i-STAT 1 System Manual for Waived Tests

For facilities with a CLIA Certificate of Waiver

This manual describes the use of the i-STAT 1 handheld analyzer and certain cartridges that are classified by the FDA as waived tests.

Regulatory Requirements

To use the i-STAT 1 handheld analyzer (handheld) and cartridges classified as "waived" for patient testing, your facility must have a CLIA Certificate of Waiver, and meet all applicable state and local laboratory testing laws. Further, **the instructions provided in this Manual must be followed, or your facility will be in non-compliance with the CLIA Certificate of Waiver program.**

Training Requirements

Before testing patient samples, new operators should read the testing procedures they will perform. Operator competency can be assessed using a quiz such as the ones provided in the Testing Procedures sections of this Manual. It is recommended that at least one person in the facility be familiar with all information in the i-STAT 1 System Manual for Waived Tests.

Blood Collection

This manual does not include instructions on blood collection. Each testing site should have personnel trained on proper blood collection techniques. For training on blood collection (phlebotomy), seek assistance from local hospitals, universities and vocational schools. Training programs can be found on the internet (for example www.phleb.com). The Clinical and Laboratory Standards Institute (CLSI) has blood collection guidelines (phone: 610.688.0100, website: www.clsi.org).

This Manual is divided into four sections:

The **Start-up** section contains an Overview of the i-STAT System and information required to prepare, use and maintain the handheld.

The **Testing Procedures** section contains all the information required to receive and store cartridges and controls, and to perform patient and control tests.

The **System Resources** section contains a wide range of information that may be useful as a reference, although only applicable or needed in waived test settings on an occasional basis.

The **Regulatory Guide** section provides supplemental regulatory information for facilities that will be performing waived testing with the i-STAT 1 System.

For assistance, contact Technical Support:
Call 800.284.0702, option 1, or send email to: techsvc@apoc.abbott.com

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Abbott Point of Care

CLIA CERTIFICATE OF WAIVER

The application for a CLIA Certificate of Waiver, form CMS-116, can be obtained from the CMS website, www.cms.hhs.gov, or your local State Agency. State Agency information can be obtained from the CMS web site or by calling (410) 786-3531. Also see the CMS brochure "Clinical Laboratory Improvement Amendments (CLIA) – How to Obtain a CLIA Certificate of Waiver" for valuable information on Waived Tests. This brochure is available from Technical Support or the CMS web site.

MEDWATCH REPORTING

Product problems should be reported to Abbott Point of Care Inc. at 1-800-284-0702, option 1 for resolution and tracking. Product problems and serious adverse events may also be reported to the FDA website: www.fda.gov/medwatch, or by calling (800) FDA-1088.

NOTE:

The i-STAT System has features and functions that are needed in large hospitals to make compliance with laboratory regulations for non-waived tests and data management easier. Since these features and functions are not needed in a waived test setting, they will not be described in this manual. If you are interested in these additional features and functions, you can purchase the i-STAT 1 System Manual or speak with your Abbott Point of Care representative. Use of cartridges not included in this manual will require a CLIA Certificate of Compliance or Certificate of Accreditation and compliance with the CLIA regulations for non-waived tests.

TRADEMARKS

i-STAT is a registered trademark of the Abbott group of companies.

US PATENTS: www.abbott.us/patents

Symbol Technologies Corporation is the owner of US Patent No. 5,532,469.