## INR Conversion Table

| Patient PT Ratio | ISI | ISI | ISI | ISI | ISI | ISI | ISI | ISI | ISI | ISI | ISI | ISI | ISI | ISI | ISI | ISI | ISI | ISI | ISI | ISI |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| R | 1.1 | 1.2 | 1.3 | 1.4 | 1.5 | 1.6 | 1.7 | 1.8 | 1.9 | 2.0 | 2.1 | 2.2 | 2.3 | 2.4 | 2.5 | 2.6 | 2.7 | 2.8 | 2.9 |
| 1.0 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| 1.1 | 1.11 | 1.12 | 1.13 | 1.14 | 1.15 | 1.16 | 1.18 | 1.19 | 1.20 | 1.21 | 1.22 | 1.23 | 1.25 | 1.26 | 1.27 | 1.28 | 1.29 | 1.31 | 1.32 |
| 1.2 | 1.22 | 1.24 | 1.27 | 1.29 | 1.31 | 1.34 | 1.36 | 1.39 | 1.41 | 1.44 | 1.47 | 1.49 | 1.52 | 1.55 | 1.58 | 1.61 | 1.64 | 1.67 | 1.70 |
| 1.3 | 1.33 | 1.37 | 1.41 | 1.44 | 1.48 | 1.52 | 1.56 | 1.60 | 1.65 | 1.69 | 1.73 | 1.78 | 1.83 | 1.88 | 1.93 | 1.98 | 2.03 | 2.08 | 2.14 |
| 1.4 | 1.45 | 1.50 | 1.55 | 1.60 | 1.66 | 1.71 | 1.77 | 1.83 | 1.90 | 1.96 | 2.03 | 2.10 | 2.17 | 2.24 | 2.32 | 2.40 | 2.48 | 2.57 | 2.65 |
| 1.5 | 1.56 | 1.63 | 1.69 | 1.76 | 1.84 | 1.91 | 1.99 | 2.07 | 2.16 | 2.25 | 2.34 | 2.44 | 2.54 | 2.65 | 2.76 | 2.87 | 2.99 | 3.11 | 3.24 |
| 1.6 | 1.68 | 1.76 | 1.84 | 1.93 | 2.02 | 2.12 | 2.22 | 2.33 | 2.44 | 2.56 | 2.68 | 2.81 | 2.95 | 3.09 | 3.24 | 3.39 | 3.56 | 3.73 | 3.91 |
| 1.7 | 1.79 | 1.89 | 1.99 | 2.10 | 2.22 | 2.34 | 2.46 | 2.60 | 2.74 | 2.89 | 3.05 | 3.21 | 3.39 | 3.57 | 3.77 | 3.97 | 4.19 | 4.42 | 4.66 |
| 1.8 | 1.91 | 2.02 | 2.15 | 2.28 | 2.41 | 2.56 | 2.72 | 2.88 | 3.06 | 3.24 | 3.44 | 3.64 | 3.86 | 4.10 | 4.35 | 4.61 | 4.89 | 5.19 | 5.50 |
| 1.9 | 2.03 | 2.16 | 2.30 | 2.46 | 2.62 | 2.79 | 2.98 | 3.18 | 3.39 | 3.61 | 3.85 | 4.10 | 4.38 | 4.67 | 4.98 | 5.31 | 5.66 | 6.03 | 6.43 |
| 2.0 | 2.14 | 2.30 | 2.46 | 2.64 | 2.83 | 3.03 | 3.25 | 3.48 | 3.73 | 4.00 | 4.29 | 4.59 | 4.92 | 5.28 | 5.66 | 6.06 | 6.50 | 6.96 | 7.46 |
| 2.1 | 2.26 | 2.44 | 2.62 | 2.83 | 3.04 | 3.28 | 3.53 | 3.80 | 4.09 | 4.41 | 4.75 | 5.12 | 5.51 | 5.93 | 6.39 | 6.88 | 7.41 | 7.98 | 8.60 |
| 2.2 | 2.38 | 2.58 | 2.79 | 3.02 | 3.26 | 3.53 | 3.82 | 4.13 | 4.47 | 4.84 | 5.24 | 5.67 | 6.13 | 6.63 | 7.18 | 7.77 | 8.41 | 9.09 | 9.84 |
| 2.3 | 2.50 | 2.72 | 2.95 | 3.21 | 3.49 | 3.79 | 4.12 | 4.48 | 4.87 | 5.29 | 5.75 | 6.25 | 6.79 | 7.38 | 8.02 | 8.72 | 9.48 | 10 | 11 |
| 2.4 | 2.62 | 2.86 | 3.12 | 3.41 | 3.72 | 4.06 | 4.43 | 4.83 | 5.28 | 5.76 | 6.29 | 6.86 | 7.49 | 8.18 | 8.92 | 9.74 | 11 | 12 | 13 |
| 2.5 | 2.74 | 3.00 | 3.29 | 3.61 | 3.95 | 4.33 | 4.75 | 5.20 | 5.70 | 6.25 | 6.85 | 7.51 | 8.23 | 9.02 | 9.88 | 11 | 12 | 13 | 14 |
| 2.6 | 2.86 | 3.15 | 3.46 | 3.81 | 4.19 | 4.61 | 5.08 | 5.58 | 6.14 | 6.76 | 7.44 | 8.18 | 9.00 | 9.91 | 11 | 12 | 13 | 15 | 16 |
| 2.7 | 2.98 | 3.29 | 3.64 | 4.02 | 4.44 | 4.90 | 5.41 | 5.98 | 6.60 | 7.29 | 8.05 | 8.89 | 9.82 | 11 | 12 | 13 | 15 | 16 | 18 |
| 2.8 | 3.10 | 3.44 | 3.81 | 4.23 | 4.69 | 5.19 | 5.76 | 6.38 | 7.07 | 7.84 | 8.69 | 9.63 | 11 | 12 | 13 | 15 | 16 | 18 | 20 |
| 2.9 | 3.23 | 3.59 | 3.99 | 4.44 | 4.94 | 5.49 | 6.11 | 6.80 | 7.56 | 8.41 | 9.35 | 10 | 12 | 13 | 14 | 16 | 18 | 20 | 22 |
| 3.0 | 3.35 | 3.74 | 4.17 | 4.66 | 5.20 | 5.80 | 6.47 | 7.22 | 8.06 | 9.00 | 10 | 11 | 13 | 14 | 16 | 17 | 19 | 22 | 24 |
| 3.1 | 3.47 | 3.89 | 4.35 | 4.87 | 5.46 | 6.11 | 6.84 | 7.66 | 8.58 | 9.61 | 11 | 12 | 13 | 15 | 17 | 19 | 21 | 24 | 27 |
| 3.2 | 3.59 | 4.04 | 4.54 | 5.10 | 5.72 | 6.43 | 7.22 | 8.11 | 9.12 | 10 | 12 | 13 | 15 | 16 | 18 | 21 | 23 | 26 | 29 |
| 3.3 | 3.72 | 4.19 | 4.72 | 5.32 | 5.99 | 6.75 | 7.61 | 8.58 | 9.66 | 11 | 12 | 14 | 16 | 18 | 20 | 22 | 25 | 28 | 32 |
| 3.4 | 3.84 | 4.34 | 4.91 | 5.55 | 6.27 | 7.09 | 8.01 | 9.05 | 10 | 12 | 13 | 15 | 17 | 19 | 21 | 24 | 27 | 31 | 35 |
| 3.5 | 3.97 | 4.50 | 5.10 | 5.78 | 6.55 | 7.42 | 8.41 | 9.54 | 11 | 12 | 14 | 16 | 18 | 20 | 23 | 26 | 29 | 33 | 38 |
| 3.6 | 4.09 | 4.65 | 5.29 | 6.01 | 6.83 | 7.76 | 8.82 | 10 | 11 | 13 | 15 | 17 | 19 | 22 | 25 | 28 | 32 | 36 | 41 |
| 3.7 | 4.22 | 4.81 | 5.48 | 6.24 | 7.12 | 8.11 | 9.25 | 11 | 12 | 14 | 16 | 18 | 20 | 23 | 26 | 30 | 34 | 39 | 44 |
| 3.8 | 4.34 | 4.96 | 5.67 | 6.48 | 7.41 | 8.47 | 9.67 | 11 | 13 | 14 | 17 | 19 | 22 | 25 | 28 | 32 | 37 | 42 | 48 |
| 3.9 | 4.47 | 5.12 | 5.87 | 6.72 | 7.70 | 8.82 | 10 | 12 | 13 | 15 | 17 | 20 | 23 | 26 | 30 | 34 | 39 | 45 | 52 |
| 4.0 | 4.59 | 5.28 | 6.06 | 6.96 | 8.00 | 9.19 | 11 | 12 | 14 | 16 | 18 | 21 | 24 | 28 | 32 | 37 | 42 | 49 | 56 |
| 4.1 | 4.72 | 5.44 | 6.26 | 7.21 | 8.30 | 9.56 | 11 | 13 | 15 | 17 | 19 | 22 | 26 | 30 | 34 | 39 | 45 | 52 | 60 |
| 4.2 | 4.85 | 5.60 | 6.46 | 7.46 | 8.61 | 9.94 | 11 | 13 | 15 | 18 | 20 | 24 | 27 | 31 | 36 | 42 | 48 | 56 | 64 |
| 4.3 | 4.98 | 5.76 | 6.66 | 7.71 | 8.92 | 10 | 12 | 14 | 16 | 18 | 21 | 25 | 29 | 33 | 38 | 44 | 51 | 59 | 69 |
| 4.4 | 5.10 | 5.92 | 6.86 | 7.96 | 9.23 | 11 | 12 | 14 | 17 | 19 | 22 | 26 | 30 | 35 | 41 | 47 | 55 | 63 | 73 |
| 4.5 | 5.23 | 6.08 | 7.07 | 8.21 | 9.55 | 11 | 13 | 15 | 17 | 20 | 24 | 27 | 32 | 37 | 43 | 50 | 58 | 67 | 78 |



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BIO/DATA CORPORATION

# PLASTINEX®

## THROMBOPLASTIN

For use in the Prothrombin Time Test

### PRODUCT DESCRIPTION

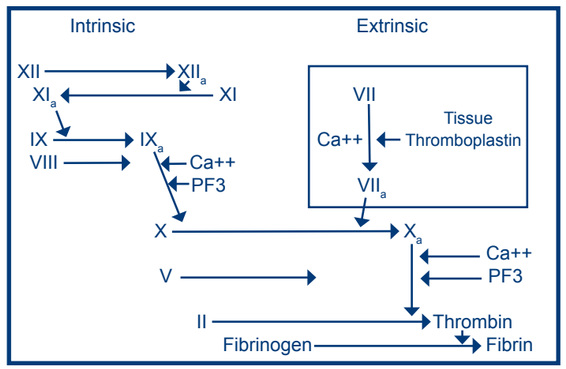
Plastinex is a lyophilized preparation of rabbit brain thromboplastin, calcium salt, buffers and stabilizers. Upon reconstitution the reagent is a “combined” thromboplastin, containing both the tissue factor and calcium ions required for plasma coagulation by way of the "extrinsic” hemostatic pathway. The International Sensitivity Index (ISI) of the reagent (for most optical or optical/mechanical coagulation analyzers) appears on the vial label along with the lot number and expiration date.

### INTENDED USE

Plastinex is for use in performing the one stage prothrombin time (PT) and coagulation factor assays which are based on a modified prothrombin time.
The prothrombin time is the method of choice for monitoring oral anticoagulation therapy.[1] It is also a fundamental screening test for a deficiency or abnormality of extrinsic coagulation factor VII, and the factors common to both the intrinsic and extrinsic hemostatic pathways: fibrinogen, I, V, and X. When used in conjunction with deficient substrate plasma, the PT provides the basis for the determination of the percent (%) activity of specific coagulation factors.

### PRINCIPLE

The capability of blood to form a fibrin clot by way of the extrinsic hemostatic pathway requires tissue thromboplastin, calcium, factor VII (proconvertin), factor V (proaccelerin), factor X (Stuart-Prower factor), factor II (prothrombin) and factor I (fibrinogen).[2,3] When tissue thromboplastin and calcium are added to a sample of citrated plasma, the actions of the intrinsic factors are bypassed and the reaction becomes specific for the coagulation factors involved in the extrinsic and common pathways. [4]




### PRECAUTIONS

Plastinex is FOR IN VITRO DIAGNOSTIC USE ONLY and is NOT FOR INGESTION OR INJECTION.

### MATERIALS PROVIDED

Plastinex
Catalog Number 101158, 20 x 4.0mL
Catalog Number 102672, 15 x 10.0mL

Store at 2°-8°C prior to reconstitution

### MATERIALS REQUIRED BUT NOT PROVIDED

1. Purified water (distilled, deionized or reagent grade) pH = 5.3 – 7.2
2. Pipettes (10.0mL, 4.0mL, and 0.2mL volume capacities)
3. Citrated control plasmas (see PRODUCT AVAILABILITY)

### INSTRUMENTATION

Prothrombin time endpoints may be detected by manual methods or with any automated or semi-automated coagulation timer. Follow the manufacturer’s instructions for operating the timer in use.

### COLLECTION AND PREPARATION OF TEST PLASMA

Test plasma for the prothrombin time should be prepared from citrated whole blood. Specimen collection tubes containing such anticoagulants as heparin, EDTA or oxalate are NOT suitable.

1. Blood Collection[5]
   Blood collection for the prothrombin time should be performed with techniques that prevent hemolysis and avoid contamination of the specimen (e.g. tissue factor, heparin from an indwelling catheter, etc.)

   a. Evacuated Blood Collection Tube:
      Draw blood using tubes with non-wettable interior that contain 0.11 M sodium citrate anticoagulant. Follow the established phlebotomy guidelines of the institution for order to draw. It is generally recommended that tubes for coagulation tests and assays be the SECOND or THIRD tube drawn.

      Invert gently three or four times to mix. Do not cause frothing.

   b. Syringe Technique:
      Draw blood. Gently but immediately transfer nine parts of blood to a non-evacuated collection tube containing one part of 0.11 M sodium citrate anticoagulant. (See LIMITATIONS) This collection tube should also have a non-wettable interior. Cap and mix gently three or four times, avoiding frothing of the specimen.

2. Prepare platelet poor plasma samples to equal < 10,000 platelets per cubic milliliter by centrifuging blood at 2500 x g for 15 minutes or by selecting the PFP setting on the Bio/Data Corporation's Platelet Function Centrifuge, Model PDQ®.

3. Using a non-wettable pipette, remove plasma from the packed cells, being careful not to disturb the buffy coat and platelets. Transfer the plasma to a non-wettable container. Plasma that is visibly hemolyzed or contains > 10,000 platelets per cubic milliliter or red cells is not suitable for coagulation testing.

4. If testing is delayed, the following maximum times between specimen collection and sample testing may apply. Suggested storage conditions are also listed.
   a. Two hours at 22° - 24° C.
   b. Four hours at 2° - 4° C.
   c. Two weeks at -20° C. (See NOTE)
   d. Six months when rapidly frozen and stored at -70° C. (See NOTE)

NOTE: Prior to freezing, the plasma may be centrifuged again to assure that all cells are removed.

### RECONSTITUTION

1. Tap the vial to dislodge the material adhering to the stopper.
2. Remove the aluminum seal by lifting the tab.
3. Remove the stopper and reconstitute the vial contents with the volume of purified water specified on the label.
4. Replace the stopper and SHAKE the vial to thoroughly disperse the contents. Let stand for no less than 15 minutes prior to use to assure complete rehydration of the contents.

NOTE: Once reconstituted, Plastinex is stable for five days when stored at 2° - 8° C.

### TEST PROCEDURE

NOTE: FOR BEST RESULTS SUSPENSION OF THE REAGENT SHOULD BE MAINTAINED BY MAGNETIC STIRRING OR INVERSION IMMEDIATELY PRIOR TO USE.

1. Pre-incubate reconstituted reagent to 37° C.
2. Pipette 0.1mL of test or control plasma into a test cuvette.
3. Incubate at 37° C for at least 2 minutes, but not more than 10 minutes.

4. Inject 0.2mL of the pre-incubated reagent, simultaneously starting the timer.
5. Record the clotting time.
6. Repeat steps 2 through 5 for a duplicate sample. Duplicate results should correlate within ± five percent (5%)

NOTE: The procedure pertains to manual and semi-automated coagulation systems. For use with automated coagulation systems, refer to the instruction manual for the instrument in use.

## QUALITY CONTROL

The precision and accuracy of prothrombin times may be affected by a number of influences. Significant interlaboratory differences arise from the variety of coagulation timers used to measure clotting endpoints. [5] Intralaboratory variables which may impact prothrombin time results include: pH of purified water used for reagent reconstitution, pipetting technique, incubation temperatures, incubation times, reagent contamination, and lot to lot reagent variations. [6] Periodic quality control analyses, performed on a regular basis, will help to identify the occurrence of any deviations which may lead to erroneous test results.

Three varieties of control plasma are available for performing quality assurance tests with Plastinex (see PRODUCT AVAILABILITY). These controls represent three levels of prothrombin times: normal results and two levels of abnormal results.

Each laboratory should establish acceptance limits for each lot of control plasma by performing replicate studies, generally over a 20 day period, with one measurement on the control material per analytical run and one analytical run per day. In daily operation of the control procedure, samples of control material are included with each analytical run. A "multi-rule" statistical control procedure is then applied to establish acceptance of the analytical run. [7]

## RESULTS

The format with which prothrombin times are reported should be established based on the application of the test results. When Plastinex® is used for the evaluation of a bleeding diathesis, the prothrombin time should be reported as the clotting endpoint in seconds to the nearest tenth of a second. [8]

For monitoring oral anticoagulant therapy, the prothrombin time may be reported as the clotting time in seconds; as the ratio of the patient clotting time to the clotting time of a normal plasma; or, alternatively, for patients stabilized on oral anticoagulant therapy, as the International Normalized Ratio (INR). The International Sensitivity Index (ISI) of the Plastinex is used to calculate the INR. The ISI value for each lot number of Plastinex is printed on the vial label.

## EXPECTED VALUES

The results obtained with Plastinex are influenced by the coagulation endpoint detection method. In general, normal results for prothrombin times performed on a photo optical coagulation timer will be in the range of 10 to 13 seconds. When a mechanical based coagulation timer is used, normal values are generally in the range of 10.5 to 13.5 seconds. For manual methods, normal results ranging from 11 to 13.5 seconds are to be expected.

Therapeutic ranges for monitoring oral anticoagulation therapy, when reported in seconds, will vary depending on the coagulation endpoint timer in use. Because of this, it is essential that each laboratory determine relevant ranges for its respective patient population. [9, 11]

When Plastinex is used to evaluate the integrity of the extrinsic coagulation mechanism, results outside the normal range could be indicative of single or multiple factor deficiencies in the extrinsic coagulation pathway. Such deficiencies may be hereditary or acquired as the result of liver disease, vitamin K deficiency or drug reaction. Additional procedures such as an APTT and mixing studies may aid in the identification of a factor deficiency or an inhibitor.

When Plastinex is used for therapeutic monitoring of oral anticoagulation therapy, results should be evaluated relative to the parameters established by the institution. These parameters may be expressed as clotting times; ratios of patients clotting times to the normal clotting time; or the INR.

## LIMITATIONS

Incorrect blood to anticoagulant ratio may result in spurious test results. The usual ratio is one part sodium citrate to nine parts of blood. The standard 9:1 ratio of blood to anticoagulant produces altered test results in patients with extremely high (>55%) or low (<20%) hematocrit levels. The patient specimen must be redrawn with an adjusted ratio of whole blood to anticoagulant according to the following formula. [17]

$C = 1.85 \times 10^{-3} (10 - H) \times V$
C = volume of anticoagulant in milliliters
V = volume of whole blood in milliliters
H = Hematocrit in percent

## PERFORMANCE CHARACTERISTICS

Plastinex has been tested with photo optical, mechanical and manual endpoint detection systems. Its precision and sensitivity are sufficient to provide a reliable method of evaluating abnormalities in the extrinsic coagulation pathway as well as monitoring oral anticoagulation therapy.

## REFERENCES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## INR

The International Normalized Sensitivity Index (INR) is the reported value recommended by the World Health Organization[1] and the International Committee on Thrombosis and Haemostasis[2] for patients receiving oral anticoagulant therapy. The INR results are values which accompany the prothrombin time (PT) and are intended to standardize reporting specifically for the assessment of patients stabilized on oral anticoagulant therapy. Reporting the INR value minimizes the problems encountered when comparing PT results derived from different thromboplastin reagents, instruments and assay methodologies.

## ISI

The International Sensitivity Index (ISI) is a value assigned to the reagent/instrument combination using the method established by the World Health Organization (WHO). The standard method for calibrating a new thromboplastin requires performing prothrombin times on patients stabilized on oral anticoagulants as well as normal healthy individuals with both the test thromboplastin and a reference thromboplastin. The ISI value of the reagent in use is part of the equation for determining the INR.

## Normal Prothrombin Time ($PT_N$)

The mean normal PT is determined by establishing a NORMAL POPULATION MEAN for each laboratory. This must be done when evaluating each new lot of thromboplastin reagent or new reagent/instrument system.

The INR is determined by the following equation:

## $INR = R^{ISI}$

$$R = \frac{\text{Patient Prothrombin Time (PT)}}{\text{Mean Normal Prothrombin Time } (PT_N)}$$

Methods of INR calculation using a scientific calculator:

| | PRESS | EXPLANATION |
|---|---|---|
| EX: | 25.5 | patient PT |
| | -- | divided by |
| | 12.2 | Normal PT ($PT_N$) |
| | = | Patient Ratio (display shows 2.090) |
| | $Y^x$ | exponential function key |
| | 2.34 | ISI value (Example) |
| | = | result of INR (display shows 5.61) |

Report as INR = 5.6

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## PRODUCT AVAILABILITY

| PRODUCT | CATALOG NUMBER | NET CONTENTS |
|---|---|---|
| Plastinex® | | |
| Thromboplastin Reagent | 101158 | 20 x 4.0mL |
| | 102672 | 15 x 10.0mL |
| **ALSO AVAILABLE** | | |
| Cephalinex®, APTT Reagent | 101162 | 20 x 3.0mL |
| (Silica Activated) | 102677 | 15 x 10.0mL |
| Coagulation Control Plasma | | |
| Citrex® I (Normal) | 101166 | 20 x 1.0mL |
| Citrex II (Abnormal) | 101170 | 20 x 1.0mL |
| Citrex III (Abnormal) | 101174 | 20 x 1.0mL |
| Thrombinex® | | |
| (Bovine thrombin) | 101628 | 20 x 2.0mL |
| Calcium Chloride Solution | | |
| 0.025M | 100989 | 473mL |




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