i-STAT PT*plus* Control Levels 1 and 2

NAME

i-STAT PT*plus* Control Level 1 (REF 06P17-17)
i-STAT PT*plus* Control Level 2 (REF 06P17-18)

INTENDED USE

The i-STAT PT*plus* Controls are used for the quality control of the i-STAT PT*plus* cartridge.

REAGENTS

Contents: Each Level of control contains lyophilized human plasma with coagulation factors, stabilizers, and preservatives. Reconstitution solution contains Calcium Chloride and blue dye.

Control	Qty. (per box)	Concentration (% by weight)
Level 1	5 x 1.0 mL	Human plasma (80-95%) Buffer/solution (5-20%)
Level 2	5 x 1.0 mL	
Reconstitution Solution	**Qty. (per box)**	**Concentration (mmol/L)**
$CaCl_2$ Control Level 1	5 x 1.5 mL	Calcium chloride (10.0 ± 1.0 mmol/L)
$CaCl_2$ Control Level 2	5 x 1.5 mL	

Warnings And Precautions

- For *in vitro* diagnostic use only.
- Handle this product using the same safety precautions used when handling any potentially infectious material. The human plasma used in the preparation of this product has been tested by FDA approved test methods and found negative/nonreactive for HIV-1, HIV-2, HBsAg, and HCV. However, no known test method can offer complete assurance that products derived from human blood will not transmit infectious disease.
- Dispose of this product as biohazardous waste according to all local, state, and national regulations.

- Safety Data Sheets are available on the website at www.globalpointofcare.abbott.

Storage Conditions

- Refrigerated storage at 2 to 8 °C (35 to 46 °F) should be maintained until the printed expiration date on the box and vial labels. Do not use beyond the expiration date on the box and vial labels.
- Control fluids may also be stored at room temperature for up to 4 hours (18 to 30 °C or 64 to 86 °F). If left out longer than 4 hours at room temperature, they should be discarded.

INSTRUMENTS

The i-STAT PT*plus* Control levels 1 and 2 are intended for use with the i-STAT PT*plus* cartridge (REF 03P89-50) on the i-STAT System. The i-STAT System should be used by healthcare professionals trained and certified to use the system and should be used according to the facility's policies and procedures.

The i-STAT System incorporates a comprehensive group of components needed to perform blood analysis at the point of care. A portable i-STAT analyzer, a cartridge with the required tests, and 2-3 drops of blood will allow the caregiver to view quantitative test results.

For a detailed description of the instrument and system procedures, refer to the i-STAT System Manual located at www.globalpointofcare.abbott.

PROCEDURE

Preparation for Analysis:

Prior to testing, vials containing the lyophilized plasma and $CaCl_2$ reconstituting fluid should stand at room temperature 18-30 °C (64-86 °F) for a minimum of 45 minutes and maximum of 4 hours. Record the in-use expiry date/time on the vial labels once removed from refrigerated storage. For best results, vials, cartridges, and analyzers should be at the same temperature.
For procedure for liquid quality control testing see the i-STAT 1 User guide located at www.globalpointofcare.abbott.

Procedure for Quality Testing:

Press power and allow analyzer to power on.

1. Access the Control option under Quality Tests in the Administration Menu.
2. Enter the required information. The analyzer allows 15 minutes (or the customized timeout) to insert the cartridge after the last data entry.

Reconstitute only one level of control plasma at a time. CONTROL FLUIDS MUST BE USED IMMEDIATELY (less than 30 seconds) AFTER COMPLETING THE RECONSTITUTION AND MIXING STEPS.

1. After 45 minutes of room temperature equilibration, remove the cap and stopper from one lyophilized human plasma control vial and remove the cap from one vial of calcium chloride reconstituting fluid.
2. Pour the entire contents of the calcium chloride vial into the lyophilized human plasma

control vial. Place the stopper back in the reconstituted control vial, sealing the vial appropriately so that the contents do not leak or spill out.

3. Allow the vial to sit at room temperature for 1 minute.
4. Mix the contents of the vial by swirling gently for 1 minute, then inverting slowly for 30 seconds.

Note: To minimize foaming of the control sample, avoid vigorous or rapid mixing motion. Visually inspect the control vial to ensure that the sample is fully reconstituted. If not, discard and start over with fresh vials.

5. Using a plastic transfer pipette, plastic syringe, or plastic capillary tube with no anticoagulant, immediately transfer the solution from the vial into the PT*plus* cartridge.
6. Immediately seal the cartridge and insert it into the cartridge port.

Note: Additional i-STAT PT*plus* cartridges may be tested with the remaining fluid if used within 30 seconds of complete reconstitution of the sample.

ACCEPTABLE CRITERIA

Target Value

Target values (determined by testing multiple vials of each level using multiple lots of cartridges and i-STAT analyzers that have passed the Electronic Simulator test) are printed on a Value Assignment Sheet and are also provided in an electronic file, electronic value assignment sheet (eVAS) posted on the APOC website at www.globalpointofcare.abbott.

Ensure that the lot number printed on the Value Assignment Sheet matches the lot number on the label of the vial and that the software version above the target value table matches the software version in the analyzer.

Ranges

Refer to Value Assignment Sheet (VAS) or electronic version (eVAS) for the target (mean), the acceptable range and units of measurement for:

Assay	Unit(s)
PT	INR, seconds

The ranges displayed represent the maximum deviation expected when controls and cartridges are performing properly.

Should results outside the ranges be obtained, refer to the Limitation section below.

Limitation:

Target Values are specific to the i-STAT System. Results obtained from these reconstituted plasma controls with other methods may differ due to sample matrix effects.

Verify that the following conditions are met and then repeat the test:

- The correct value assignment sheet is being used and the correct cartridge type and lot number listing is being used.
- Expiration date printed on cartridge pouch and control vial has not been exceeded.
- Room temperature expiration date for cartridge and control have not been exceeded.
- Cartridge and control have been stored correctly.
- The control has been handled correctly – see the PROCEDURE.
- The analyzer being used has passed an Electronic Simulator test.

If the results are still out of range despite meeting the above criteria, repeat the test using a new box of control fluids and/or cartridges. If the results are still out of range, contact your local support service provider.

Note: Follow facility policy regarding control results that do not fall within assigned ranges.

METROLOGICAL TRACEABILITY

The i-STAT System test for Prothrombin Time measures the International Normalized Ratio (INR) (dimensionless) expressing the relative time interval required for complete activation, by thromboplastin, of the coagulation cascade in capillary or venous whole blood. i-STAT PT*plus* cartridge prothrombin time values assigned to the i-STAT controls are traceable to the World Health Organization (WHO) international reference measurement procedures and the International Reference Preparation recommended by the WHO[1]. i-STAT System controls are validated for use only with the i-STAT System and assigned values may not be commutable with other methods.

KEY TO SYMBOLS

Symbol	Definition/Use
	Use by or expiration date. An expiration date expressed as YYYY-MM-DD means the last day the product can be used.
LOT	Manufacturer's lot number or batch code. The lot number or batch will appear adjacent to this symbol.
	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community.
	Temperature limitations. The upper and lower limits for storage are adjacent to upper and lower arms.
REF	Catalog number, list number, or reference
	Do not re-use. Do not re-refrigerate.
	Manufacturer
	Consult instructions for use or see System Manual for instructions.
IVD	*In vitro* diagnostic medical device
CE 0344	A mark that indicates conformity to the legal requirements of the appropriate European Union (EU) Directive(s) with respect to safety, health, environment and consumer protection.
	Device for near-patient testing
CONTROL	Control
	Biological Risks
	Caution: Read all warnings and precautions in instructions for use

	Importer in the European Community

ADDITIONAL INFORMATION

The i-STAT PT*plus* Controls (Level 1 and 2) are used as part of a near-patient testing system.

To obtain additional product information and technical support, refer to the APOC website at www.globalpointofcare.abbott.

Product issues and adverse events should be reported to Abbott through your Abbott Point of Care support service. For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/746/EU on In vitro Diagnostic Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to Abbott and its authorized representative and to your national authority.

REFERENCES

1. L. Poller, The Prothrombin Time (Synonymous with thromboplastin time or Quick test), World Health Organization, Geneva, WHO/LAB/98.3, 1998.

Technical Support: please contact your local service provider for service information.

For customers in the European Union: A summary of safety and performance (SSP) for this device is available at https://ec.europa.eu/tools/eudamed/ after the launch of the European Database on Medical Devices. Search for the device using the UDI-DI provided on the outer packaging of the device. A copy of the SSP can also be requested from the European Authorized Representative or the manufacturer.

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CE 0344

IVD

CONTROL