

UPDATE

iSTAT Testing Change

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THE ISSUE:

Upstate was notified on 1/15/2020 that the iSTAT CHEM8 and CG4 cartridges made by Abbott were deemed **not cleared** for use by the FDA.

THE SOLUTION SO FAR:

FDA has **cleared the CHEM8 cartridge** including all analytes. Abbott has **not yet submitted** the CG4 cartridge to the FDA for clearance. Upstate has purchased sufficient of the CG8 cartridges for both campuses to provide for needed blood gas testing. Since the CG8 is available for blood gas testing, the **CG4 cartridges have been removed from all sites at both campuses.**

WHERE WE'RE AT SO FAR:

1. CHEM8 and CG8 both contain some of the same electrolyte tests. To avoid confusion and potential double-billing, locations with **both** of these cartridges will have orders for **ONLY** the blood gas testing on the CG8. Order sets and preference lists in these areas will be updated Thursday March 12th
 - Locations with this testing strategy – Downtown and Community Adult ED, Pediatric ED, 12F, 8E, 6H, and 6I.
 - EPIC orders: iSTAT CG8 = POC2721 (venous blood gas), POC2720 (arterial blood gas)
iSTAT CHEM8 = POC2701
2. Other locations using **ONLY** CG8 cartridges will still have **all testing** reported from this cartridge.

IMPORTANT NOTES:

There are **no FDA approved** iSTAT cartridges testing lactate at this time. Lactate testing will **only** be available via samples sent to **the main laboratories.**

None of these cartridges are currently **waived** by the FDA and thus **may NOT** be used in physician office clinics. At this time, the only clinic affected by this is the cardiology clinic at our Community Campus.

UPDATE

Cleared by FDA



The CHEM8 cartridge measures:



sodium, potassium, chloride, blood urea nitrate (BUN), ionized calcium, CO₂, glucose, creatinine, and hematocrit

The CG8 cartridge measures:



sodium, potassium, ionized calcium, glucose, hematocrit, pH, pCO₂, and pO₂. (TCO₂, HCO₃, base excess, and O₂ saturation are calculated)

The Crea cartridge measures:



creatinine.

NOT cleared by FDA



The CG4 cartridge measures:



pH, pCO₂, pO₂, and lactate.