Cat no.	size
666001	2*5
666002	6*5
666003	6*8

INTENDED USE
Intended for prothrombin time (PT) determination.

DIAGNOSTIC CHARACTERISTICS
(Prothrombin time) is a screening assay used in the monitoring of oral anticoagulation therapy with vitamin K antagonists and for the detection of acquired or inherited bleeding disorders. The coagulation time measures the extrinsic hemostatic pathway and depends on the activity of coagulation factors II (Prothrombin), V(Proaccelerin), VII (Proconvertin), and X (Stuart factor) and fibrinogen, and for this reason it is used to establish the therapeutic range in vitamin K antagonists treatments, which prolongs PT. Prolonged PT may also be due to acquired or inherited deficiencies in coagulation factors I, II, V, VII, or X, liver failure, vitamin K deficiency, and DIC (disseminated intravascular coagulation)

PRINCIPLE OF THE METHOD
Tissue Thromboplastin in the presence of calcium activates the extrinsic pathway of human blood coagulation mechanism. When reagent is added to normal citrated plasma, the clotting mechanism is initiated, forming a solid gel clot within a specified period of time. The time required for clot formation would be prolonged if there is acquired or congenital deficiency of factors/ factor activity in the extrinsic pathway of the coagulation mechanism or reduction in the activity of Vitamin K dependent clotting factors during oral anticoagulant therapy

COMPOSITION
GENOPLASTIN is a ready to use liquid Calcified Thromboplastin Reagent, which is derived from rabbit brain.
Each batch of reagent undergoes rigorous quality control at various stages of manufacture for its sensitivity and performance

STORAGE
Store at 2 - 8°C
The reagent is stable until expiration date stated on label.

REAGENT PREPARATION
Single reagent ready to use.

ADDITIONAL EQUIPMENT
12 x 75 mm test tubes (plastic tubes are preferred), pipettes,
Stop watch, Water bath or heating block at 37°C,
Fresh normal Plasmas for establishing MNPT.

SPECIMEN
Though no special preparation of the patient is required prior to sample collection by approved techniques, it is preferable that patients are not heavily exercised before blood collection. Fasting or only light non-fatty meals prior to blood collection provide samples with desirable lower opacity. Withdraw blood without undue venous stasis or frothing into a plastic syringe fitted with a short needle of 19 to 20 SWG. The Vein puncture must be a 'clean' one and, if there is any difficulty, take a new syringe and needle and try another vein. Transfer the blood into anticoagulated tubes, after detaching the needle from the syringe. Do not delay mixing blood with anticoagulant. Avoid foam formation during mixing.

Manual methods
1. Bring the reagent vial to room temperature (20-30°C). Mix the contents of the vial to homogenise the suspension completely.
2. Aspirate from the reagent vial enough reagent for immediate testing requirements in a thoroughly clean and dry test tube.
(Plastic test tubes are preferred).
3. Prewarm the reagent and bring to 37°C before use in test procedure (5-10 minutes may be required depending on the reagent volume to attain 37°C before testing).
4. Recap the reagent vial and replace immediately to 2-8°C.
5. To a 12 x 75 mm tube add 0.1 ml of plasma (PPP) and place the tube in a water bath for 3 to 5 minutes at 37°C.
6. To the tube forcibly add 0.2 ml of reagent (prewarmed at 37°C for at least 3 minutes) and simultaneously start a stopwatch. Shake the tube gently to mix contents.
7. Gently tilt the tube back and forth and stop the stopwatch as soon as the first fibrin strand is visible and the gel / clot Formation begins .Record the time in seconds'.
8. Repeat steps 4-6 for a duplicate test on the same sample.
9. Find the average of the duplicate test values. This is the Prothrombin Time (PT).

CALCULATIONS
Manual Method
a) The results may be reported directly in terms of the mean of the double determination of PT of the test plasma in 'seconds'.

b) Or as a ratio 'R': $$R = \frac{\text{Mean of the patient plasma PT in seconds}}{\text{MNPT for the reagent}}$$

c) Or as International Normalized Ratio (INR), $INR = (R)^{ISI}$,
where ISI = International Sensitivity Index of the reagent (Refer reagent vial label).
It is recommended by the WHO that MNPT should be established for each lot of PT reagents by each laboratory, since PT results are dependent on the combination of reagent lot, instrument and technique followed at each laboratory. Usually plasma from at least 20 normal healthy individuals should be used to establish the MNPT.
The average of such PT results in seconds = MNPT.

REFERENCE VALUES
Normal values using GENOPLASTIN are between 10-14 seconds.
Between manual and Turbo densitometric instrument results a variation Of 1-2 seconds may be expected.
For photo optical instruments, it is recommended that each laboratory must establish its own normal range. It is mandatory that each laboratory must establish its own MNPT for each lot of GENOPLASTIN .
Oral Anticoagulant Therapeutic range: INR = 2.0 - 3.5

QUALITY CONTROL
It is recommended to use the Genesis Control Plasma level Iand II to verify the performance of the measurement procedure.
Each laboratory should establish its own internal Quality Control

BIBLIOGRAPHY
1. Biggs R. and R.G. McFarlane: Human Blood Coagulation and its disorders, Blackwell Scientific Publications, Oxford 1962.

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3. CRC Handbook Series in Clinical Laboratory, Science, Section 1: Haematology, Volume III, 1980.

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