English

Cascade® Abrazo® aPTT Test Cards

REF **Cat. No. 5722**

CE

Contents
50 aPTT test cards, individually sealed in foil pouches

INTENDED USE

The Cascade Abrazo aPTT test cards are to be used with the Cascade Abrazo analyzer and are intended for the determination of the activated Partial Thromboplastin Time (aPTT) of citrated whole blood or plasma.
The aPTT test cards, together with the analyzer, are especially suited for professional use in decentralized areas of testing near the site of patient care, as well as for use in the more traditional clinical laboratory.

SUMMARY

The aPTT test is sensitive to deficiencies in the intrinsic and common pathways of the coagulation process.[1,2] Although the aPTT test is sensitive to severe deficiencies of all clotting factors except Factor VII, its primary use is in screening for deficiencies in Factors VIII, IX, XI, XII, prekallikrein (Fletcher factor), and high molecular weight kininogen (Fitzgerald factor).
The aPTT test was first reported in 1953 by Langdell, et al.[1] The authors described the effect of crude cephalin on hemophilic plasma. Later modifications included the addition of an activator to provide optimal contact activation, thereby minimizing the influence of other surfaces.[2] While the aPTT test card is similar to other aPTT tests, 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 aPTT test card. Many of the variables encountered with sample transport and handling are avoided.

PRINCIPLE

The Cascade Abrazo aPTT test consists of the recalcification of plasma in the presence of phospholipid (platelet substitute) and an activator, with the subsequent measurement of the time necessary for clot formation. The test is sensitive to deficiencies of the intrinsic and common pathways, including Factors II, V, VIII, IX, X, XI, XII, prekallikrein, and high molecular weight kininogen. The aPTT test should not be used to detect deficiencies of fibrinogen or Factor VII.

REAGENT

For *in vitro* diagnostic use only.

Components	Storage	Stability
Ellagic Acid Activator, calcium chloride, buffers, stabilizers, and paramagnetic iron oxide particles	2–8°C (36–46°F) 20–25 °C (68–77 °F)	Unopened – until the expiration date on the pouch label or Unopened – 2 weeks

CAUTION: 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.

SPECIMEN COLLECTION AND PREPARATION

The aPTT test cards may be used with citrated whole blood or plasma collected and processed according to the CLSI Guideline: Collection, Transport and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays, H21-A5.[3] 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. Test whole blood specimens within 30 minutes of collection.[10]
CAUTION: Clot times may be affected due to improperly filled sodium citrate blood collection tubes.
CAUTION: When handling blood specimens, all samples should be treated as biohazards.[7-9]

PROCEDURE

Materials provided: The following materials are contained in the Abrazo aPTT Test Kit (Cat. No. 5722).
50 Cascade Abrazo aPTT 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 aPTT Level 1 Control	5743
Cascade Abrazo aPTT Level 2 Control	5744
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 (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 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. Remove the test card from its foil pouch and hold it backwards with the barcode facing the Abrazo, approx. 6 to 8 inches from the Abrazo.
4. 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 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.[7-9]

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 quality 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 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.

At least two levels of 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

A study was conducted at three clinical sites which included 216 normal healthy donors. The CLSI C28-A3[6] non parametric 95% reference interval for citrated whole blood was 22.4 to 39.5 seconds and for citrated plasma was 25.0 to 40.7 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. The results are displayed at the end of the test procedure. The aPTT test is capable of reporting results up to 300 seconds. Verify results < 15 seconds and > 300 seconds by repeat testing.
If a test result appears inconsistent with the patient's clinical presentation, the result should be verified by testing a fresh sample or evaluated using an alternative diagnostic method.

LIMITATIONS

The influence of many seemingly insignificant environmental factors can affect aPTT testing.[4] Recommended specimen handling procedures should be strictly followed.
Whole blood samples containing heparin that are allowed to stand at room temperature will exhibit a progressive shortening of the aPTT.[4] This is thought to be due to the release of Platelet Factor 4 (PF4) from the platelets, which is known to have a neutralizing effect on heparin.[5] When performing an aPTT test, avoid handling samples in a manner that could induce the release of PF4 from platelets. This includes traumatic collection, refrigeration, or delay in testing or processing.
The aPTT test cards are not suitable for monitoring oral anticoagulant therapy nor can they detect deficiencies of Factor VII or fibrinogen.
HEPARIN SENSITIVITY: The use of Abrazo aPTT to monitor heparin therapy and guide dosing is not recommended. **The performance of this test has not been studied and established for the purpose of dosing heparin.** The effect of heparin as an anticoagulant can depend on many factors, including the source, type, and manufacturer of heparin used; differences in an individual's response to the drug; and the action of other medications being given. When screening for the presence of heparin, aPTT results can vary with the amount of heparin administered, the timing of sample collection, the manner in which the sample is handled, and the type of heparin being used.[5] aPTT values should not be considered interchangeable with other POC instruments or laboratory analyzers.[3,4]

INTERFERENCES

The presence of oxalate, EDTA, or any additive other than sodium citrate may interfere with the test.[3] Hemolysis should not affect the results; however, it is often an indication of poor specimen quality. Moderate lipemia and a hematocrit of 0% to 60% will not normally interfere with the results obtained with the aPTT test card.
The following table lists those factors that do not normally interfere with the aPTT test:

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

PERFORMANCE CHARACTERISTICS

SENSITIVITY: The aPTT has been shown to be sensitive to clotting factors in the intrinsic pathway and may be used to screen for moderate and severe deficiencies of these factors. It is not sensitive to deficiencies of fibrinogen or factor VII and may not detect mild or moderate Factor IX deficiencies.

PRECISION: Precision studies performed using the aPTT test cards and two levels of quality control plasma (n = 20 for each) produced the following results. Since values obtained with controls from other manufacturers may differ, operators should establish their own expected ranges for controls.

Within-run, Between-Run and Between-Day*

aPTT	Grand mean	S_r within run		S_{rr} between run		SD_{dd} between day		S_t total	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV
Level 1	28.2	0.7	2.6	0.2	0.8	0.3	1.0	0.8	2.9
Level 2	59.7	1.6	2.7	1.1	1.9	0	0	1.9	3.3

Lot-to-lot

Lot Number	1			2			3		
Sample	**Mean**	**SD**	**%CV**	**Mean**	**SD**	**%CV**	**Mean**	**SD**	**%CV**
Level 1 Control Plasma	27.7	0.9	3.2	27.2	1.1	3.9	25.5	0.9	3.3
Level 2 Control Plasma	59.6	3.2	5.3	58.1	2.2	3.8	58.0	2.6	4.4

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

COMPARISON: Multiple site comparison studies were done on citrated plasma and citrated whole blood with the following results.

Citrated Plasma - n = 342, r = 0.82

Citrated Whole Blood - n = 342, r = 0.78

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