



The i-STAT System and Waived Status

OVERVIEW

The FDA has granted waived status for the following two i-STAT test cartridges:

- Crea (L/N 03P84-25) and G (L/N 03P83-25) (granted November 13, 2008).

Waived status is applicable only when testing venous samples collected in evacuated tubes with lithium heparin (green top tubes) with any of the above listed cartridges with the i-STAT 1 Analyzer (Handheld). These new test categorizations can be found on the list of waived tests available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/testswaived.cfm>.

Waived testing may be performed under all types of CLIA certificates: Certificate of Waiver (CW), Certificate of Provider-Performed Microscopy Procedures, Certificate of Compliance (COC), and a Certificate of Accreditation (COA). If you are currently maintaining a COC or COA because you are drawing venous samples collected in evacuated tubes with lithium heparin (green top tubes) and performing testing using the i-STAT Crea and G cartridge(s) with the i-STAT 1 Analyzer, you may “downgrade” to a CW the next time your Certificate is renewed.

THE i-STAT 1 SYSTEM MANUAL FOR WAIVED TESTS

The i-STAT 1 System Manual for Waived Tests is intended for facilities with a Certificate of Waiver. If you have a standard i-STAT System Manual and are using the i-STAT System under a Certificate of Compliance (COC) or a Certificate of Accreditation (COA), it is not necessary to order the Waived Manual. This Technical Bulletin is intended as an update to the standard i-STAT System Manuals for the use of the waived cartridges.

You do not need to have the Waived Manual if you maintain this Technical Bulletin in your current i-STAT System Manual. If desired, you can purchase the i-STAT 1 System Manual for Waived Tests (Abbott List Number 06F20-03) at no charge by contacting your Abbott Point of Care sales representative or customer service representative.

The Centers for Medicare and Medicaid Services (CMS), The Joint Commission, the College of American Pathologists, COLA and the American Association of Laboratory Accreditation (A2LA) Healthcare Facilities Accreditation Program (HFAP) will expect a facility to follow the instructions in the Waived Manual and summarized in this Technical Bulletin when using i-STAT waived cartridges to test venous samples as previously described. Laboratories will be expected to follow the instructions in the standard i-STAT Manual and the regulations for Moderate Complexity tests when using other i-STAT cartridges (other than Crea and G) or if testing sample types other than venous with the Crea and G cartridges.

Note: If the manufacturer’s instructions are not followed for any test categorization, the test defaults to high complexity.

PROFICIENCY TESTING

The Proficiency Testing Providers listed in the Technical Bulletin “Proficiency Testing and the i-STAT System,” have been informed of which cartridge types have waived status. It will take time for the providers to update their survey forms.

Note that Accrediting Organizations and certain States may have additional waived testing requirements including those for the laboratory director and personnel requirements, policies and procedures, operator competency, specimen handling, results and control reporting and instrument maintenance. Some states may restrict the list of approved waived tests.

The following are **additional** manufacturer’s quality system instructions for i-STAT cartridges granted waived status. A list of **all** of the manufacturer’s instructions are included in both the i-STAT 1 System Manual for Waived Tests and the standard i-STAT 1 System Manual.

Additional Manufacturer’s Quality System Instructions for Waived Tests	
New Shipment of Cartridges	Check one cartridge from each newly received lot with the appropriate i-STAT control: <ul style="list-style-type: none">• Crea Cartridges: use i-STAT or Tri Controls Level 1 Control,• G Cartridges: use i-STAT or Tri Controls Level 3 Control.
Ensure Proper Cartridge Storage (Including Monthly Check)	Verify that cartridges stored at room temperature are within expiration date and that cartridges have been out of the refrigerator less than the time frame indicated on the cartridge box. If the temperature at which cartridges are stored is in doubt, use a liquid control to verify that the cartridges are performing properly. Check storage conditions monthly by testing the one cartridge from refrigerated storage with the appropriate i-STAT level control. Select the one cartridge to be tested using the following order: Creatinine, and Glucose. If the cartridge being tested is a: <ul style="list-style-type: none">• Crea: use i-STAT or Tri Controls Level 1 Control.• G: use i-STAT or Tri Controls Level 3 Control.• Test the cartridge on any Handheld.

Note on control testing: Cartridges and controls have been selected based on sensitivity to thermal stress. Other control levels and hematocrit controls will not enhance the detection of thermal stress and are therefore not required.

If both moderate complexity and waived tests are performed in same unit/area:

- Handhelds could be identified as “waived testing only” or “moderate complexity testing only” to make it easier to comply with the regulatory requirements;
- You still need to follow the manufacturer’s requirements for the waived test(s), which include for example monthly quality control testing as outlined above, even if you decide to comply with moderate complexity requirements for the waived test(s),

CPT CODE INFORMATION

Please refer to the website www.codemap.com/abbott for the updated CPT (Current Procedural Terminology) codes for the waived cartridges.

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