# English Cascade® Abrazo® PT-C Test Cards



### 50 PT-C test cards, individually sealed in foil pouches

### INTENDED USE

The Cascade Abrazo PT-C test cards are intended for use 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 and calcium to measure prothrombin time (PT) on citrated whole blood and citrated plasma. The PT-C test cards, together with the analyzer, are portable and suited for professional use in decentralized areas of testing near site of patient care as well as the more traditional central laboratory. The intended end user will be a trained medical personnel.

#### SUMMARY

The PT test was first reported by Quick<sup>1</sup> 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 this test: (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.<sup>2</sup>

The PT-C test card is based on Quick's method; however, 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-C test card. Many of the variables encountered with sample transport and handling are avoided.

#### PRINCIPLE

The Cascade Abrazo PT-C test card provides a one-stage method that measures the clotting time of the sample after combining it with tissue thromboplastin and calcium 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-C test card screens for deficiencies in Factors II (prothrombin), V, VII, and X, as well as monitoring the effects of warfarin therapy.

### REAGENT

| 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               |
| stabilizers, and paramagnetic     |                   | or                              |
| iron oxide particles              | 20–25°C (68–77°F) | Unopened – 2 week               |

CAUTION: Any pouches not kept refrigerated should be dated and should not be used beyond this 2 week period. It should be noted that stability and sensitivity of thromboplastins are susceptible to elevated temperatures. For optimal test card performance, remove PT-C test cards from refrigerated storage (2 to 8°C, or 36 to 46°F) and warm to room temperature (20 to 25°C, or 68 to 77°F) immediately prior to use. PT-C cards are stable at room temperature (20 to 25°C, or 68 to 77°F) for 7 days. Performance of the test cards stored at temperatures above 25°C or 77°F may be affected.

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 FDArequired 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.58

#### SPECIMEN COLLECTION AND PREPARATION

The PT-C test cards may be used with citrated whole blood or plasma collected and processed according to the CLSI Guideline HO3-A610 and H21-A5.3 Test whole blood specimens within 30 minutes of collection.10 Add whole blood to 109 mM (3.2%) of the dihydrate form of sodium citrate, in a proportion of nine parts whole blood to one part anticoagulant. Mix the blood by gentle inversion with the anticoagulant immediately on collection. Collection in 109 mM (3.2%) sodium citrate is recommended by the International Society for Thrombosis and Hemostasis and is used for international reference material International Sensitivity Index (ISI) assignments. CAUTION: Clot times may be affected due to improperly filled sodium citrate blood collection tubes

#### PROCEDURE

Materials provided: The following materials are contained in the Abrazo PT-C Test Kit (Cat. No. 5721).

# 50 Cascade Abrazo PT-C Test Cards

| viateriais 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-C Level 1 Control               | 5741     |
| Cascade Abrazo PT-C Level 2 Control               | 5742     |
| Cascade 35 µL Micropipette                        | 5718     |
| Pipette tips 1-200 µL (960/pkg)                   | 1475     |
|   |          |

Materials required but not provided:

Blood sampling materials such as venipuncture needles, syringes, alcohol swabs, vacuum tubes containing sodium citrate Sample transfer devices (pipettes or droppers) capable of delivering approximately 30 to 35 µL

# STEP BY STEP

1. Refer to the Abrazo Operator's manual for appropriate analyte set up procedures.

2. Equilibrate test cards at room temperature (20 to 25°C, or 68 to 77°F) for a minimum of 15 minutes before removing from the foil nouch

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

- 3. Select patient test from main menu on Abrazo. Hold the test card in its foil pouch backwards with the barcode facing the Abrazo, approx. 6 to 8 inches from the Abrazo.
- 4. Tilt the card in its pouch 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 displays prompts for each step of the procedure. CAUTION: The Abrazo will only perform tests on test cards and sample types that have been entered into the instrument's setup menu.

5. When prompted, place the test card in the analyzer, select sample type, and allow to warm. Once the card is warmed, the Abrazo starts a countdown for the sample addition.

CAUTION: Failure to select the correct sample type could lead to incorrect test results.

- 6. Holding the sample transfer device at least one inch above the sample well (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. 9. 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.

#### Procedural Notes

- The analyzer is preset to provide a constant temperature of 37 ± 0.3°C (98.6 ± 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 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 guality control and check with appropriate licensing/accrediting bodies to ensure that QC programs meet established standards. It is recognized nationally that medical and laboratory instrumentation be enrolled in a quality assurance program. Participation in inter-laboratory QC survey programs allows for the comparison with systems in other laboratories and may help identify possible errors not detected by intralaboratory QC testing alone

There are two types of quality control available for use 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 mini-mum, 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 normal individuals were tested with the PT-C test card. The CLSI C28-A39 non parametric 95% reference interval for citrated whole blood (n=216) was 10.4 to 15.2 seconds and for citrated plasma (n=215) was 10.5 to 14.8 seconds. 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 and /or INR depending on the test setup. 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

# Example: Patient Time = 20.0 sec

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-C test is capable of reporting results up to 150 seconds. Verify results > 150 seconds by repeat testing. International Normalized Ratio (INR): The International Sensitivity Index (ISI) is encoded in the 2D barcode along with the other

calibration information and is passed to the analyzer when the barcode is scanned.

Authorities recommend that the INR should be reported only for those patients who have been stabilized on warfarin therapy.<sup>2</sup> 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. The concentration of trisodium citrate used to anticoagulate blood samples is an important variable in the calculation of the INR. Clinical studies indicate that the concentration of citrate affects the ISI assignment for PT-C test cards. The ISI encoded on PT-C test cards is based on determinations with samples collected in 109 mM (3.2%) citrate as recommended by the International Society for Thrombosis and Hemostasis.4

Many commonly administered drugs, diseases, and other factors can affect the results obtained in PT testing.<sup>2</sup> 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.<sup>2</sup>

#### INTERFERENCES

Heparin levels greater than 0.4 U/mL may cause prolonged PT-C results.

Hemolysis should not affect the results; however, it is often an indication of poor specimen quality. PT-C results may be affected in patients receiving LMWH and Fondaparinux.

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

Factors Concentration ≥50 mg/dL Fibrinogen Hematocrit 0 - 60% Bilirubin 0 - 20 mg/mL

#### 0 - 20 g/L Lipemia PERFORMANCE CHARACTERISTICS

PRECISION: The precision studies were performed using three lots of Cascade Abrazo PT-C cards and one lot each of Cascade Abrazo PT-C 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-C test cards.

#### Within-run Precision N= 240

|         | Grand | within run |     | between run |     | between day |     | Total |     |
|---------|-------|------------|-----|-------------|-----|-------------|-----|-------|-----|
| PT-C    | mean  | SD         | %CV | SD          | %CV | SD          | %CV | SD    | %CV |
| Level 1 | 11.9  | 0.3        | 2.5 | 0           | 0   | 0           | 0   | 0.3   | 2.2 |
| Level 2 | 32.8  | 1.48       | 4.5 | 0.73        | 2.2 | 0.22        | 0.7 | 1.66  | 5.1 |

# Lot to Lot Precision'

| N= 80           |      |      |     |      |      |     |      |      |     |
|-----------------|------|------|-----|------|------|-----|------|------|-----|
| Lot Number      | 1    |      |     | 2    |      |     | 3    |      |     |
| Sample          | Mean | SD   | %CV | Mean | SD   | %CV | Mean | SD   | %CV |
| Level 1 Control | 11.9 | 0.27 | 2.3 | 12.1 | 0.22 | 1.8 | 12.1 | 0.21 | 1.8 |
| Level 2 Control | 32.6 | 1.81 | 5.5 | 33.7 | 1.15 | 3.4 | 33.1 | 1.29 | 3.9 |

Operator to Operator Precision\*

|                 | Operator 1 |      |     | Operator 2 |      |     | Operator 3 |      |     |
|-----------------|------------|------|-----|------------|------|-----|------------|------|-----|
| Sample          | Mean       | SD   | %CV | Mean       | SD   | %CV | Mean       | SD   | %CV |
| Level 1 Control | 11.9       | 0.27 | 2.3 | 11.8       | 0.39 | 3.3 | 11.9       | 0.24 | 2.1 |
| Level 2 Control | 32.6       | 1.81 | 5.5 | 32.8       | 1.9  | 5.8 | 32.7       | 1.24 | 3.8 |

\*Precision studies were performed according to EP5-A2.11

SPECIFICITY: Studies show that the Helena Cascade Abrazo PT-C test card is sensitive to deficiencies of Factors II, V, VII and X. COMPARISON: Clinical Studies were performed on citrated whole blood at the point of care setting, citrated whole blood in the laboratory, and citrated plasma in the laboratory and compared to citrated plasma results performed on the clinical laboratory instrumentation. 202 normal PT samples were collected and 203 abnormal PT samples were collected.

The abnormal PT samples consisted of patients receiving warfarin therapy and patients with prolonged PTs not on warfarin therapy. The following r values were obtained for seconds and INR for sample types listed:

| Sample      | Seconds | INR  |  |  |
|-------------|---------|------|--|--|
| CWB POC     | 0.95    | 0.95 |  |  |
| CWB Lab     | 0.96    | 0.96 |  |  |
| Plasma I ah | 0.94    | 0.94 |  |  |

Clinical conditions of patients with prolonged PTs include the following disease states: Liver disease, Cirrhosis, Diabetes, Hypertension, Hepatocellular Carcinoma, Melanoma, Sepsis, Sickle Cell Disease, Renal Disease, Congestive Heart Failure, Congenital Heart Failure, Atrial Fibrillation.

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