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To: Aculabs Point of Care Participating Facilities

**Update Regarding CLIA Waived Status for CHEM8+ Cartridges**



**EAST BRUNSWICK, N.J., Jan 16, 2020**

Abbott Diagnostics has provided Aculabs notice that their CHEM8+ cartridges, along with their EG4+ cartridges, have had their CLIA-waived status revoked. As a result, all facilities who utilize the CHEM8+ and EG4+ cartridge have been instructed to discontinue their use.

**– BACKGROUND –**

The i-STAT CHEM8+ cartridge contains nine measured assays (sodium, potassium, chloride, blood urea nitrogen (BUN), ionized calcium, TCO<sub>2</sub>, glucose, creatinine, and hematocrit) and the i-STAT CG4+ cartridge contains four measured assays (ph, PCO<sub>2</sub>, pO<sub>2</sub>, and lactate). Both of these cartridges have been marked for use with venous, arterial, and capillary specimens in CLIA non-waived settings and the CHEM8+ has also been marketed for use with venous whole blood specimens in CLIA-waived settings.

**– ISSUE –**

Since obtaining FDA clearance for the WHITE i-STAT CHEM8+ and CG4+ cartridges and CLIA waived status for the WHITE i-STAT CHEM8+ cartridge, Abbott Point of Care (“Abbott”) modified the WHITE CHEM8+ and CG4+ cartridges and introduced a BLUE CHEM8+ and CG4+ cartridge.

After these modifications, changes were observed in the performance of these cartridges. Abbott did not pursue FDA clearing or CLIA waived categorization for the BLUE CHEM8+ and CG4+ cartridges. Currently, the i-STAT BLUE CHEM8+ and CG4+ cartridges are not FDA cleared and do not have CLIA waived status.

Aculabs is in discussions with Abbott, along with other stakeholders, to determine what options are available. At this time, Aculabs recommends discontinuing the use of the i-STAT and the CHEM8+ cartridge. We are very sorry for the inconvenience and, as more information becomes available, will continue to make sure to pass it along.

Sincerely,

Peter Gudaitis  
President, Aculabs