REF Cat. No. 5720

CONTENTS

50 PT-WB test cards, individually sealed in foil pouches

INTENDED USE

The Cascade Abrazo PT-WB test card is to be used in conjunction with the Cascade Abrazo coagulation analyzer. The test cards are intended for use in performing a quantitative, one-stage, clotting method utilizing tissue thromboplastin to measure prothrombin time (PT) on fresh whole blood. The PT-WB tests, together with the Abrazo analyzer, are for use in point of care sites as an aid in monitoring warfarin therapy by trained medical professionals

SUMMARY

The PT test was first reported by Quick1 in 1935. It has become one of the most useful tests for evaluating the extrinsic and common pathways of the coagulation process. There are two major applications for a prothrombin time: (1) as a screening tool for inherited or acquired disorders of factors II, V, VII, and X; and (2) as a method for monitoring oral anticoagulant drug therapy. The warfarin type drugs reduce the activity of Factors II (prothrombin), VII, IX, and X.²

The Cascade Abrazo system is designed to eliminate many of the variables encountered with other coagulation methods. Precise pipetting of reagent or sample and manual timing skills are not a factor with the PT-WB test card. Many of the variables encountered with sample transport and handling are avoided.

PRINCIPLE

The Cascade Abrazo PT-WB test card provides a one-stage method that measures the clotting time of the sample after combining it with tissue thromboplastin in a prewarmed card. By providing tissue thromboplastin, the intrinsic pathway factors (Factors VIII, IX, XI, and XII) are not detected, and a deficiency in one or more of them will not be reflected in the result. The PT-WB test card is a prothrombin time test for monitoring the effects of warfarin therapy.

RFAGENT

For in vitro diagnostic use only.

Components	Storage	Stability
Thromboplastin extracted from	2–8°C (36–46°F)	Unopened – until the expiration
human placenta, buffers,		date on the pouch label
stabilizers, and paramagnetic		or
iron oxide particles	20-25°C (68-77°F)	Unopened – 2 weeks

Any pouches not kept refrigerated should be dated and used within 2 weeks. CAUTION: Exposure of the test cards at any time to magnetic objects or fields (for example, an MRI instrument) can potentially prevent the analyzer from performing the test properly

CAUTION POTENTIAL BIOHAZARD: Human source material. Treat as potentially infectious. Thromboplastin batches prepared from human placentas have been examined for hepatitis B surface antigen (HBsAg) and for antibodies to HCV and HIV by FDA-required tests and found to be nonreactive. Because no known test method can offer complete assurance that hepatitis B virus, Human Immunodeficiency Virus (HIV) or other infectious agents are absent, all human-based products should be handled in accordance with good laboratory practices, using appropriate precautions.54

SPECIMEN COLLECTION AND PREPARATION

The PT-WB test cards can be used only with fresh whole blood collected and processed according to CLSI Guideline: Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; H03-A63 or Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; H04-A6.⁴ Fresh specimens can be obtained by the fingerstick method or by venipuncture.

CAUTION: Do not collect the fresh whole blood specimen until the PT-WB test card has been warmed in the analyzer and the prompt is displayed. Test fresh whole blood specimens immediately after collection. Collecting the specimen before warming the test card can cause erroneous results.

After the site has been prepared and punctured, wipe away the first drop of blood with gauze since it is likely to contain excess tissue fluid. A second drop of blood will form over the puncture site. Blood flow from the puncture is enhanced by holding the puncture site buncture site. Diodo now nom the puncture is eminanced by notaing the puncture site downward and gently applying continuous pressure to the surrounding tissue (or proximal to the puncture site when the blood is obtained from a finger). Strong repetitive pressure (milking) should not be applied; it may cause hemolysis or contamination of the specimen with tissue fluid.⁴

Use Dispo Capillary pipette referred to in "Materials provided" below to collect sample from fingerstick. Dispense sample immediately onto test card.

PROCEDURE

Materials provided: The following materials are contained in the Abrazo PT-WB Test Kit (Cat. No. 5720).

50 Cascade Abrazo PT-WB Test Cards

Materials provided but not contained in the kit:

Item	Cat. No.
Cascade Abrazo Analyzer	5710
Cascade Abrazo Electronic QC (EQC) Test Card	5848
Cascade Abrazo PT-WB Level 1 Control	5739
Cascade Abrazo PT-WB Level 2 Control	5740
Cascade PT-WB Dispo Capillary Pipettes (500/pkg)	5800
Materials Required But Not Provided:	

· Blood sampling materials such as lancets, venipuncture needles, syringes, alcohol swabs, gauze

STEP-BY-STEP

Refer to the Abrazo Operator's manual for appropriate analyte set up procedures. 2. Equilibrate test cards at room temperature (15 to 25°C, or 59 to 77°F) for a minimum of 15 minutes before removing from the foil pouch.

CAUTION: The test card <u>must</u> be used within 15 minutes <u>after</u> the pouch is opened. Pouches of cards should <u>not</u> be repeatedly warmed and returned to the . refrigerator

- 3. Select patient test from main menu on Abrazo. Remove the test card from its foil pouch and hold it backwards with the barcode facing the Abrazo, approximately 6 to 8 inches from the Abrazo.
- Tilt the card backwards slightly (approx. 15 degrees) and scan the encoded 2D barcode in the middle of the card. The analyzer interprets the encoded information
- on the test card and display prompts for each step of the procedure. When prompted, place the test card in the analyzer, and allow to warm. Once the card is warmed, the Abrazo starts a countdown for the sample addition. CAUTION: The Abrazo will only perform tests on test cards and sample types that have been entered into the instrument's setup menu. Holding the sample transfer device at least one inch above the sample well
- 6. (colored circle) on the test card, add 30 to 35 µL of free-falling sample. NOTE: Do not allow the transfer device nor the hanging sample drop to contact the test card when applying the sample. Sample placement automatically initiates testing. 7. At the end of the test, confirm that the test was performed with the analyzer set to
- the appropriate sample type. The sample type is displayed along with the result at the end of the test.
- 8. When the card is removed from the analyzer at the end of each test, ensure that the entire reaction chamber was filled with sample. If an inadequate amount of sample was added to the card, repeat the test, using a fresh card
- After testing is complete, inspect the test card. Refer to the Operator Manual for images of the test card for comparison.
- 10. Dispose of the test card and other contaminated items in a manner approved for biohazardous material.74

PROCEDURAL NOTES

- The analyzer is preset to provide a constant temperature of 37 \pm 0.3°C (98.6 \pm 0.5°F) and will automatically prewarm the test card before prompting the user to apply the sample drop. All other calibrations necessary are encoded on the 2D barcode of each test card. Refer to the operator's manual for details.
- To maintain a fully charged battery, leave the unit plugged into its power supply which is, in turn, plugged into an AC outlet.
- The Operator Identification Code and the Quality Control Lockout are optional features. Refer to the operator's manual if either of these features has been enabled
- Operate the analyzer only at ambient temperatures between 15 to 32°C (59 to 90°F).
- Ensure that the sealed pouch containing a test card has reached room temperature and that the analyzer is either plugged into an appropriate AC wall outlet or has a sufficiently charged battery.
- Collect the sample as described in Specimen Collection and Preparation
- After the test card is inserted into the Abrazo, the card should not be touched until the test has been completed.

QUALITY CONTROL

Calibration: Operator calibration is not required. Calibration of both the analyzer and test cards was performed at the time of manufacture.

Daily quality control (QC) is good laboratory practice and is required by most states in the U.S. and the Clinical Laboratory Improvement Amendment, 1988 (CLIA '88). Quality control procedures are part of an overall quality assurance program to ensure the accuracy and reliability of patient results and reports. Monitoring the results of QC analyses can alert you to possible system performance problems. Healthcare professionals should follow proper local and national guidelines for quality control and check with appropriate licensing/accrediting bodies to ensure that QC programs meet established standards. Participation in proficiency survey programs allows for the comparison with systems in other laboratories and may help identify possible errors not detected by intra-laboratory QC testing alone.

There are two types of quality control that may be used on the Cascade Abrazo: Electronic Quality Control (EQC Test Card) and plasma controls.

The EQC Test Card ensures that the electronic components of the Cascade Abrazo analyzer are working properly. The purpose of the EQC Test Card is to offer a simple and economic alternative to the daily use of Cascade Abrazo test cards and plasma controls. However, the EQC test card is *not* intended to permanently replace plasma controls

EQC quality control must be performed every 8 hours of operation when patient samples are tested. It is imperative that, at a minimum, plasma controls are tested

- in the following situations:With each new box of test cards or at least once per week
- With each new shipment of test cards
- With each new lot number of test cards or controls
- Whenever improper storage or handling of test cards is suspected Whenever patient results appear abnormally high or low

This testing is in addition to the daily EQC testing. For more detailed information about quality control for the Cascade Abrazo, refer to the Cascade Abrazo Operator's Manual, the EQC test card package inserts, or contact your local authorized distributor

REFERENCE VALUES

Samples from 198 normal individuals were tested with the PT-WB test card. The CLSI C28-A3⁹ nonparametric 95% reference intervals obtained for fresh whole blood are 11.1 to 16.7 seconds and 0.8 to 1.2 INR. These results should be used as a guideline only. Operators should establish their own expected values based on their own population of normal individuals. It is suggested that a minimum of 20 individuals be included in the study. Specimens should be collected and handled in the same manner that the operator expects to use for patients.

RESULTS

The analyzer reporting units are in seconds. The results are displayed at the end of the test procedure. The analyzer automatically calculates the ratio of the patient's result to the mean of the normal range.

Patient Time = 20.0 sec Example:

Mean Normal PT= 9.7 sec

Ratio = 2.1

A mean value is encoded on each card and can be modified through the supervisory menu. Refer to the operator's manual for instructions. The PT-WB test is capable of reporting results up to 150 seconds. Verify results > 150 seconds by repeat testing. International Normalized Ratio (INR): The analyzer will calculate the INR if

requested. The International Sensitivity Index (ISI) is encoded on the 2D barcode along with the other calibration information and is passed to the analyzer when a test is initiated.

Authorities recommend that the INR should be reported only for those patients who have been stabilized on warfarin therapy.² Therefore, it is left to the operator to make this decision

INR = [Patient PT Time/Mean Normal PT] ISI

LIMITATIONS

This device was not evaluated in the pediatric population. Clinical studies were performed on patients 18 years of age or older. Many commonly administered drugs, diseases, and other factors can affect the results obtained in PT testing.² If unexpected results are found, the test should be verified by repeat testing. If the results are confirmed, more in-depth testing may reveal a deficiency of one or more factors. Since normal values vary from laboratory to laboratory, depending on the technique used, each laboratory should establish its own reference interval. For INR reporting, the geometric mean of the normal reference interval should be used.⁹ Since desired ratios may vary depending upon clinical practice and test methodologies, the optimum therapeutic range for this method should be established by each user.²

INTERFERENCES

Heparin levels greater than 0.4 U/mL may cause prolonged PT-WB results. Hemolysis should not affect the results; however, it is often an indication of poor specimen quality. PT-WB results may be affected in patients receiving LMWH and Fondaparinux.

The following table lists those factors that do not normally interfere with the PT-WB test

Concentration
65 - 1000 mg/dL
0 - 60%
0 - 20 mg/mL
0 - 18 g/L

Platelet inhibitors (clopidogrel and Aspirin) will not negatively impact the PT-WB test.

PERFORMANCE CHARACTERISTICS

PRECISION: The precision studies were performed using three lots of Cascade Abrazo PT-WB cards and one lot each of Cascade Abrazo PT-WB controls Level 1 and Level 2. The studies were performed by three non-laboratorian operators (POC) at a single site across 6 Cascade Abrazo analyzers over a period of 20 days. Each operator performed 2 runs per day, 2 tests per run on each lot of Abrazo PT-WB test cards

Within-run, between run, and between day Precision* N= 240

	Grand	within run		between run		between day		total	
PT-WB	mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Level 1	11.1	0.26	2.4	0.28	2.5	0.00	0.0	0.38	3.4
Level 2	33.9	1.80	5.3	1.77	5.2	0.26	0.8	2.54	7.5

Lot to Lot Precision*

N= 80									
Lot Number	1			2			3		
Sample	Mean	SD	%CV	Mean	SD	%CV	Mean	SD	Γ
Level 1 Control	11.1	0.23	2.1	11.1	0.2	1.8	11	0.27	
Level 2 Control	34.4	2.3	6.7	33.3	1.74	5.2	32.9	1.55	Г

Operator to Operator Precision*

	Operator 1			Operator 2			Operator 3			
Sample	Mean	SD	%CV	Mean	SD	%CV	Mean	SD	%CV	
Level 1 Control	11.1	0.23	2.1	11.2	0.43	3.9	11.1	0.46	4.0	
Level 2 Control	34.4	2.30	6.7	34.0	1.93	5.7	33.3	3.24	9.7	

*Precision studies were performed according to EP5-A2.12

SPECIFICITY: Studies show that the Helena Cascade Abrazo PT-WB test card is sensitive to deficiencies of Factors II, V, VII and X.

COMPARISON: Clinical studies with 293 fresh whole blood samples from normal donors and patients receiving warfarin therapy were done comparing Abrazo PT-WB cards against a commercially available whole blood PT test. Comparisons of samples gave correlation coefficients of 0.94 for clotting time in seconds and 0.96 for INR values

Clinical conditions requiring warfarin therapy included atrial fibrillation (66%), pulmonary embolism (12%), deep vein thrombosis (10%), mechanical heart valve (5%), and others (7%).*

nt relative to 147 abnormal patients collected at clinical sites

PT-WB whole blood fingerstick samples collected at Point-of-care were compared to plasma samples using standard laboratory method in 40 normal donors and 127 patients receiving warfarin therapy. The comparison of sample INR values gave a correlation coefficient of 0.93.

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ADDITIONAL REFERENCES

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