Abbott Point of Care
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Princeton, New Jersey

i-STAT TBI Individual Quality Control Plan (IQCP) Example

How to Use This Document:

The following pages provide an example of an IQCP for the *i-STAT TBI* test. This sample is intended to help guide you as you create an IQCP tailored to your own facility.

When developing your facility's IQCP:

- Use your facility's official IQCP template, if one is available.
- Customize the content to reflect your specific facility's details. This includes updating items such as:
    - Facility name and address
    - Names and titles of individuals responsible for approving the IQCP
    - Any procedures or terminology unique to your organization

This document is meant to show you the types of information that may be included in an IQCP. You should review and adjust the content as needed to ensure it accurately represents your facility's practices and requirements.

Quality Control Plan Example for Traumatic Brain Injury (TBI) with the i-STAT Alinity System

The Policy and Procedure for the i-STAT Alinity System has been updated and includes the following information. The policy and procedure can be found where system policies and procedures are stored.

The Quality Control Plan (QCP) and changes based on the Risk Assessment can be found in the i-STAT Alinity System policy and procedure. A copy of the Risk Assessment is located in the "Policy & Procedure document" under the point of care section.

The QC requirements for the i-STAT Alinity System for utilizing the i-STAT TBI test cartridge at General Hospital include:

DAILY

- Ensure proper cartridge storage:
    a) Refrigerator storage conditions for cartridges are 2° C to 8°C (35° to 46°F) until expiration date.
    b) Room temperature storage conditions for cartridges are 14 days at 18° to 30° C (64° to 86°F).
    c) Cartridges are not exposed to temperatures exceeding 30°C (86°F).
    d) Cartridges are not used after expiration date printed on individual package and box.
    e) Cartridges are not outside refrigerator for longer than time frame indicated on cartridge box (write date on cartridge box or individual cartridge packages to indicate room temperature expiration date).
    f) Since QC material is frozen, and takes approximately 15 min to thaw, it can be taken out and stored at room temp or in fridge up to 4 hours prior to testing.
    g) A cartridge is used immediately after it is removed from its package.
    h) A cartridge taken from refrigerated storage will stand in its package at least 5 minutes before use, or a box of cartridges will stand at room temperature for 60 minutes (1 hour) before use.

MONTHLY OR INTERVAL BETWEEN EXTERNAL QUALITY CONTROL DUE DATE

- Analyze both levels of i-STAT TBI controls with each new lot/shipment. Record results and release cartridges based on passing QC results.
- Results must be within the Value Assignment Sheet ranges established by Abbott. Testing is performed on any i-STAT Alinity that passes the Electronic Simulator test.

MONTHLY

- Review Quality Check Failure reports to identify and address trends.

TWICE PER YEAR

- Ensure that the thermal probe check is performed on each analyzer.
- Update software and check each updated i-STAT Alinity with the external electronic simulator.

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PERIODIC

- Check temperature strip with a new shipment of controls and / or cartridges. Consider cartridges for acceptability testing only if the temperature strip reading is within acceptable range.
- Check new and replacement i-STAT Alinity analyzers with the Electronic Simulator (internal or external) before use.
- Analyze both levels of i-STAT TBI controls when testing results are questioned by a physician, if warranted by Electronic Simulator test failure or as needed if cartridge storage conditions are in question. Control results are considered acceptable if they are within manufacturer's Value Assignment Sheet ranges.
- Train staff on avoidance of pre- and post-analytical errors, such as those associated with sample collection, delays in testing, and inadequate sample mixing, and post-analytical errors (results reporting and communication)
- Review "Factors Affecting Results" with staff (as listed in the Instruction for Use document). Train testing personnel on backup provisions for testing such as backup i-STAT Alinity analyzers in other point of care areas or use of the main laboratory for testing patient samples if other options are not available.

The sample requirements for the test are:

- Suitable Sample Type:
  - Venous whole blood collected with EDTA anticoagulant.
- Handling:
  - A drop of sample will be dispensed from the EDTA tube to the cartridge using a transfer device.

Testing Personnel are fully trained in all aspects of the i-STAT TBI cartridge testing process and have been verified as competent before patient testing is performed. Ongoing competency assessments are performed as per the CLIA regulations. Key points of training and competency assessment for this test include:

- Access to the i-STAT Alinity System is only given to trained personnel who have been verified as competent
- Patient armband is checked for correct name and date of birth before collection of patient sample. Testing is performed immediately at the bedside
- Operators follow manufacturer's "Daily" quality system instructions in this plan
- If applicable, room and refrigerated storage temperatures are monitored daily with automated system that alarms when temperatures are out of range

The i-STAT Alinity System, to include the cartridges, incorporates customizable features to prevent errors. The test system will not:

- Allow personnel without a User ID to perform testing
- Run a test if the Electronic Simulator fails
- Report a result if a quality check fails — Quality Check Failure or star-out (“***”) will be displayed
- Run a test if the software has not been updated to the current version

TESTING ENVIRONMENT

- The handheld must not be moved while a test is in progress
- Instrument operating temperature is 15°C to 40°C (59°F to 104°F)
- A designated testing area that meets the environmental conditions will be used

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Post-Analytical Phase (Result Reporting and Interpretation): The i-STAT Alinity analyzers used for testing are interfaced to the LIS to remove the risk of transcription errors. Tests are run at the point of care and the results are immediately available to the ordering physician.

QUALITY ASSESSMENT IQCP REVIEW: The monitoring of the IQCP includes, but is not limited to, the following risk assessment components: testing personnel, environment, specimens, reagents, and test system. Re-evaluation of the IQCP should be considered when changes occur in any of these areas. Documents considered for QA review may include:

- QC review to be conducted by the reviewer's name and / or title
- Quality Check Failure reports to be conducted by the reviewer's name and / or title
- Patient result reviews to be conducted by the reviewer's name and / or title
- Specimen rejection logs to be conducted by the reviewer's name and / or title
- Turnaround time reports to be conducted by the reviewer's name and / or title
- Records of preventive measures, corrective actions, and follow-up to be conducted by the reviewer's name and / or title
- Personnel competency records to be conducted by the reviewer's name and / or title

AUTHORIZATION OF THE IQCP

The Risk Assessment (RA) has reviewed all relevant potential failures and potential causes that could lead to errors in test results and has included an assessment of the pre-analytical, analytical, and post-analytical phases of testing. We have developed a QCP based on the Risk Assessment (RA) to ensure we will meet the quality goals within the organization. We have determined that the i-STAT Alinity Quality Control requirements are acceptable for these tests, as performed in our laboratory when the additional quality control components noted above have been used to control for risks. When external (liquid) quality controls are tested, they will be tested at both levels and the results will be compared against the ranges on the value assignment sheets for those controls to determine acceptability of results.

The QCP will be reviewed regularly to ensure that it remains effective to control for risks with the i-STAT Alinity System. It will also be reviewed, including but not limited to, when there is a significant change to the testing personnel, environment, specimens, reagents, and / or test system or when significant changes are noted from the review of QA documents (such as QC review, QCF reports).

I authorize use of this IQCP with the i-STAT TBI test cartridge on the i-STAT Alinity System at General Hospital.

Laboratory Director Approval: Name / Signature of Laboratory Director
Date: MM/DD/YYYY

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