT i-STAT analyzer, a workbook on the Step By Step Guide in Developing an Individualized Quality Control Plan (IQCP) and an interview with the Clinic Director (CD) and Laboratory Manager (LM), the surveyor determined the laboratory failed to establish a complete IQCP, which included the three required steps: Risk Assessment (to include five components); Quality Control Plan; and Quality Assessment. The surveyor noted the Risk Assessment Step was missing in the IQCP from the date of the last survey on 12-22-2022 to the date of the current survey on 5-13-2025. The findings include: 1. A review of the Policy and Procedure manual for ABBOTT i-STAT analyzer revealed a Summary of Method Review document the laboratory utilized as the IQCP for the Chem8+ testing. It was signed by the Laboratory Director on 2-2023. The document included the following documentation for: A) Specimen,

	Sample Collection, Handling B) Reagents and Storage C) Liquid -based QC Samples D) Analyzer Maintenance E) Proficiency Testing F) Care Of Components G) Software Upgrades H) Quality Assessment 2. A further review of the Policy and Procedure manual revealed a workbook from the Center for Medicare and Medicaid Services indicating the three required steps, Risk Assessment (to include five components); Quality Control Plan; and Quality Assessment when the laboratory developed an IQCP tailored to its unique testing, environment and patients. 3. At 11: 02 AM, a review of the "IQCP" under Summary of Method Review, revealed the laboratory did not provide documentation of risk assessment associated with the five necessary elements, to ensure the risk associated with each element was assessed across the entire testing process, pre-analytic, analytic, and post-analytic processes. The instructions for risk assessment were not included on the document. 4. During the exit conference on 5-13-2025 at 1:30 PM, the CD and LM confirmed the above findings.