SPECTRUM

The Creative Approach to Bioscience

SP- UNICELIN
(APTT Reagent)

REF: 626 001 30 test
REF: 626 002 150 test
REF: 626 003 160 test
REF: 626 004 180 test
REF: 626 005 240 test
REF: 626 006 300 test (for sensa 1 / Sensa 2)

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Use by/Expiration Date
IVD	For in-vitro diagnostic use		CAUTION. Consult instructions for use
LOT	Batch Code/Lot number		
REF	Catalogue Number		Manufactured by
	Consult instructions for use		(Xi) - Irritant
	Temperature Limitation		

Intended Use

Spectrum Diagnostics SP- UNICELIN reagent is intended for partial Thromboplastin (APTT) determination using ellagic acid, as an activator.

Background

The arrest of bleeding depends upon primary platelet plug formed along with the formation of a stable fibrin clot. Formation of this clot involves the sequential interaction of a series of plasma proteins in a highly ordered and complex manner and also in the interaction of these complexes with blood platelets and materials released from the tissues.
Activated Partial Thromboplastin Time (APTT) is prolonged with a deficiency of coagulation factors of the intrinsic pathway of the human coagulation mechanism such as factor XII, XI, IX, VIII, X, V, II, and Fibrinogen. Determination of APTT helps in estimating abnormality in most of the clotting factors of the intrinsic pathway and is also a sensitive procedure for generating heparin response curves for monitoring heparin therapy.

Assay Principle

Cephaloplastin activates the coagulation factors of the intrinsic pathway of the coagulation mechanism in the presence of calcium ions. APTT is prolonged by deficiency of one or more of these clotting factors of the intrinsic pathway and in the presence of coagulation inhibitors like heparin.

Reagent

SP-UNICELIN is a liquid ready-to-use activated cephaloplastin reagent for the determination of APTT. It is a phospholipid preparation derived from rabbit brain with ellagic acid as an activator.

0.025 mol/L calcium chloride

Reagent Storage and Stability

Store the reagent at 2 – 8 °C. Never freeze the reagent. The reagent is stable up to the expiry date given on label when stored at 2 – 8°C, 1 week at 18–25 °C, 2 days at 37 °C.Once opened, the reagent is stable for 1 month at the specified temperature.

Note

1. Avoid exposure of the reagent to elevated temperature and contamination.
2. Immediately replace cap after use and store at recommended temperature.
3. Reagent contain 0.01 g/dL Thimerosal as a preservative. Avoid contact with skin and mucosa.On disposal, flush with plenty of water.

Precautions and Warnings

For in-vitro diagnostic use only.Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Specimen Collection and Preparation

No special prepartion of the patient is required prior to sample collection. Withdraw blood without doing venous stasis and avoid haemolysis. The veinpuncture must be a clean one and, if there is any difficulty, take a new syringe and needle and try another vein. Mix exactly nine parts of freshly collected blood with one part of trisodium citrate (0.11mol/L, 3.2 %). Centrifuge immediately for 15 minutes at 3000 rpm and transfer the plasma into a clean test tube. Plasma must be tested within 3 hours of blood collection.

Pooled Plasma

Prepare a fresh normal plasma pool (FNP) from at least five normal healthy donors and process as above. Plasma must be tested within 3 hours of blood collection.

Procedure

1. Before use, the reagent should be mixed well by gentle swirling , do not shake.
2. Aspirate from the reagent vial enough reagent for the immediate test requirement in extremely clean and dry test tube. Bring this reagent to room temperature before prewarming at 37 °C.The calcium chloride solution should be brought to 37 °C before use.
3. To 12 x 75 mm test tube, add 0.1 ml test plasma and 0.1 ml SP- UNICELIN. Shake tube briefly to mix the reagent and plasma, place tube at 37 °C for 3 minutes.
4. Add forcibly 0.1 ml prewarmed calcium chloride and simultaneously start stop watch. Shake tube briefly to mix contents, keep at 37°C for 20 seconds.
5. Following 20 seconds incubation, remove the tube, gently tilt back and forth until a gel clot forms, stop the watch and ,record the time.
6. Repeat for a duplicate test using the same test plasma.
7. Find the average from the duplicate test values. This is the Activated Partial Thromboplastin Time (APTT of patient plasma)
8. Similarly repeat the steps 2-4 twice , and record values using FNP in place of test plasma (APTT of FNP).

NOTE
If **Sensa1 or Sensa2** is being used to perform the tests, refering to no. 3 and 4 in manual method, volumes of reagents and sample will be as follows :

SP- UNICELIN : 50µl
Specimen : 50µl
Calcium Chloride : 50µl

The rest of the procedure is resumed as the manual method.

Calculation and reporting of results

a) The result may be reported directly in terms of the mean of the double determination of the APTT of the test plasma

OR

b) as a ratio R as follows:

$$R = \frac{\text{APTT of patient plasma (in seconds)}}{\text{APTT of FNP (in seconds)}}$$

Expected Values

Normal values are between 22-34 seconds.

Remarks

1. Each laboratory must establish its own normal population range as well as normal and abnormal range.
2. Clotting time of patients on anticoagulant therapy depends upon the type and dosage of anticoagulant and also the time lag between the specimen collection and the dose.
3. Abnormalities of coagulation factor VII, factor XIII, and platelets are not detected by this method.
4. Platelet factor IV, a heparine-neutralising factor can be released due to platelet aggregation or damage. In order to prevent this phenomenon in-vitro the specimen should be collected with a minimum of trauma.
5. Decrease in APTT time is observed in males under estrogen therapy and oral contraceptive administration in females.

Performance Characteristics

All the performance characteristics are found in the corresponding Technical Report and available on request

Waste Disposal

This product is made to be used in professional laboratories.
Please consult local regulations for a correct waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment. refer to special instructions/safety data sheets.

References

1. Biggs, R.ed.: Human Blood Coagulation, Haemostasis and Thrombosis, Blackwell Scientific Publications, Oxford, England,1972.
2. Hoffmann, J.J.M.L and Neulendijk P.N.: Thrombos. Haemosta.(Stuttgard) 39, 640 (1978).

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
626 001	30 test
626 002	150 test
626 003	160 test
626 004	180 test
626 005	240 test
626 006	300 test

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CE

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