



i-STAT CONVERSION GUIDE

This guide provides assistance to customers transitioning from an existing testing platform to the *i-STAT System*, including components for conversion. Supply orders, pricing, and service agreements can be finalized with an Abbott | Point of Care Diagnostics (APOC) *i-STAT* Sales Specialist.

INVENTORY

Verify required *i-STAT* equipment and supplies are onsite and ready for use before starting implementation. Your local *i-STAT* representative can assist with ordering new or replacement items.

HARDWARE

- *i-STAT 1* analyzer
- Simulator
- Printer
- Downloader
(downloader cable connections)

DOWNLOADERS

- Are downloaders currently installed?
- Is reprogramming needed?
- Are downloaders labeled/identified for location assignment?

CONSUMABLES

- Cartridges
- Controls & Calver
- Dispensing Tips
- Collection device
(review appropriate collection device in IFU)

NOTE: Confirm consumables and pricing are loaded in ordering system with accurate part numbers

PERFORMANCE VERIFICATION (PV)

Follow internal policy and procedures approved by Laboratory Director; direct follow-up questions to accrediting organization.

APOC PV Support | APOC resource will schedule a Performance Verification review to discuss a plan to verify the *i-STAT System*. Performance Verification is not a manufacturer's requirement, therefore, APOC will assist with the protocol approved by the laboratory director.

***i-STAT* Supply Calculator** | *i-STAT* supplies will be calculated according the number of analyzers, precision levels, method comparison and calibration replicates. Optional quality control plan, training cartridges and any additional cartridges for interface testing will be calculated at the customer's request.

Data Collection Worksheets | Worksheets will be supplied by an APOC resource at the customer's request. If a performance verification report is needed, submit request to an APOC representative.

POLICY & PROCEDURE

Review policy and procedures and identify changes needed, then obtain required signatures to revised policy.

- Review new blood collection requirements
- Evaluate existing use-model and establish changes (as needed)
- Review sample types and implement accordingly
- Assess new reportable ranges and update systems
- Visit the [Instructions for Use](#) page in the *i-STAT System* support area of the globalpointofcare.abbott website for information about test cartridges used with the *i-STAT 1* system.

INDIVIDUALIZED QUALITY CONTROL PLAN

- Evaluate risk assessment
- Ensure controls are done in accordance with IQCP
- Review QC Plan
- Confirm signature and date is updated with changes



PROFICIENCY TESTING

Laboratories performing non-waived testing generally enroll in an approved program for each specialty for which they seek certification.

NETWORKING

Contact IT resources for network assignment changes; an APOC resource can provide guidance.

- Ports and power outlets available for assigned locations
- IP's/VLANs still assigned for *i-STATs*

DATA MANAGEMENT/INTERFACING

Contact data manager vendor to determine if any changes are required for data management system. If testing is not currently interfaced and will not be interfaced in the conversion, the interfacing section does not apply.

- Verify order sets, power plans, and test batteries to ensure still active.
- Identify if order changes are needed
- If not active, contact resource to enable or re-add
- LIS updates for reportable or critical ranges
- Interface testing may be required

DE Customization Changes | Contact APOC resource to assist with changes to DE customization.

DE Customization training modules and customization instructions are available in the [i-STAT System Support](#) area of www.globalpointofcare.abbott:

- Access [DE Training Modules](#) modules in the Training & Education section
- The *i-STAT 1 System Manual* contains instructions for customization- located on the [Documentation](#) page.

SOFTWARE UPDATES

Due to the continuous manufacturing process improvements to the *i-STAT System*, it is necessary to update standardization values to maintain long-term consistency of performance. *i-STAT 1* software updates are released twice a year.

- Verify CLEW/JAMS software is updated.
- Visit the [Software](#) page to access software and instructions for updating *i-STAT 1* analyzers.

CLINICAL AWARENESS TRAINING

Inform clinicians and departmental leads of any changes (i.e. reportable range changes).

- New staff/department training requirements
- Competency and training documents up to date
- Interactive Remote Training is available.: Visit the [Online Training](#) page to download training schedules or contact your APOC resource.
- Your APOC resource can also assist with customized trainings.

i-STAT FOR *IN VITRO* DIAGNOSTIC USE ONLY. THIS MATERIAL IS INTENDED FOR A U.S. AUDIENCE ONLY.

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