

# iSTAT Testing Change

## THE ISSUE:

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

## THE SOLUTION:

Abbott is attempting to remedy this situation. In the meantime Upstate is purchasing alternative cartridges from Abbott for use in the iSTAT which will perform the majority of the testing currently performed using the CHEM8 and CG4 cartridges.

## WHERE WE'RE AT SO FAR:

1. Downtown Campus already uses some CG8 cartridges, but we do not currently have the supply needed to replace all of the CHEM8 and CG4 that is being used at this time.
2. Community Campus does NOT currently use the CG8 cartridge and must purchase these.
3. Both campuses have the Crea cartridge available at this time.
4. Considering the potential patient impact, we are NOT pulling the CHEM8 and CG4 cartridges at this time. Instead, these cartridges **may be used** until we have the stock of CG8 cartridges to fully support the iSTAT testing needs of both campuses.
5. At that time, the CHEM8 and CG4 cartridges will be retrieved by the Point-of-Care staff at both locations and CG8 cartridges will be distributed.

## IMPORTANT NOTES:

The replacement cartridges do **NOT** allow for testing of lactate. 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**.

The CG8 cartridge is **NOT 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.

NOT cleared by FDA

### The CHEM8 cartridge measures:



sodium, potassium, chloride, blood urea nitrate (BUN), ionized calcium, CO<sub>2</sub>, glucose, creatinine, and hematocrit

### The CG4 cartridge measures:



pH, pCO<sub>2</sub>, pO<sub>2</sub>, and lactate.

Cleared by FDA

### The CG8 cartridge measures:



sodium, potassium, ionized calcium, glucose, hematocrit, pH, pCO<sub>2</sub>, and pO<sub>2</sub>.

### The Crea cartridge measures:



creatinine.