



# Individualized Quality Control Plan (IQCP) Guide

Aiding the development of an IQCP for the i-STAT 1 System

*i-STAT* is for *in vitro* diagnostic use only.

*i-STAT* is a trademark of the Abbott in various jurisdictions.

IQCP Guide for the i-STAT 1 System Art:772336-00A Rev. Date: 01-Mar-2023

The Centers for Medicare and Medicaid Services (CMS) introduced the Individualized Quality Control Plan (IQCP) as a quality control (QC) option for nonwaived testing under the Clinical Laboratory Improvement Amendments (CLIA) in 2016.

This approach, centered on risk management, allows laboratories to tailor a QC plan based on their unique environment, personnel, patient population, sample, reagents, and test system to identify, assess, and mitigate the risks that could lead to errors in test results based on the lab's testing process.

For information on the CLIA IQCP option, see the IQCP resources at the end of this document.

Per CLIA, the IQCP has 3 key elements:

1. **Risk Assessment** (RA) to identify potential failures and sources of errors in pre-analytical, analytical, and post-analytical processes and to evaluate the frequency and impact of those failures and error sources.
2. **Quality Control Plan** (QCP) to describe the practices, resources, and procedures to control the quality of a particular test process, ensure the accuracy and reliability of test results, and ensure that test result quality is appropriate for patient care.
3. **Quality Assessment** (QA) to monitor the ongoing effectiveness of the IQCP.



Abbott Point of Care offers product documentation in the form of the *i-STAT 1 System Manual*, product user guides (UG), Technical Bulletins (TB/TBS), Cartridge and Test Information (CTI) sheets and Instructions for Use (IFU) to aid in the performance of a Risk Assessment (RA) for the *i-STAT 1 System*.

Product updates are released and made available on our website, [www.globalpointofcare.abbott](http://www.globalpointofcare.abbott).

**Important:** This guide and related worksheet are not a manufacturer’s requirement. They are intended as an aid in the development of your IQCP Risk Assessment and Quality Control Plan.

These resources aid laboratories in supporting regulatory compliance with the Individualized Quality Control Plan (IQCP) option when using the *i-STAT 1 System*.

## Risk Assessment (RA) Resources

1. Risk Information Worksheet .....	4
2. i-STAT 1 System Manual .....	5
3. i-STAT 1 System TBs .....	6
4. Additional Documentation .....	7
5. i-STAT 1 System Control Methods Information .....	8
A. Sample (Collection, Preparation, & Testing).....	9
B. Operator (Collection, Preparation & Testing).....	15
C. Reagents (Reagent Degradation, Quality Control, & Calibration Verification Solutions).....	16
D. Laboratory Environment (Atmospheric, Utility, & General Environment).....	19
E. Test System (Measuring System & Downloader/Recharger/Printer System).....	23
6. Additional Tools to Help with the RISK Assessment.....	30

## Quality Control Plan (QCP)

1. QCP Template.....	32
2. Quality Control (QC) Plan Example .....	33

## Resources

1. IQCP Resources .....	35
-------------------------	----



**For *in vitro* diagnostic use only.** Not all products are available in all regions. Check with your local representative for availability in specific markets.

©2023 Abbott Point of Care. *i-STAT* is a trademark of the Abbott in various jurisdictions.

## 1. Risk Information Worksheet

To facilitate completion of a Risk Assessment (RA) and adherence with the Individualized Quality Control Plan (IQCP) option, Abbott Point of Care provides a guide to aid in understanding the documentation resources available and a worksheet to capture the risk-mitigation features and control methods associated with the *i-STAT 1 System*.

These resources (located at: [www.globalpointofcare.abbott](http://www.globalpointofcare.abbott)) present potential risks in the testing process, potential failures, and related failure causes that laboratories may want to include in the RA and related Quality Control Plan (QCP). This directs laboratories to suggested areas to review for specific risk-related information in the *i-STAT 1 System Manual* and/or other documents. Other steps in the testing process, potential failures, and failure causes may need to be considered; therefore, additional sections of the *i-STAT 1 System Manual* and/or related documents may be referenced.

The worksheet can be modified as needed to eliminate and/or add any potential failures and potential causes for those failures for the lab’s testing process. Once the selected information is reviewed, the worksheet can serve as evidence of regulatory compliance with the review of the manufacturer’s risk-related information for the potential failures and potential causes that can lead to errors in patient test results.

### Example of Risk Information Worksheet in Microsoft Word\*

*i-STAT 1 System Individualized Quality Control Plan (IQCP) Template*

Facility: Locations Used: Cartridge:				Risk Assessment and Quality Control Plan
Step Where Potential Failure Could Occur	Potential Failure	Potential Cause	Risk Information Location	Risk w/ Acceptable Frequency and Impact? Yes (Y) No (N) If "N", Identify Analyte(s) with Unacceptable Risk and Add Additional Steps for Significant Unacceptable Risks
Sample Collection Preparation	Sample Integrity - Contaminated	Contaminated with Alcohol	Section 10: Sample Collection	
Sample Collection Preparation	Sample Integrity - Contaminated	Contaminated with Other Cleansing Agents	Cartridge and Test Information Sheet: PT/ INR	
Sample Collection Preparation	Sample Integrity - Contaminated	Anticoagulants in Intravenous (IV) Line Fluids	Section 10: Sample Collection	

\*Microsoft® Word is a trademark of Microsoft.

Utilizing this workbook, while reviewing each line of the Risk Information worksheet and the related *i-STAT 1 System* documentation resources will aid in determining the acceptability of the risk frequency and impact for each failure/cause combination for the testing process.

When the answer to the question “Risk with Acceptable Frequency and Impact?” is “No” (or “N”) for a potential failure/potential cause combination, the space provided may be used to record additional steps for inclusion in the QCP approach.

Where there are differences in the assessment of the acceptability of risk for one or more *i-STAT* cartridges, there should be a recording of “N” or “No” for those specific cartridges. Additional steps for these significant unmitigated risks may be added and incorporated into the QCP.

## 2. i-STAT 1 System Manual

The *i-STAT 1 System Manual* is available on Abbott's website, [www.globalpointofcare.abbott](http://www.globalpointofcare.abbott). Once you have registered for access, login and navigate to SUPPORT > i-STAT 1 and i-STAT Alinity SUPPORT > CHOOSE YOUR PRODUCT > i-STAT 1 RESOURCES LOGIN and at Operator Documentation select ACCESS MANUALS to access the most current version of the *i-STAT 1 System Manual*.

### Important product support information:

1. Abbott Point of Care's support of *Central Data Station* (CDS) system ended November 2020.
2. For customers using *i-STAT/DE* versions <2.8.0.1, support ended December 2022.
3. *i-STAT E3+* and *EC4+* cartridges were no longer marketed after May 2020 in the U.S. With the spring 2023 global software release, these cartridges will be removed from the analyzer software. Product information will be removed from the *i-STAT 1 System Manual* by November 2023.
4. *i-STAT 6+* cartridge was no longer marketed after May 2020 in the U.S. The spring 2024 global software release will remove this cartridge from the analyzer software. Product information will be removed from the *i-STAT 1 System Manual* by November 2024.
5. Abbott Point of Care is discontinuing support for the following products:
  - *i-STAT Martel* printer and its accessories. Replacement product is no longer available. Product information and technical support will be available for these products through November 2023. Please transition to the *i-STAT 1* printer kit (List # 04P74-04).
  - *i-STAT 1* downloaders, serial (DS-300) and network (DN-300), and their accessories. Replacement product is no longer available. Product information and technical support will be available for these products through November 2024. Please transition to *i-STAT 1 DRC 300* kit (List # 04P73-04).
  - *i-STAT 1* downloader/rechargers, serial (DRS-300) and network (DRN-300), and their accessories. Replacement product is no longer available. Product information and technical support will be available for these products through November 2024. Please transition to *i-STAT 1 DRC 300* kit (List # 04P73-04).



**For *in vitro* diagnostic use only.** Not all products are available in all regions. Check with your local representative for availability in specific markets.

©2023 Abbott Point of Care. *i-STAT* is a trademark of the Abbott in various jurisdictions.

### 3. i-STAT 1 System Technical Bulletins

The technical bulletins listed below may be used with the Risk Information worksheet to aid in finding risk-related information for the *i-STAT 1 System*. For a complete listing, refer to [www.globalpointofcare.abbott](http://www.globalpointofcare.abbott). Login and navigate to SUPPORT > i-STAT 1 and i-STAT Alinity SUPPORT > CHOOSE YOUR PRODUCT > i-STAT 1 RESOURCES LOGIN. At Administrator Documentation select Technical Bulletins to access additional product information related to the i-STAT 1 System.

<b>i-STAT 1 System Technical Bulletins</b>	
Related to	Title
ANALYZER SOFTWARE	INSTRUCTIONS FOR UPDATING i-STAT 1 HANDHELD SOFTWARE USING WWW.GLOBALPOINTOFCARE.ABBOTT
	INSTRUCTIONS FOR UPDATING i-STAT 1 HANDHELD SOFTWARE
	NETWORK OPTIONS FOR UPDATING THE i-STAT 1 HANDHELD USING WWW.GLOBALPOINTOFCARE.ABBOTT
CONNECTIVITY	CONFIGURING WIRELESS SETTINGS IN AN i-STAT 1 WIRELESS ANALYZER
	i-STAT 1 WIRELESS SPECIFICATIONS
	PROCEDURE FOR USING THE i-STAT 1 WIRELESS ANALYZER
CUSTOMIZATION	ACT TEST RESULT CALIBRATION OPTIONS: PREWARMED vs. NON-PREWARMED RESULT CALIBRATION
	K2EDTA AND K3EDTA CUSTOMIZATION FOR HEMATOCRIT ON THE i-STAT 1 System
	SAMPLE TYPE CUSTOMIZATION ON THE i-STAT 1 ANALYZER
COMPONENTS	THE PRESENCE OF LATEX RUBBER IN I-STAT 1 System COMPONENTS
LINEARITY	i-STAT CELITE ACT AND i-STAT KAOLIN ACT HEPARIN LINEARITY PROCEDURE
PRINTER	i-STAT PRINTER RECHARGEABLE BATTERY NOTICE
TROUBLESHOOTING	ANALYZER CODED MESSAGES
	INSTRUCTIONS FOR RESTORING ANALYZERS THAT PRODUCE *** FOR HEMATOCRIT AND QUALITY CHECK CODE 23
	LATCH RETURN TOOL INSTRUCTIONS FOR USE
	CONTACT PIN CLEANING KIT INSTRUCTIONS FOR USE

#### 4. i-STAT 1 System Additional Documentation

The documents listed below may be used with the Risk Information worksheet to aid in finding risk-related information for the *i-STAT 1 System*.

<b>i-STAT 1 System Additional Documentation</b>	
Related to	Title
CUSTOMIZATION	i-STAT/DE User Guide, see <a href="http://www.globalpointofcare.abbott">www.globalpointofcare.abbott</a> for most current version
	i-STAT/DE CUSTOMIZATION WORKSPACE GUIDE
	<ul style="list-style-type: none"> <li>• CUSTOMIZING ACTION AND REFERENCE RANGES</li> <li>• CUSTOMIZING REPORTABLE RANGE</li> <li>• CUSTOMIZING ANALYTE ENABLE OPTIONS</li> </ul>
DATA MANAGEMENT	<b>INFO HQ EXPRESS</b>
	INFO HQ EXPRESS USER MANUAL, see <a href="http://www.globalpointofcare.abbott">www.globalpointofcare.abbott</a> for most current version
	INFO HQ HL7 SPECIFICATION
	<b>INFO HQ MANAGER</b>
	INFO HQ MANAGER USER MANUAL, see <a href="http://www.globalpointofcare.abbott">www.globalpointofcare.abbott</a> for most current version
	INFO HQ HL7 SPECIFICATION

## 5. i-STAT 1 System Control Methods Information

To further assist laboratories with completing their Risk Assessment (RA), specific features and control methods for each potential area of risk have been cited in this document. In addition, Abbott Point of Care offers many resources that may be used to address all of the risks listed here. These include:

- **i-STAT Interactive Remote Training (IRT)** to ensure the staff's expertise and success with the system; training should be in parallel with any existing organizational policies.
- The **i-STAT 1 System Manual** and supporting documents, such as IFU, CTI Sheets, TBs, and the *i-STAT 1 System Procedure Manual* (for US only). These resources are available online at [www.globalpointofcare.abbott](http://www.globalpointofcare.abbott)
- **Analyzer Coded Messages (Quality Check Codes)** designed into the *i-STAT 1 System* and produced when a problem with the sample, calibration, sensors, mechanical or electrical functions of the analyzer are detected. The message directs the operator to the likely cause of the quality check code, indicates the appropriate action, and provides a cause code number. The code number is stored in the analyzer's memory and can be manually tracked on a **Log Sheet** or viewed in the **Data Management System** (by department, operator, location, or analyzer).
- **Technical Support Services** to help operators and laboratory personnel better understand the test system.
- The **Operator Lockout** feature intended to prevent operators who have not been trained from utilizing cartridges.
- The **Advanced Quality Feature for Operator Competency Notification** informs the operator via the analyzer when certification of competency is due to expire.
- Observation during **Competency Assessment** presents an opportunity to ensure that an operator is performing testing accurately.

As a reminder, any related organizational policies and procedures should be followed to ensure the highest level of quality throughout the testing process.

To help explain the potential risks and control measures built into the *i-STAT 1 System*, a summary table is provided on the following pages.



**5. i-STAT 1 System Control Methods Information, continued**

**A. SAMPLE (Collection, Preparation, & Testing)**

POTENTIAL FAILURE (that can lead to errors in test results)	POTENTIAL CAUSE	CONTROL METHODS (engineered controls, external controls, training, competency, etc.)
<b>Sample Integrity: Contaminated</b>	<b>Alcohol, Other Cleansing Agents, Anticoagulants in Line, Intravenous (IV) Fluids, Admixtures With Other Fluids/ Materials</b>	<ul style="list-style-type: none"> <li>· Train on your facility’s policies and procedures for sample collection to prevent potential causes from impacting results.</li> <li>· Refer to <i>i-STAT 1 System Manual</i> - Section “Sample Collection”. For specific test information, refer to the <i>i-STAT</i> cartridge IFU or CTI sheet.</li> </ul>
<b>Sample Integrity: Inadequate Sample</b>	<b>Poor Circulation at Sample Site, Poor Vascular Access, Poor Technique</b>	<ul style="list-style-type: none"> <li>· Train on your facility’s policies and procedures for sample collection and handling.</li> <li>· Refer to <i>i-STAT 1 System Manual</i> - Section “Sample Collection”. For specific test information, refer to the <i>i-STAT</i> cartridge IFU or CTI sheet.</li> </ul>
	<b>Inadequate Sample Volume</b>	<ul style="list-style-type: none"> <li>· Train on your facility’s policies and procedures for sample collection and handling.</li> <li>· Refer to <i>i-STAT 1 System Manual</i> - Section “Sample Collection”. For specific test information, refer to the <i>i-STAT</i> cartridge IFU or CTI sheet.</li> </ul>
	<b>Hemolysis</b>	<ul style="list-style-type: none"> <li>· Train on your facility’s policies and procedures for sample collection and handling to include appropriate site selection, proper equipment selection and use (e.g., impact of lengthy tourniquet application and needle size).</li> <li>· Refer to <i>i-STAT 1 System Manual</i> - Section “Sample Collection”. For specific test information, refer to the <i>i-STAT</i> cartridge IFU or CTI sheet.</li> </ul>



**For *in vitro* diagnostic use only.** Not all products are available in all regions. Check with your local representative for availability in specific markets.

©2023 Abbott Point of Care. *i-STAT* is a trademark of the Abbott in various jurisdictions.

**A. SAMPLE (Collection, Preparation, & Testing) continued**

POTENTIAL FAILURE (that can lead to errors in test results)	POTENTIAL CAUSE	CONTROL METHODS (engineered controls, external controls, training, competency, etc.)
Sample Integrity: Inappropriate Sample	Sample Collected on Wrong Patient	<ul style="list-style-type: none"> <li>Train on your facility’s policies and procedures for patient identification.</li> <li>The <i>i-STAT</i> with-patient-testing use model and the <b>Advanced Quality Feature</b> for <b>Positive Patient ID</b> (PPID) support collection of samples on the correct patient. Refer to the <i>i-STAT/DE User Guide</i> for information on the Positive Patient ID feature.</li> <li><b>Comment Codes</b> (e.g., code “99”, “reject sample/recollect”) can be used if the user recognizes that the wrong patient was tested to prevent results from entering patient medical record (when programmed into the LIS interface). Refer to the <i>i-STAT/DE User Guide</i> for information on the comment code customization option.</li> </ul>
	Incorrect Sample Type, Collected in Wrong Tube or Syringe/Wrong Additives	<ul style="list-style-type: none"> <li>Train on your facility’s policies and procedures for collecting samples.</li> <li>For acceptable sample type, correct tube or syringe type, and acceptable additives for each test, refer to the <i>i-STAT</i> cartridge IFU or CTI sheet and <i>i-STAT 1 System Manual</i> - Section “Sample Collection” and “Cartridge and Test Information.”</li> <li>The <i>i-STAT 1 System</i> allows the operator to select a sample type on the <b>Chart Page</b> when sample type customization feature is utilized. For more information on this feature, refer to the <i>i-STAT 1 System TB Sample Type Customization on the i-STAT 1 Analyzer</i> and the <i>i-STAT/DE User Guide</i>.</li> <li><b>Comment Codes</b> (e.g., code “99,” “reject sample/recollect”) can be used if the user recognizes that incorrect sample collection occurred to prevent results from entering patient medical record (when programmed into the LIS interface). For more information on customization options for comment codes, please refer to the <i>i-STAT/DE User Guide</i>.</li> <li><b>STATNotes</b> offers options to prevent results from crossing the interface (e.g., “reject sample”). An Abbott Point of Care representative is required to implement this feature. For more information, please contact your local Abbott Point of Care representative.</li> </ul>

**A. SAMPLE (Collection, Preparation, & Testing) continued**

POTENTIAL FAILURE (that can lead to errors in test results)	POTENTIAL CAUSE	CONTROL METHODS (engineered controls, external controls, training, competency, etc.)
<b>Sample Integrity: Inappropriate Sample (cont)</b>	<b>Sample Clots/ Has Clots Due to Inadequate Mixing of Sample, Not Testing Sample Without Anticoagulant Immediately</b>	<ul style="list-style-type: none"> <li>• Train on your facility’s policies and procedures for collecting samples.</li> <li>• <b>Analyzer Coded Messages (Quality Check Codes)</b> designed into the <i>i-STAT 1 System</i> indicate when a cartridge has a lack of sample movement that is likely due to clots in the sample. The code number is stored in the analyzer memory and can be manually tracked on a log sheet or viewed in the data management system (by department, operator, location, or analyzer). Refer to the <i>i-STAT 1 System Manual</i> - Section “Sample Collection,” Section “Troubleshooting the Analyzer,” <i>i-STAT 1 System TB Analyzer Coded Messages</i> and <i>i-STAT</i> cartridge IFU and CTI sheets.</li> </ul>
	<b>Air in Syringe/ Sample Exposed to Air, Improper Sample Handling/ Partial Draw Tubes</b>	<ul style="list-style-type: none"> <li>• Train on your facility’s policies and procedures based on syringe manufacturer’s instructions for handling blood collected in syringes for blood gas testing.</li> <li>• Refer to <i>i-STAT 1 System Manual</i> - Section “Sample Collection.” For specific test information, refer to the <i>i-STAT</i> cartridge IFU.</li> </ul>
<b>Sample Integrity: Patient Condition Inappropriate for Testing Method</b>	<b>Hematocrit (HCT), Interference— Patient Undergoing CPB</b>	<ul style="list-style-type: none"> <li>• Train on your facility’s policies and procedures for use of <b>Cardiopulmonary Bypass (CPB)</b> sample type. CPB option is only available for <i>i-STAT</i> cartridges that include HCT. CPB sample type is no longer needed once total protein returns to normal. Refer to the <i>i-STAT/DE User Guide</i> for more information on the customization options for CPB, and the <i>i-STAT</i> cartridge IFU for HCT interferences.</li> </ul>
	<b>Medications Interfere With Method</b>	<ul style="list-style-type: none"> <li>• Refer to <i>i-STAT 1 System Manual</i> - Section “Sample Collection,” Section Procedure for Cartridge Testing” and the <i>i-STAT</i> cartridge IFUs and CTI sheets for a list of known medications that interfere with method.</li> </ul>
	<b>Lipemia</b>	<ul style="list-style-type: none"> <li>• Refer to the <i>i-STAT</i> cartridge IFU for information on lipemia.</li> </ul>



**A. SAMPLE (Collection, Preparation, & Testing) continued**

POTENTIAL FAILURE (that can lead to errors in test results)	POTENTIAL CAUSE	CONTROL METHODS (engineered controls, external controls, training, competency, etc.)
<b>Sample Integrity: Incorrect Procedure/Technique</b>	<b>Icing Samples</b>	<ul style="list-style-type: none"> <li>Train to not ice samples. Icing may increase the potassium and will affect oxygen levels. Refer to <i>i-STAT 1 System Manual</i> - Section “Sample Collection” and <i>i-STAT</i> cartridge IFU.</li> </ul>
	<b>Incorrect Time Before Testing/Time to Transport Sample</b>	<ul style="list-style-type: none"> <li>The <i>i-STAT</i> with-patient-testing use model supports immediate testing/elimination of need for sample transport.</li> <li>Train on time allowed for testing with focus on immediate testing for lactate, ACT, and PT/INR. Refer to <i>i-STAT 1 System Manual</i> - “Cartridge and Test Information” and <i>i-STAT</i> cartridge IFUs and CTI sheets.</li> </ul>
	<b>Sample Inadequately Mixed</b>	<ul style="list-style-type: none"> <li>Train on your facility’s policies and procedures for mixing sample after collection to prevent clotting and remixing if testing is not immediate.</li> <li>Refer to <i>i-STAT 1 System Manual</i> - Section “Sample Collection” and <i>i-STAT</i> cartridge IFUs and CTI sheets.</li> </ul>
	<b>Incorrect Patient Identification Information Entered Into Instrument</b>	<ul style="list-style-type: none"> <li>Train on your facility’s policies and procedures for patient identification.</li> <li>The <i>i-STAT</i> with-patient-testing use model and the <b>Advanced Quality Feature</b> for <b>Positive Patient ID</b> support collection of samples using the correct patient identification. <b>Barcode Scanning</b> reduces the risk of manual entry error. <b>Set Max/Min ID Length</b> to help prevent the user from making ID entry errors. <b>Repeat ID Entry</b> is an option for manual and scanned ID entry. Refer to <i>i-STAT 1 System Manual</i> - Section “Customization” and <i>i-STAT/DE User Guide</i>.</li> </ul>

**A. SAMPLE (Collection, Preparation, & Testing) continued**

POTENTIAL FAILURE (that can lead to errors in test results)	POTENTIAL CAUSE	CONTROL METHODS (engineered controls, external controls, training, competency, etc.)
<b>Sample Integrity: Incorrect Procedure/ Technique (cont)</b>	<b>Sample Mislabeled/ Not Labeled</b>	<ul style="list-style-type: none"> <li>Train on your facility’s policies and procedures for sample labeling if immediate testing cannot be performed.</li> </ul>
	<b>Improper Handling of Cartridge</b>	<ul style="list-style-type: none"> <li>Train to procedure for handling cartridges. Refer to the <i>i-STAT 1 System Manual</i> - Section “Procedure For Handling Cartridges”.</li> <li><b>Analyzer Coded Messages</b> are designed into the <i>i-STAT 1 System</i> to indicate when there is an issue with cartridge handling. Refer to the <i>i-STAT 1 System Manual</i> - Section “Procedure For Handling Cartridges,” Section “Troubleshooting the Analyzer” and <i>i-STAT 1 System TB Analyzer Coded Messages</i>.</li> </ul>
<b>Sample Integrity: Inappropriate Amount of Sample Presented</b>	<b>Cartridge Underfill, Cartridge Overfill, Introduction of Air Bubble, and Clot in Cartridge</b>	<ul style="list-style-type: none"> <li>Train to procedure for handling cartridges. Refer to the <i>i-STAT 1 System Manual</i> - Section “Sample Collection” and Section “Procedure For Handling Cartridges.”</li> <li><b>Analyzer Coded Messages</b> designed into the <i>i-STAT 1 System</i> indicate when a cartridge has been underfilled, overfilled, has an air bubble, or has a clot inhibiting sample movement. The message directs the operator to the likely cause, indicates the appropriate action, and provides a cause code number that can be used to obtain additional information. Refer to the <i>i-STAT 1 System Manual</i> - Section “Troubleshooting the Analyzer” and <i>i-STAT 1 System TB Analyzer Coded Messages</i>.</li> <li>The <b>Quality Check Code</b> number is stored in the analyzer memory and can be tracked manually by your facility’s process or viewed in the data management system (by department, operator, location, or analyzer).</li> </ul>



**A. SAMPLE (Collection, Preparation, & Testing) continued**

POTENTIAL FAILURE (that can lead to errors in test results)	POTENTIAL CAUSE	CONTROL METHODS (engineered controls, external controls, training, competency, etc.)
<b>Introduction of Cartridge to Test Device</b>	<b>Cartridge Type Scanned Does Not Match Cartridge Type Inserted Into Analyzer</b>	<ul style="list-style-type: none"> <li>• An <b>Analyzer Coded Message</b> (Code 15) designed into the <i>i-STAT 1 System</i> indicates when the cartridge lot number scanned does not match the cartridge type inserted in the analyzer. The message directs the operator to the likely cause, indicates the appropriate action, and provides a cause code number that can be used to obtain additional information. Refer to the <i>i-STAT 1 System Manual</i> - Section “Procedure for Cartridge Testing” and <i>i-STAT 1 System TB Analyzer Coded Messages</i>.</li> <li>• The <b>Quality Check Code</b> number is stored in the analyzer memory and can be tracked manually by your facility’s process or viewed in the data management system (by department, operator, location, or analyzer).</li> </ul>
	<b>Cartridge Not Inserted Properly</b>	<ul style="list-style-type: none"> <li>• The <i>i-STAT 1 System</i> will not process a cartridge that has not been inserted correctly. Train on proper insertion of cartridge into the analyzer. Refer to <i>i-STAT 1 System Manual</i> - Section “Procedure for Handling Cartridges,” Section “Troubleshooting the Analyzer” and <i>i-STAT 1 System TB Analyzer Coded Messages</i>.</li> </ul>
	<b>Removal of Cartridge Before Completion of Test</b>	<ul style="list-style-type: none"> <li>• The <i>i-STAT 1</i> analyzer displays the message “Cartridge Locked” until the system unlocks the cartridge after the testing process is complete. Train to procedure for “Removing Cartridge from Analyzer.” Any attempt to remove cartridge before testing is complete may cause damage to the analyzer. Refer to <i>i-STAT 1 System Manual</i> - Section “i-STAT 1 Analyzer” and Section “Procedure for Handling Cartridges.”</li> </ul>

**B. OPERATOR (Collection, Preparation, & Testing)**

POTENTIAL FAILURE (that can lead to errors in test results)	POTENTIAL CAUSE	CONTROL METHODS (engineered controls, external controls, training, competency, etc.)
Capacity	Lack of Training, Incompetency, Untrained Operator	<ul style="list-style-type: none"> <li>· The <i>i-STAT 1 System</i> design ensures that the quality of results is not dependent upon operator technique. It also allows for the design of a quality control system that automatically monitors those aspects of the measurement process that are most likely to impact quality, including the characteristics of the individual sensors and the operator’s actions. Refer to <i>i-STAT 1 System Manual</i> - Section “Theory.”</li> <li>· The <i>i-STAT 1 System</i> connectivity and data management options allow the operator to easily transfer data into the medical record without manually entering information (risking transcription errors). Reports provide tracking of system use by department, operator, location, or analyzer. Refer to <a href="http://www.globalpointofcare.abbott">www.globalpointofcare.abbott</a> for connectivity and data management options.</li> <li>· <b>Start-Up Messages</b> are displayed if a problem is detected when the analyzer is turned on. The message will identify the problem and indicate the next step to be taken. <b>Analyzer Coded Messages</b> include those related to the unit-use cartridge (including handling), analyzer, operator, sample, and environment. Refer to <i>i-STAT 1 System Manual</i> - Section “Troubleshooting the Analyzer” and <i>i-STAT 1 System TB Analyzer Coded Messages</i>.</li> <li>· Use of <b>Operator List</b> prevents untrained operators from accessing the system. Customization also allows application of rules for certification/recertification and operator list, with Warning and/or Lockout available as options. Refer to the <i>i-STAT/DE User Guide</i>.</li> <li>· For additional system information, refer to <i>i-STAT 1 System Manual</i> - Section “i-STAT 1 Analyzer,” Section “Sample Collection,” Section “Procedure for Cartridge Handling,” Section “Quality Control” and <i>i-STAT</i> cartridge IFU and CTI sheets.</li> </ul>



**For *in vitro* diagnostic use only.** Not all products are available in all regions. Check with your local representative for availability in specific markets.

©2023 Abbott Point of Care. *i-STAT* is a trademark of the Abbott in various jurisdictions.

**RISK ASSESSMENT**  
**CONTROL METHODS INFORMATION**  
**REAGENTS (Reagent Degradation, Quality Control,  
& Calibration Verification Solutions)**

**C. REAGENTS (Reagent Degradation, Quality Control,  
& Calibration Verification Solutions)**

POTENTIAL FAILURE (that can lead to errors in test results)	POTENTIAL CAUSE	CONTROL METHODS (engineered controls, external controls, training, competency, etc.)
<b>Cartridge Reagent Degradation</b>	<b>Improper Shipping</b>	<ul style="list-style-type: none"> <li>· A <b>temperature strip</b> is provided in shipment to monitor temperature during transit. The packaging of materials for shipment is designed to reduce risk from thermal stress. Refer to <i>i-STAT 1 System Manual</i> - Section “Quality Control” which contains a log to document receipt.</li> </ul>
	<b>Improper Storage</b>	<ul style="list-style-type: none"> <li>· Monitor temperature by manual or automated system to ensure proper storage conditions. If storage conditions are in doubt or are verified as out of range, test cartridges with controls and follow your facility’s policy on the use of incorrectly stored reagents.</li> <li>· Cartridges should be individually dated with room temperature storage expiration. Refer to <i>i-STAT 1 System Manual</i> - Section “i-STAT Cartridge” and Section “Quality Control,” which contains the <i>i-STAT 1 System QC Log: Expiration Date and Storage Conditions Log</i>.</li> </ul>
	<b>Used Past Expiration</b>	<ul style="list-style-type: none"> <li>· <b>Cartridge Barcode Scanning</b> will prohibit testing if cartridge lot is past expiration date printed on cartridge box and pouch. Train on recording the room temperature expiration date on cartridge pouches/portion packs and cartridge boxes once they are removed from refrigerated storage. Refer to <i>i-STAT 1 System Manual</i> - Section “i-STAT Cartridge,” Section “Quality Control,” which contains the <i>i-STAT 1 System QC Log: Expiration Date and Storage Conditions Log</i> and <i>i-STAT 1 TB Analyzer Coded Messages</i>.</li> </ul>



**RISK ASSESSMENT**  
**CONTROL METHODS INFORMATION**  
**REAGENTS (Reagent Degradation, Quality Control,  
& Calibration Verification Solutions)**

**C. REAGENTS (Reagent Degradation, Quality Control,  
& Calibration Verification Solutions) continued**

POTENTIAL FAILURE (that can lead to errors in test results)	POTENTIAL CAUSE	CONTROL METHODS (engineered controls, external controls, training, competency, etc.)
<b>Quality Control Material Degradation</b>	<b>Improper Shipping</b>	<ul style="list-style-type: none"> <li>• A <b>temperature strip</b> is provided in shipment to monitor temperature during transit; packaging of materials for shipment is designed to reduce risk from thermal stress. Refer to <i>i-STAT 1 System Manual</i> - Section “Quality Control.”</li> </ul>
	<b>Improper Storage</b>	<ul style="list-style-type: none"> <li>• Monitor temperature by manual or automated system to ensure proper storage conditions. Follow your facility’s policy on the use of incorrectly stored controls.</li> <li>• Train on proper storage of QC materials. Vials should be individually dated with room temperature storage expiration. Refer to <i>i-STAT 1 System Manual</i> - Section “Quality Control.”</li> </ul>
	<b>Used Past Expiration</b>	<ul style="list-style-type: none"> <li>• <b>Control Barcode Scanning</b> will prohibit testing if APOC controls are past expiration date printed on vial. Train on recording room temperature expiration dating to QC vials. Expiration specifications vary depending on control type. Refer to <i>i-STAT 1 System Manual</i> - Section “Quality Control.”</li> </ul>
<b>Quality Control Material—Inaccurate Preparation and Use</b>	<b>Procedure Not Followed for Preparation, Mixing, Use/ Wrong VAS Used</b>	<ul style="list-style-type: none"> <li>• Train on correct use of controls. Refer to <i>i-STAT 1 System Manual</i> - Section “Quality Control.”</li> <li>• Use correct version of the Value Assignment Sheets (VAS), located at <a href="http://www.globalpointofcare.abbott">www.globalpointofcare.abbott</a>.</li> <li>• The Advanced Quality Features (AQF) include option for automatic Pass/Fail determination via an eVAS (Electronic Value Assignment Sheet) with APOC QC results that are recorded in the analyzer. Refer to the <i>i-STAT/DE User Guide</i>.</li> </ul>



**RISK ASSESSMENT**  
**CONTROL METHODS INFORMATION**  
**REAGENTS (Reagent Degradation, Quality Control,  
& Calibration Verification Solutions)**

**C. REAGENTS (Reagent Degradation, Quality Control,  
& Calibration Verification Solutions) continued**

POTENTIAL FAILURE (that can lead to errors in test results)	POTENTIAL CAUSE	CONTROL METHODS (engineered controls, external controls, training, competency, etc.)
<b>Calibration Verification Material Degradation</b>	<b>Improper Shipping</b>	<ul style="list-style-type: none"> <li>· A <b>temperature strip</b> is provided in shipment to monitor temperature during transit; packaging of materials for shipment is designed to reduce risk from thermal stress. Refer to <i>i-STAT 1 System Manual</i> - Section “Quality Control.”</li> </ul>
	<b>Improper Storage</b>	<ul style="list-style-type: none"> <li>· Monitor temperature by manual or automated system to ensure proper storage conditions. Follow your facility’s policy on the use of incorrectly stored calibration verification material.</li> <li>· Train on proper storage of cal ver materials. Vials should be individually dated with room temperature storage expiration. Refer to <i>i-STAT 1 System Manual</i> - Section “Calibration Verification.”</li> </ul>
	<b>Used Past Expiration</b>	<ul style="list-style-type: none"> <li>· <b>Cal Ver Barcode Scanning</b> will prohibit testing if APOC controls are past expiration date printed on vial. Train on adding expiration dating to Cal Ver vials. Expiration specifications vary depending on Cal Ver type. Refer to <i>i-STAT 1 System Manual</i> - Section “Calibration Verification” for details.</li> </ul>
<b>Calibration Verification Material—Inaccurate Preparation and Use</b>	<b>Procedure Not Followed for Preparation, Mixing, Use/ Wrong VAS Used</b>	<ul style="list-style-type: none"> <li>· Train on correct use of Cal Ver materials. Refer to <i>i-STAT 1 System Manual</i> - Section “Calibration Verification” and <i>i-STAT 1 System TB i-STAT Celite ACT</i> and <i>i-STAT Kaolin ACT Heparin Linearity Procedure</i>.</li> <li>· Use correct version of the Value Assignment Sheets (VAS), located at <a href="http://www.globalpointofcare.abbott">www.globalpointofcare.abbott</a>.</li> </ul>

**D. LABORATORY ENVIRONMENT (Atmospheric, Utility, & General Environment)**

POTENTIAL FAILURE (that can lead to errors in test results)	POTENTIAL CAUSE	CONTROL METHODS (engineered controls, external controls, training, competency, etc.)
<b>Atmospheric Environment</b>	<b>Improper Temperature</b>	<ul style="list-style-type: none"> <li>• <b>Temperature monitoring</b> with automated recording or a daily temperature log sheet can be used to ensure the test system is used within the manufacturer’s recommended range. Train on your facility’s policies and procedures for monitoring room temperature.</li> <li>• The analyzer takes a room temperature measurement before initiating a test cycle. If out-of-range temperature conditions occur, a <b>Quality Check Code</b> will display on the analyzer with recommended action step (e.g., “Temperature Out of Range/Check Status Page”). Testing is disabled. The analyzer’s temperature reading can be found on the Status Page. Refer to <i>i-STAT 1 System Manual</i> - Section “i-STAT 1 Analyzer,” Section “i-STAT Cartridge,” Section “Electronic Simulator,” Section “Quality Control,” Section “Troubleshooting the Analyzer” and <i>i-STAT 1 System TB Analyzer Coded Messages</i>.</li> </ul>
	<b>Improper Humidity</b>	<ul style="list-style-type: none"> <li>• <b>System Design</b> allows for use 10- 90% non-condensing humidity. Refer to <i>i-STAT 1 System Manual</i> Section “i-STAT 1 Analyzer” and Section “Electronic Simulator.”</li> <li>• The internal or external <b>Electronic Simulator test</b> will fail if high humidity interferes with measurements. Refer to <i>i-STAT 1 System Manual</i> - Section “Quality Control” and <i>i-STAT 1 System TB Analyzer Coded Messages</i>.</li> </ul>
	<b>Improper Barometric Pressure/Altitude</b>	<ul style="list-style-type: none"> <li>• Results for barometric pressure are available with each test record. Results for the barometric pressure can be verified against a known barometric pressure as needed to comply with local or accrediting organization requirements. Refer to <i>i-STAT 1 System Manual</i> - Section “i-STAT 1 Analyzer,” Section “Quality Control,” Section “Calibration Verification” and Section “Proficiency or External Quality Control.”</li> <li>• An <b>Analyzer Coded Message</b> is displayed when there is a problem with the pressure transducers in the analyzer; a message explains the action step to be taken. Refer to <i>i-STAT 1 System TB Analyzer Coded Messages</i>.</li> </ul>



**For *in vitro* diagnostic use only.** Not all products are available in all regions. Check with your local representative for availability in specific markets.

©2023 Abbott Point of Care. *i-STAT* is a trademark of the Abbott in various jurisdictions.

**D. LABORATORY ENVIRONMENT (Atmospheric, Utility, & General Environment)**

POTENTIAL FAILURE (that can lead to errors in test results)	POTENTIAL CAUSE	CONTROL METHODS (engineered controls, external controls, training, competency, etc.)
<b>Atmospheric Environment (cont)</b>	<b>Dust and Debris</b>	<ul style="list-style-type: none"> <li>• <b>Analyzer Coded Messages</b> can indicate if there is interference with the sensors or contact between the cartridge and the analyzer. A <b>Ceramic Conditioning Cartridge</b> is available to condition the pins in the analyzer as needed. A <b>Contact Pin Cleaning kit</b> is used to remove fiber and dirt contamination in the analyzer when Codes 48, 57 or 68 are generated. Refer to the <i>i-STAT 1 System Manual</i> - Section “Procedure for Cartridge Handling,” Section “Troubleshooting the Analyzer” and <i>i-STAT 1 System TB Analyzer Coded Messages</i>.</li> </ul>
<b>Utility Environment</b>	<b>Inadequate Electrical Availability</b>	<ul style="list-style-type: none"> <li>• The <b><i>i-STAT 1</i> analyzer</b> is powered by batteries and does not require a power outlet. Refer to <i>i-STAT 1 System Manual</i> - Section “<i>i-STAT 1</i> Analyzer.”</li> <li>• The <i>i-STAT 1</i> printer is powered by rechargeable-batteries. Refer to <i>i-STAT 1 System Manual</i> - Section “Portable Printer.”</li> <li>• Install power cable/power supply so they do not pose a trip hazard. The AC power supply adapter plug acts as a disconnect device for the <i>i-STAT 1 DRC-300</i> downloader/recharger, therefore, the socket outlet must be easily accessible. Using the Y-splitter cable to connect the <i>i-STAT 1</i> printer to the <i>i-STAT 1 DRC-300</i> reduces the number of power outlets required. Refer to <i>i-STAT 1 System Manual</i> - Section “<i>i-STAT 1</i> Downloader/Recharger.”</li> </ul>

**D. LABORATORY ENVIRONMENT (Atmospheric, Utility, & General Environment)**

POTENTIAL FAILURE (that can lead to errors in test results)	POTENTIAL CAUSE	CONTROL METHODS (engineered controls, external controls, training, competency, etc.)
<b>Utility Environment (cont)</b>	<b>Radio Frequency Interference/ Electromagnetic Interference</b>	<ul style="list-style-type: none"> <li>An <b>Analyzer Coded Message</b> and action message are provided when the analyzer detects noise on the thermal circuit that may be a result of electrical interference. Refer to the <i>i-STAT 1 System Manual</i> - Section “Troubleshooting the Analyzer” and <i>i-STAT 1 System TB Analyzer Coded Messages</i>.</li> <li>The <b><i>i-STAT 1 Wireless Analyzer</i></b> complies with FCC and IEC Radio Frequency Emissions requirements. Refer to <i>i-STAT 1 System TB Wireless Analyzer Specifications</i>. After reviewing the technical specifications of the Wi-Fi module (such as maximum transmit power, supported channels, and data rates), facilities must assess if other equipment is compatible (immune) to that transmitter.</li> </ul>
	<b>Vibration/Motion</b>	<ul style="list-style-type: none"> <li>Train on the importance of testing in a vibration-free environment as appropriate and to not move the analyzer while testing is in progress as appropriate. Refer to <i>i-STAT 1 System Manual</i> - Section “Procedure for Handling Cartridges,” Section “Procedure For Cartridge Testing” and CTI sheets.</li> </ul>
<b>Utility Environment</b>	<b>Not Testing on Flat/Level Surface</b>	<ul style="list-style-type: none"> <li>Train on the importance of testing on a flat/level surface. Refer to <i>i-STAT 1 System Manual</i> - Section “Procedure for Handling Cartridges,” Section “Procedure for Cartridge Testing,” Section “Quality Control,” Section “Calibration Verification” and Section “Proficiency or External Quality Control Testing,”</li> </ul>
<b>General Environment</b>	<b>Inadequate Airflow/ Ventilation</b>	<ul style="list-style-type: none"> <li>Train on use of the <i>i-STAT 1</i> analyzer and downloader/recharger and effect on ambient temperature. Refer to <i>i-STAT 1 System Manual</i> - Section “<i>i-STAT 1</i> Downloader/Recharger,” Section “Troubleshooting the Analyzer” and <i>i-STAT 1 System TB Analyzer Coded Messages</i>.</li> </ul>

**D. LABORATORY ENVIRONMENT (Atmospheric, Utility, & General Environment)**

POTENTIAL FAILURE (That can lead to errors in test results)	POTENTIAL CAUSE	CONTROL METHODS (Engineered controls, external controls, training, competency, etc.)
<b>Measuring System: Sample Analysis/ Analytical Process</b>	<b>Poor Precision</b>	<ul style="list-style-type: none"> <li>· The Abbott Point of Care <b>Performance Verification (PV) Protocols</b> offer guidance for the laboratory director’s consideration and are available upon request. PV protocols are not manufacturer’s recommendation but a guidance to assist with regulatory requirements.</li> <li>· Refer to <i>i-STAT</i> cartridge IFU and CTI sheets.</li> </ul>
	<b>Poor Trueness/ Correlation With Laboratory Method</b>	<ul style="list-style-type: none"> <li>· The Abbott Point of Care <b>Performance Verification (PV) Protocols</b> offer guidance for the laboratory director’s consideration and are available upon request. PV protocols are not manufacturer’s recommendation but a guidance to assist with regulatory requirements. <b>Comparative Method Testing</b> as part of regulatory compliance offers information about the ongoing accuracy of the test system.</li> <li>· <b>Calibration Verification Testing</b> offers evidence of the system’s accuracy across the reportable range. Refer to <i>i-STAT 1 System Manual</i> - Section “Calibration Verification.”</li> <li>· <b>Proficiency Testing (PT) Surveys</b> offer evidence of comparative results with peers who use the test system. Refer to <i>i-STAT 1 System Manual</i> - Section “Proficiency or External QC Testing.”</li> <li>· Refer to <i>i-STAT</i> cartridge IFU and CTI sheets.</li> </ul>

**E. TEST SYSTEM (Measuring System & Downloader/Recharger/Printer System)**

POTENTIAL FAILURE (that can lead to errors in test results)	POTENTIAL CAUSE	CONTROL METHODS (engineered controls, external controls, training, competency, etc.)
<b>Measuring System: Sample Analysis/ Analytical Process (cont)</b>	<b>Interferences</b>	<ul style="list-style-type: none"> <li>Train on interferences to assist operators with identifying those substances that can impact test results. Refer to the <i>i-STAT</i> cartridge IFUs and CTI sheets available at <a href="http://www.globalpointofcare.abbott">www.globalpointofcare.abbott</a>.</li> </ul>
	<b>Used Beyond Intended Use</b>	<ul style="list-style-type: none"> <li>Train on the intended use of the tests being performed to minimize the risk for off-label use. Refer to the <i>i-STAT</i> cartridge IFUs and CTI sheets available at <a href="http://www.globalpointofcare.abbott">www.globalpointofcare.abbott</a>.</li> </ul>
	<b>Used Beyond Limitations for Use</b>	<ul style="list-style-type: none"> <li>Train on limitations and factors affecting results found in the <i>i-STAT</i> cartridge IFUs and CTI sheets.</li> </ul>
	<b>Incorrect Analysis Mode</b>	<ul style="list-style-type: none"> <li>Train on selecting the correct testing option from the test menu and the administration menu. Refer to <i>i-STAT 1 System Manual</i> - Section “<i>i-STAT 1 Analyzer</i>”</li> <li>Measurement limits are not applied to results in the Cal Ver test path. Results above and below the measurement range will be reported. Refer to <i>i-STAT 1 System Manual</i> - Section “<i>Calibration Verification</i>.”</li> <li>The use of the Proficiency Test path for proficiency samples will ensure consistency with customization settings for HCT and ACT tests. Refer to <i>i-STAT 1 System Manual</i> - Section “<i>Proficiency or External QC Testing</i>.”</li> </ul>
	<b>Incorrect Analyte Selected</b>	<ul style="list-style-type: none"> <li>If <b>Test Selection</b> is enabled through customization, analytes are displayed on the screen of the analyzer and tests may be selected.</li> <li>Customization also allows <b>Analyte Enable</b> globally or by panel. This allows for selected tests to be enabled or disabled.</li> <li><b>STATNotes</b> can be used to prevent the result from entering the patient chart. Refer to <i>i-STAT 1 System Manual</i> - Section “<i>Customization</i>” and navigate to <a href="http://www.globalpointofcare.abbott">www.globalpointofcare.abbott</a> for <i>i-STAT/DE</i> documentation.</li> </ul>



**E. TEST SYSTEM (Measuring System & Downloader/Recharger/Printer System)**

<b>POTENTIAL FAILURE</b> (that can lead to errors in test results)	<b>POTENTIAL CAUSE</b>	<b>CONTROL METHODS</b> (engineered controls, external controls, training, competency, etc.)
<b>Measuring System: Sample Analysis/ Analytical Process (cont)</b>	<b>Incorrectly Programming Parameters</b>	<ul style="list-style-type: none"> <li>Verify customizable parameters (e.g., reporting units of measure, repeat ID entry) after they have been set. Review method comparison data to assist with identifying unintended parameter settings.</li> <li><i>i-STAT/DE</i> with a data management software (Info HQ or third party) allows an analyzer customization profile to be assigned to all analyzers in the facility or to locations within the facility. If the customization profile differs by location, operators must be trained not to move analyzers from one location to another. Refer to <i>i-STAT/DE Customization Workspace Guide</i>.</li> </ul>
	<b>Instrument Error</b>	<ul style="list-style-type: none"> <li>An <b>Analyzer Coded Message</b> with actions to take will be displayed if a condition related to the analyzer is detected. Refer to <i>i-STAT 1 System Manual</i> - Section “Troubleshooting the Analyzer” and <i>i-STAT 1 System TB Analyzer Coded Messages</i>.</li> <li>Train to follow internal policy on maintaining extra set of batteries.</li> </ul>
	<b>Readout Device Failure</b>	<ul style="list-style-type: none"> <li>Train to handle instrument appropriately to prevent from being dropped, which can cause damage to the screen. Refer to <i>i-STAT 1 System Manual</i> - Section “Procedure for Cartridge Testing.”</li> <li>Train to report when instrument is dropped and to report readout failure. Refer to <i>i-STAT 1 System Manual</i> - Section “Routine Care of the Analyzer and Downloader” and Section “Troubleshooting the Analyzer.”</li> </ul>



**E. TEST SYSTEM (Measuring System & Downloader/Recharger/Printer System)**

<b>POTENTIAL FAILURE</b> (that can lead to errors in test results)	<b>POTENTIAL CAUSE</b>	<b>CONTROL METHODS</b> (engineered controls, external controls, training, competency, etc.)
<b>Measuring System: Sample Analysis/ Analytical Process (cont)</b>	<b>Loss/ Corruption of Data</b>	<ul style="list-style-type: none"> <li>· Data is maintained by an internal battery for up to seven years. Stored results will not be lost when changing the batteries in the analyzer or when updating the software. Refer to <i>i-STAT 1 System Manual</i> - Section “i-STAT 1 Analyzer.”</li> <li>· The <b>Clear Memory</b> function can be password protected to prevent removal of data from the analyzers by the operators. Refer to <i>i-STAT 1 System Manual</i> - Section “i-STAT 1 Analyzer.”</li> <li>· The <i>i-STAT/DE User Guide</i> contains information to customize the analyzer:                         <ul style="list-style-type: none"> <li>· to alert system administrator when results have not been downloaded in the required time frame.</li> <li>· to alert operators that a scheduled download is required.</li> <li>· to warn operators that results must be uploaded (the message is “Upload Required”).</li> <li>· to warn operators that the memory space for unsent records is low and when the stored memory is full.</li> </ul> </li> <li>· The Admin Menu on the <i>i-STAT 1</i> analyzer allows assessment of unsent data under “Analyzer Status”. Refer to <i>i-STAT 1 System Manual</i> - Section “i-STAT 1 Analyzer.” Train to download results frequently.</li> <li>· A data management system (DMS) can be programmed to backup at a specified time to a specified location. Refer to <i>i-STAT/DE User Guide</i>. If a DMS is not in use, manual log sheets or printouts can be maintained for a record of results. Refer to <i>i-STAT 1 System Manual</i> - Section “Portable Printer.”</li> </ul>



**E. TEST SYSTEM (Measuring System & Downloader/Recharger/Printer System)**

<b>POTENTIAL FAILURE</b> (that can lead to errors in test results)	<b>POTENTIAL CAUSE</b>	<b>CONTROL METHODS</b> (engineered controls, external controls, training, competency, etc.)
<b>Measuring System: Sample Analysis/ Analytical Process (cont)</b>	<b>Electronic Components Failure</b>	<ul style="list-style-type: none"> <li>· <b>Analyzer Coded Messages</b> designed into the <i>i-STAT 1 System</i> indicate when there is an issue related to electronic component failure; a message informs the user of the issue and any actions to take. Refer to <i>i-STAT 1 System Manual - Section “Troubleshooting the Analyzer”</i> and <i>i-STAT 1 System TB Analyzer Coded Messages</i>.</li> <li>· The Electronic Simulator test checks that the analyzer is taking accurate and sensitive signal measurements from cartridges; to be most effective, the analyzer should be customized to lock out testing until the simulator test passes. Refer to <i>i-STAT 1 System Manual - Section “Electronic Simulator”</i> and Section “Customization.”</li> <li>· The external Electronic Simulator checks that the thermal probes that maintain the required temperature during the test cycle are within specifications. Train on how to perform the thermal probe check and that it is required to be tested twice a year. Refer to <i>i-STAT 1 System Manual - Section “Quality Control”</i>.</li> </ul>
	<b>Electronic Components Failure—Dropped Device</b>	<ul style="list-style-type: none"> <li>· Train to handle instrument appropriately to prevent from being dropped, which can cause damage to the screen. Refer to <i>i-STAT 1 System Manual - Section “Procedure for Cartridge Testing”</i> and Section “Quality Control.”</li> <li>· When the analyzer detects a potential or real problem before the test cycle is initiated or at any time during the test cycle, an analyzer coded message number, the type of problem, and the next step to be taken will be displayed. Refer to <i>i-STAT 1 System Manual - Section “Troubleshooting the Analyzer”</i> and <i>i-STAT 1 System TB Analyzer Coded Messages</i>.</li> <li>· Train to report when analyzer is dropped.</li> </ul>

**E. TEST SYSTEM (Includes Measuring System & Downloader/Recharger/Printer System)**

POTENTIAL FAILURE (that can lead to errors in test results)	POTENTIAL CAUSE	CONTROL METHODS (engineered controls, external controls, training, competency, etc.)
<b>Measuring System: Sample Analysis/ Analytical Process (cont)</b>	<b>Inadequate Battery Charge</b>	<ul style="list-style-type: none"> <li>· An <b>Analyzer coded message</b> indicates when there is an issue with adequate battery power (i.e., “Dead Batteries”); a “Battery Low” start-up message and a flashing battery icon will be displayed. Refer to <i>i-STAT 1 System Manual</i> - Section “Troubleshooting the Analyzer” and <i>i-STAT 1 System TB Analyzer Coded Messages</i>. The <b>analyzer status page</b> shows current battery charge. Refer to <i>i-STAT 1 System Manual</i> - Section “i-STAT 1 Analyzer.” Train on observation of battery level indicator, what batteries to use with system, and how to change the batteries. Refer to <i>i-STAT 1 System Manual</i> - Section “Routine Care of the Analyzer and Downloader.”</li> <li>· The downloader includes a color-coded battery charge indicator for the rechargeable battery; the rechargeable battery recharges when the analyzer is placed in a downloader/recharger. Refer to <i>i-STAT 1 System Manual</i> - Section “i-STAT 1 Downloader/Recharger.”</li> </ul>
	<b>Expired Software/ Software Corruption</b>	<ul style="list-style-type: none"> <li>· Analyzer displays a reminder message 15 days prior to software expiration; functionality ceases once software expires. If the software has expired or is corrupt, an <b>analyzer coded message</b> will be triggered with description of problem and how to address it. Refer to <i>i-STAT 1 System Manual</i> - Section “Troubleshooting the Analyzer” and <i>i-STAT 1 System TB Analyzer Coded Messages</i>.</li> <li>· <b>Software Updates</b> are available online at <a href="http://www.globalpointofcare.abbott">www.globalpointofcare.abbott</a>. Refer to <i>i-STAT 1 System Manual</i> - Section “Updating the Software.”</li> <li>· The <b>Product Update</b> for each analyzer software release includes the current software expiration date, release notes for the new software and the expiration date of the new software.</li> </ul>



**RISK ASSESSMENT**  
**CONTROL METHODS INFORMATION**  
**TEST SYSTEM (Measuring System & Downloader/Recharger/Printer System)**

**E. TEST SYSTEM (Measuring System & Downloader/Recharger/Printer System)**

<b>POTENTIAL FAILURE</b> (that can lead to errors in test results)	<b>POTENTIAL CAUSE</b>	<b>CONTROL METHODS</b> (engineered controls, external controls, training, competency, etc.)
<b>Measuring System: Sample Analysis/ Analytical Process (cont)</b>	<b>Connectivity Software Failure</b>	<ul style="list-style-type: none"> <li>With connectivity and data management, analyzer displays “Waiting to Send” message until communication established; “Communication in Progress” message appears until data transfer is complete. Analyzer Status page shows the number of unsent results. Refer to <i>i-STAT 1 System Manual</i> - Section “i-STAT 1 Downloader/Recharger” and Section “i-STAT 1 Analyzer.” <i>i-STAT/DE</i> software displays the analyzers last download location with date and time. Refer to the <i>i-STAT/DE User Guide</i>.</li> <li>Connectivity will fail if downloader/recharger or network cord is unplugged, internal network is down, or Wi-Fi is down. If Wi-Fi is down, the operator can put analyzer in the downloader/recharger (if available) to send information through wired connection. Refer to <i>i-STAT 1 System Manual</i> - Section “i-STAT 1 Downloader/Recharger” and <i>i-STAT 1 System TB Procedure for Using the i-STAT 1 Wireless</i>.</li> </ul>
<b>Measuring System: Instrument Maintenance</b>	<b>Dirty Optics</b>	<ul style="list-style-type: none"> <li>Train on cleaning the analyzer, downloader and printer according to your facility’s policies and procedures.</li> </ul>
	<b>Contamination</b>	<ul style="list-style-type: none"> <li>Train on decontamination of analyzer, downloader and printer per the <i>i-STAT 1 System Manual</i> - Section “Routine Care of the Analyzer and Downloader.”</li> </ul>
	<b>Scratches</b>	<ul style="list-style-type: none"> <li>Not applicable.</li> </ul>
<b>Printer: Instrument Failure</b>	<b>Inadequate Battery Charge</b>	<ul style="list-style-type: none"> <li>Train to keep printer charged and to recognize Power LED on printer. Refer to <i>i-STAT 1 System Manual</i> - Section “i-STAT Portable Printer.”</li> </ul>

## CONTROL METHODS INFORMATION

### TEST SYSTEM (Measuring System & Downloader/Recharger/ Printer System)

#### E. TEST SYSTEM (Measuring System & Downloader/Recharger/Printer System)

POTENTIAL FAILURE (that can lead to errors in test results)	POTENTIAL CAUSE	CONTROL METHODS (engineered controls, external controls, training, competency, etc.)
<b>Downloader: Instrument Failure</b>	<b>Inadequate Result Transmission</b>	<ul style="list-style-type: none"> <li>Train not to connect the downloader/recharger to a medical electrical system, not to place metal objects on or near the exposed gold charging contacts, to seat the analyzer properly in the downloader, to look for the “Communication in Progress” message, and not to remove the analyzer from the downloader until the “Communication in Progress” message disappears. Refer to <i>i-STAT 1 System Manual</i> - Section “i-STAT 1 Downloader/Recharger,” Section “Routine Care of the Analyzer and Downloader,” <i>i-STAT 1 System TB Procedure for Using the i-STAT 1 Wireless Analyzer</i>, <i>i-STAT/DE User Guide</i> and <a href="http://www.globalpointofcare.abbott">www.globalpointofcare.abbott</a> for connectivity and data management options.</li> </ul>

## 6. Additional Tools to Help with the RISK Assessment

**Aside from the *i-STAT 1 System*, risk-related information acquired from use of the control methods information in this guide, the CMS suggests the following resources to assist with the Risk Assessment:**

- Regulatory requirements (CLIA IQCP requirements) can be found at: [www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html](http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html). As there may be IQCP requirements from the laboratory accrediting organizations, exempt states, and other states, laboratories should contact their survey organization[s] to ensure they have the most recent copy of their requirements.
- Manufacturers' Product Documentation for the *i-STAT 1 System* is located at [www.globalpointofcare.abbott](http://www.globalpointofcare.abbott).
  - Manufacturer's cartridge IFU/CTI sheets (including intended use, limitations, specimen requirements, reagent storage, and interfering substances)
  - Manufacturer's system manual (environmental requirements, electronic QC frequency, maintenance)
  - Troubleshooting within the *i-STAT 1 System Manual*
  - Manufacturer's alerts and bulletins
- Verification or establishment of performance specifications
- Testing personnel qualifications, training, and competency records
- QC data
- Proficiency testing data
- QA information, including corrective action
- Scientific publications
- Other information as appropriate

## QUALITY CONTROL PLAN

The Quality Control Plan (QCP)<sup>1</sup>:

- Should describe the practices, resources, and procedures to control the quality of a particular test process.
- Must ensure the accuracy and reliability of test results and ensure that test result quality is appropriate for patient care.
- Must provide for the immediate detection of errors that occur due to test system failure, adverse environmental conditions, and/or operator performance.
- Must also monitor, over time, the accuracy and precision of test performance that may be influenced by changes in the test system, environmental conditions, or variance in operator performance.
- Must at least include the number, type, and frequency of testing and criteria for acceptable result(s) of the quality control(s).

If indicated by the evaluation of the Risk Assessment, the QCP may also include<sup>1</sup>:

- Electronic controls
- Procedural controls
- Training and competency assessment
- Other specified quality control activities

## 1. Quality Control Plan (QCP) Template

CLIA does not mandate that a specific template must be used to create a QCP; nevertheless, an example of a QCP template has been provided below to illustrate the types of information that the lab may consider including.

**Important:** This guide and related worksheet are not a manufacturer's requirement. They are intended as an aid in the development of your IQCP Risk Assessment and Quality Control Plan.

### EXAMPLE OF A QCP TEMPLATE

**Relevant Organizational Information** (name, address, effective date, CLIA #)

**QCP for XXXX (tests) with the *i-STAT 1* System in (test site location)**

1. **Laboratory Policy & Procedure (P/P) for System X & IQCP Organizational Policy** (where P/P's located)
2. **QCP and Changes Based on the Risk Assessment** (full details found in the P/P)
  - **Reagents** (for the tests performed; include manufacturer's QC with the number of levels, type, frequency of QC, and acceptability of results).
  - **Specimen/Sample Requirements** (suitable samples, handling, mixing, exposure to air, etc.)
  - **Testing Personnel/Operators** (competency, training, etc.)
  - **Test System** (components, features to prevent errors, etc.)
  - **Laboratory Environment** (testing surface, temperature, features to prevent errors, etc.)
3. **Post-Analytical Phase** (result reporting and interpretation)
4. **Quality Assessment IQCP Review**
5. **Authorization** (lab director's name/signature, date)



## 2. Quality Control Plan Example

This example relies heavily on the *i-STAT 1 System* P/P, the Training Plan, and the Risk Assessment to ensure a concise QCP.

NOTE: The CMS does not mandate use of either template.

**Important:** This guide and related worksheet are not a manufacturer's requirement. They are intended as an aid in the development of your IQCP Risk Assessment and Quality Control Plan.

### QUALITY CONTROL PLAN EXAMPLE Quality Control Plan for Testing using the i-STAT CG8+ cartridge with the i-STAT 1 System in the ICU

1. **The P/P** for the i-STAT 1 System can be found on the intranet at: XXXX. The Training Plan includes any mitigations based on the Risk Assessment.
2. **The QCP and Changes Based on the Risk Assessment** can be found in the P/P for the i-STAT 1 System and the Training Plan. A copy of the Risk Assessment is located at XXX.

In brief, the QC requirements for the *i-STAT 1 System* for testing *i-STAT CG8+* cartridge in the ICU include:

- **Daily**
  - Run the internal or external Electronic Simulator every 8 hours when patient testing is performed.
  - Verify proper storage of test cartridges and ensure that cartridge expiration dates have not been reached.
- **Monthly**
  - Review Quality Check Code reports monthly to identify and address trends.
- **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.
  - Perform acceptability testing (in order to meet regulatory requirements by analyzing X level(s) of XXX (vendor) liquid QC upon incoming cartridge lot/shipment; record results and release cartridges based on QC results. Results must be within the manufacturer's ranges. QC testing is performed on any analyzer that passes the Electronic Simulator test.
  - Check new and replacement analyzers with the Electronic Simulator (internal or external) before use.
  - Analyze liquid QC samples if
    - test results are questioned
    - warranted by Electronic Simulator test failure
    - cartridge storage conditions are in question.Control results are considered acceptable if they are within manufacturer's ranges.
  - Perform the thermal probe check on each analyzer every 6 months.

## 2. Quality Control Plan Example, continued

### QUALITY CONTROL PLAN EXAMPLE, continued

#### Quality Control Plan for Testing Using the i-STAT CG8+ Cartridge with the i-STAT 1 System in the ICU

3. **Post-Analytical Phase (Result Reporting and Interpretation):** The analyzers used for testing are interfaced to the Laboratory Information System (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 provider.
4. **Quality Assessment (QA) 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. Reevaluation of the QCP should be considered when changes occur in any of these areas. Documents considered for QA review may include:
  - QC review
  - Quality Check Code reports
  - Proficiency testing records (scores, testing failures, trends)
  - Patient result review
  - Specimen rejection logs
  - Turnaround time reports
  - Records of preventive measures, corrective actions, and follow-up
  - Personnel competency records

#### 5. 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 RA to ensure we will meet the quality goals within the organization. We have determined that the i-STAT Quality Control requirements are acceptable for these tests. When external (liquid) quality controls are tested, they will be tested at X level(s) and the results will be compared against the manufacturer's ranges to determine acceptability of results.

The IQCP will be reviewed regularly to ensure that it remains effective to control for risks with the *i-STAT 1 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 (see #4).

I authorize use of this QCP with the *i-STAT 1 System* for *i-STAT CG8+* cartridge testing in the ICU.

Laboratory Director Approval: Name \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

**IQCP Resource**

1. IQCP Link:  
[www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized\\_Quality\\_Control\\_Plan\\_IQCP.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html)
2. CMS/CLIA Website: [www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html)
3. Clinical and Laboratory Standards Institute. Risk Management Techniques to Identify and Control Laboratory Error Sources; Approved Guideline. 2nd Ed. CLSI document EP18-A2. Wayne, PA: 2011.
4. Clinical and Laboratory Standards Institute. Laboratory Quality Control Based on Risk Management; Approved Guideline. CLSI document EP23-A. Wayne, PA: 2011.

To learn more about the IQCP resources for the i-STAT 1 System or for more information on our products, visit [www.globalpointofcare.abbott](https://www.globalpointofcare.abbott).



**For *in vitro* diagnostic use only.** Not all products are available in all regions. Check with your local representative for availability in specific markets.

©2023 Abbott Point of Care. *i-STAT* is a trademark of the Abbott in various jurisdictions.

For *in vitro* diagnostic use only.

*i-STAT* is a trademark of Abbott in various jurisdictions.

All Rights Reserved. © 2023

Abbott Point of Care Inc.

400 College Road East • Princeton, NJ 08540 • USA

(609) 454-9000 • (609) 419-9370 (fax)

[www.globalpointofcare.abbott](http://www.globalpointofcare.abbott)

