i-STAT PT^{PLUS}

coagulation

High-precision INR results in minutes

ROLE OF PRODUCT

Precise prothrombin time (PT) and international normalized ratio (INR) results at the point of care enable prompt dose adjustment and treatment, when needed.

- To reduce the continual risk of bleeding or clotting, frequent PT (INR) monitoring in patients on anticoagulant therapy with coumarin derivitives is essential for patient safety.[1]
- Traditional lab tests for PT (INR) could take an hour,[2] prolonging time to dose adjustment and increasing the potential need for repeat visits.

KEY BENEFIT OF PRODUCT

The *i-STAT PT^{plus}* cartridge with the *i-STAT 1* system combines the speed necessary for "real-time" decisions, lab-quality results, and the convenience of a direct fingerstick application to help you confidently manage the course of your patient's care.

PERFORMANCE

- Higher precision in venous whole blood samples may offer more predictable INR management.
  - Venous whole blood precision data results in the therapeutic (2.0 - 4.5 INR)[3] range for the *i-STAT PT^{plus}* cartridge (Therapeutic: 2.85 mean (INR); 2.4 %CV; n=131)[3], compared to precision data results in the normal and therapeutic (2.0 - 3.5 INR)[5,6] range for the *i-STAT PT/INR* cartridge* (Site 1: 2.6 mean (INR); 4.7 %CV; n=181)[4].
  - Capillary whole blood precision data results in the therapeutic (2.0 - 4.5 INR)[3] range for the *i-STAT PT^{plus}* cartridge (Therapeutic: 2.82 mean (INR); 5.2 %CV; n=119)[3], compared to precision data results in the normal and therapeutic (2.0 - 3.5 INR)[5,6] range for the *i-STAT PT/INR* cartridge (Site 3: 2.5 mean (INR); 4.6 %CV; n=33)[4].

INTENDED USE

The *i-STAT PT^{plus}* cartridge is intended for use in the in vitro quantitative measurement of the clot time of the extrinsic coagulation pathway when activated by thromboplastin in non-anticoagulated whole blood (venous or capillary), using the *i-STAT 1* System.

Measurements of prothrombin time are used to aid in the monitoring of patients receiving anticoagulant therapy with coumarin derivatives. The *i-STAT PT^{plus}* PT test result is reported in seconds and as an INR. The test is intended for point of care use and is for prescription use only.

PRODUCT CODE/LIST NUMBER

- 03P89-50 *i-STAT PT^{plus}* Cartridge
- 06P17-17 *i-STAT PT^{plus}* Control Level 1
- 06P17-18 *i-STAT PT^{plus}* Control Level 2

CARTRIDGE SPECIFICATIONS

Cartridge Box	8.000" (W) x 2.750" (H) x 3.8125" (D)
Quantity per box	25 pouches
Cartridge Pouch	2.6433" (H) x 3.7402" (W)
Shipment time-temperature indicator	Included in shipment; visual non-reversible record of temperature exposure at, or above, 10°C and 34°C for exposure periods of 5 days at 30°C and 3 hours at 34°C.
Refrigerated Storage	35-46° F / 2-8° C until date indicated on box and pouch. Shelf-life is 6 months from manufacture.
Room Temp. Storage	64-86° F / 18-30° C for up to 14 days
Room Temp. Equilibration	• 5 minutes for a single cartridge • 1 hour for an entire box
Sample Type	Fresh whole blood from finger puncture or venous samples (collected into a plastic syringe or tube without anticoagulant)
Sample Size	Approximately 20uL
Panel Name	PT^{plus}
Test/Analyte(s)	PT, INR
Analysis Time	up to 300 seconds (5 minutes)
Reportable Range	8.1–80.8 seconds, 0.8–8.0 INR
Reference Range	Each facility should establish its own reference range to assure proper representation of specific populations.
Traceability	Traceable to the WHO international reference method; rTF-16.
Latex Rubber	The 'Sample Entry Well Gasket' contains natural rubber latex.
Barcode Symbology	• Pouch, linear code 128 • Box, linear code 93
CLIA Categorization	Moderate complexity

CONTROL SPECIFICATIONS

Control Box	1.75" (H) x 4.625" (W) x 1.8755" (D)
Quantity per box	10, clear siliconized glass vials • 5 - Citrated pooled lyophilized plasma • 5 - Calcium chloride (CaCl2) solution
Refrigerated Storage	35-46° F / 2-8° C until date indicated on box and vial. Shelf-life is 12 months from manufacture.
Room Temp. Equilibration	Minimum of 45 minutes to a maximum of 4 hours prior to reconstitution. Test the fluids immediately after reconstitution.
Control Level 1	normal/non-therapeutic prothrombin time and INR
Control Level 2	therapeutic prothrombin time and INR

CAL/VER SPECIFICATIONS

- *i-STAT PT*^{plus} is a factory calibrated PT test. Calibration verification material is not available, since PT and INR tests are a measure of time.

SYSTEM COMPATIBILITY

The *i-STAT PT*^{plus} cartridge is part of a broad menu of tests compatible with the *i-STAT 1* system.

To support the use of the *i-STAT PT*^{plus} cartridge, updates for the *i-STAT 1* analyzer and *i-STAT/DE* software, will be released in October 2023.

TRAINING AND COMPLIANCE

Resources designed to ensure competency of *i-STAT* users and assist in meeting regulatory compliance requirements are available for download from the website, www.globalpointofcare.abbott.

QUALITY CONTROL PLAN (QCP)

- Guide and worksheet to easily locate the system information needed for your individual QCP.

LEARNING SYSTEM

- Classroom training materials, quick references and tutorials to support competency with the *i-STAT* system.

INTERACTIVE REMOTE TRAINING

- Calender available for sessions related to the *i-STAT* system, *i-STAT/DE* and performing software updates.

ADDITIONAL INFORMATION

To obtain additional product information and support, visit www.globalpointofcare.abbott.

*Studies conducted at three external sites, using the *i-STAT PT/INR* cartridge, obtained comparative method sample population results within an INR range of 1.0 to 4.6. (Ranges as follows: Site 1 INR 1.0 - 3.9; Site 2 INR 1.0 - 4.3; Site 3 INR 1.0 - 4.6).[5]

REFERENCES

1. Kamali F, Pirmohamed M. The future prospects of pharmacogenetics in oral anticoagulation therapy. Br J Clin Pharmacol. 2006;61(6):746-751.
2. Tripathi MM, Egawa S, Wirth AG, et al. Clinical evaluation of whole blood prothrombin time (PT) and international normalized ratio (INR) using a Laser Speckle Rheology sensor. Sci Rep. 2017;7:9169. Available at: www.nature.com/articles/s41598-017-08693-5 [Accessed August 15, 2023].
3. 510(k) Pre Market Notification *i-STAT PT*^{plus} (K220282). Available at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm. [Accessed August 15, 2023].
4. *i-STAT PT/INR* Cartridge and Test Information (CTI) sheet (Art: 715236-00S). Available at: www.globalpointofcare.abbott [Accessed August 15, 2023].
5. 510(k) Pre Market Notification *i-STAT PT/INR* (K020355). Available at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm [Accessed August 18, 2023].
6. CLSI. *Point-of-Care Coagulation Testing and Anticoagulation Monitoring—Second Edition.* CLSI POCT14-Ed2. Clinical and Laboratory Standards Institute 2020. Available at www.clsi.org/standards/products/point-of-care-testing/documents/poct14/ [Accessed August 18, 2023]

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PT^{plus} Sell Sheet | 4962.REV1 (v2.0) 08/23

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