



Product Name	List Number
i-STAT CHEM8+ cartridges	09P31-26

September 2021

i-STAT CHEM8+ (blue) Cartridge: Now also U.S. FDA 510(k) Cleared for use with samples collected in non-anticoagulated blood collection devices

Dear Valued Abbott Point of Care Customer,

As a follow up to our February 2020 letter to you, Abbott Point of Care is writing to inform you that the **i-STAT CHEM8+ (blue) cartridge is now also U.S. FDA 510(k) cleared for use with venous and arterial whole blood samples collected in non-anticoagulated syringes and blood collection tubes** in non-waived settings (i.e., facilities that hold a Certificate of Compliance or Accreditation).

Specifically, this clearance applies to all measured assays contained in the i-STAT CHEM8+ (blue) cartridge including sodium, potassium, chloride, blood urea nitrogen (BUN), ionized calcium, TCO₂, glucose, creatinine and hematocrit. In addition, the i-STAT CHEM8+ (blue) cartridge offers calculated measurements of anion gap and hemoglobin.

Abbott Point of Care is in the process of updating the i-STAT CHEM8+ (blue) cartridge product labeling to reflect the support of use of a venous or arterial whole blood sample collected without an anticoagulant. The updated i-STAT CHEM8+ (blue) cartridge Instructions for Use, will be available on the Abbott Point of Care website (www.globalpointofcare.abbott) the week of November 1st, 2021.

This additional 510(k) clearance applies to all i-STAT CHEM8+ (blue) cartridges, including any cartridges that you may already have on hand. You may use these cartridges until expiry with both anti-coagulated and non-anticoagulated venous and arterial whole blood samples in alignment with the updated Instructions for Use.

NEXT STEPS

Download and review the updated i-STAT CHEM8+ (blue) cartridge Instructions for Use (IFU), available the week of November 1st, 2021 (ART 765874-00 Rev. D), from the Abbott Point of Care website (www.globalpointofcare.abbott).

If you have forwarded any i-STAT CHEM8+ (blue) cartridges to another facility, we request that you please provide a copy of this letter to them.

If you have any questions regarding this information, please contact your Abbott Point of Care Sales Specialist, Abbott Point of Care Technical Support at 1-844-256-9532 or via email at apoc_productupdates@abbott.com or visit www.globalpointofcare.abbott

Abbott Point of Care understands the i-STAT CHEM8+ (blue) cartridge field action created challenges for you. We sincerely apologize and are fully committed to partnering with you to achieve our shared mission of improving the quality and efficiency of care for the patients we serve.