



CLIA Waived Tests for the i-STAT[®] System

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988. CLIA was written to provide standards to ensure that laboratory test results are accurate, reliable and timely. These standards apply no matter where the tests are performed.

CLIA recognizes two types of laboratory tests: waived and non-waived. Waived tests must be simple to perform and have a low risk of error. Non-waived tests are less simple to perform and have additional skill, knowledge and responsibility requirements. Different CLIA standards apply to waived tests and non-waived tests.

At this time, only the i-STAT CHEM8+ cartridge is waived. All other i-STAT cartridges are non-waived.

It is the responsibility of the facility performing the laboratory tests to meet the CLIA requirements. The Centers for Medicare & Medicaid Services (CMS) brochure, *"How to Obtain a CLIA Certificate of Waiver,"* contains information on the requirements and responsibilities of a site performing waived tests. This brochure can be obtained from your i-STAT representative or on the CMS web site: www.cms.hhs.gov/.

Before a facility may perform laboratory tests, they must obtain a certificate from the CMS. A certificate is required whether or not patients are charged for the testing.

If a facility will perform only waived tests, they must have a CLIA Certificate of Waiver. Waived tests may also be performed under a Certificate of Provider-Performed Microscopy, a Certificate of Compliance or a Certificate of Accreditation. One of the latter two certificates is required to perform non-waived tests.

To obtain a CLIA certificate, a facility must first enroll in the CLIA program by completing an application (Form CMS-116) available online at www.cms.hhs.gov/clia or from the local State Agency. The completed application should be forwarded to the address of the local State Agency for the state in which the laboratory is located. A list of state agencies is available on the website listed above. The address and phone number for a state agency can also be acquired by calling the CLIA program at 1-410-786-3531.



i-STAT® System CHEM8+

One Convenient Cartridge. Eight Metabolic Tests.

The CHEM8+ cartridge for the i-STAT System gives physicians metabolic test results in about 2 minutes, right in the office. CHEM8+ provides eight metabolic tests, including ionized calcium, plus hematocrit. CHEM8+ does it all in a single, simple patient-side test, with just a few drops of blood.



➤ Rapid Results

Lab-accurate metabolic test results in about 2 minutes. Faster results mean faster, more informed treatment decisions.

➤ Array of Tests

Performs eight important metabolic tests, plus hematocrit. Measures ionized calcium, which many consider to be more clinically meaningful than total calcium.

➤ Reliable Accuracy

Clinical results you can trust—make patient care decisions with greater confidence.

➤ Small Sample

Just a few drops of blood required for eight metabolic tests. Easier on staff and patients alike.

➤ Easy-to-Use

Simple, intuitive operation makes it ideal for busy physician office environments.

Tests Performed by CHEM8+ Cartridge:

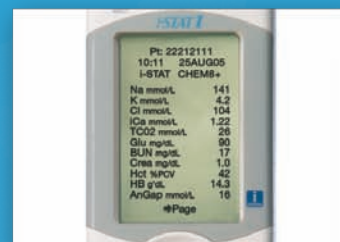
- Glucose
- Sodium
- Potassium
- Ionized Calcium
- Total CO₂
- BUN (blood urea nitrogen)
- Chloride
- Creatinine
- Hematocrit



1. Apply blood.



2. Insert cartridge.



3. Read test results.

Contact your Abbott Representative or your local Distribution Representative, or visit us at www.abbottpointofcare.com and www.codemap.com/abbott.

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