

Physician Education Express

i-STAT Cartridges

February 2020



Audience: Providers and Advanced Providers

Education Level: Yellow

Date: February 19, 2020

Summary:

On January 15, 2020, the sole source vendor for our i-STAT Point of Care (POC) testing system announced the conclusion of an FDA evaluation, in which it was determined that three i-STAT "test modules" or cartridges (namely the CHEM8+, CG4+, and G3+ cartridges) have lost FDA clearance due to an unapproved change in their design a several years ago.

As a result, the Lab's accrediting agency, the College of American Pathologists (CAP) has informed the lab on 01/15/2020 that the Clinical Laboratory Improvement Amendments (CLIA) regulated complexity of these cartridges has changed. These are now deemed high complexity Laboratory Developed Tests (LDTs); and have more stringent compliance requirements.

We are NOT pursuing the continued use of these cartridges as High Complexity LDTs due to the stringent regulations and educational requirements for testing personnel that would take effect.

The system's goal is to transition to alternate iSTAT cartridges where possible and move testing to the nearest IUH laboratory where possible.

How This Affects IU Health:

- Point of Care lactates (currently on CG4+) will be discontinued and moved to a platform in the local laboratory
- G3+/CG4+ cartridges will transition to CG8+ for blood gas
- CHEM8+ cartridges will transition to EC8+ & Crea cartridges as applicable (CG8+ where indicated for iCa)

Matrix of Available Lab Tests by Cartridge Type

| Cartridge Status | Na | K | Cl | TCO2 | A. Gap* | iCa | Glu | BUN | Crea | Lactate | Hct | Hgb ¹ | pH | pCO2 | pO2 | TCO2 ² | HCO3 ³ | BE ⁴ | sO2 ⁵ | |
|------------------|----|---|----|------|---------|-----|-----|-----|------|---------|-----|------------------|----|------|-----|-------------------|-------------------|-----------------|------------------|--|
| Chem8+ Affected | | | | | | | | | | | | | | | | | | | | |
| CG4+ Affected | | | | | | | | | | | | | | | | | | | | |
| G3+ Affected | | | | | | | | | | | | | | | | | | | | |
| CG8+ Unaffected | | | | | | | | | | | | | | | | | | | | |
| EC8+ Unaffected | | | | | | | | | | | | | | | | | | | | |
| Crea Unaffected | | | | | | | | | | | | | | | | | | | | |
| * Calculated | | | | | | | | | | | | | | | | | | | | |

Key Points

Regional Transition Timeline:

- South Central Region: 1.27.20 ceased using affected cartridges, 2.14.20 transitioned to EC8+
- East Central Region: 2.11.20 ceased using affected cartridges, all transitions completed
- Indianapolis Suburban Region: 2.11.20 ceased using affected cartridges, transitions completed
- West Central Region: 2.20.20 will cease using affected cartridges, transitions will be completed
- Academic Health Center: 3.2.20 will cease using affected cartridges, transitions will be completed

Cerner Order Set Timeline:

- 2.14.20: Cerner order sets were updated to include iSTAT EC8+ & iSTAT Creatinine, CHEM8+ will be removed from all order sets once all facilities have transitioned.
- 3.2.20: whole blood lactate will be available at the IUH Path Lab for the AHC and sepsis order sets will be updated to include Lab whole blood lactate.

Posted February 18, 2020, FDA Recall:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=179122>

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