

## Overview

### Useful For

Screening to identify a deficiency of one or more of the clotting factors of the extrinsic coagulation system (I, II, V, VII, X) due to hereditary deficiency or acquired conditions such as liver disease, vitamin K deficiency, or a specific factor inhibitor

Monitoring patients on oral anticoagulant therapy to maintain a patient in a safe therapeutic range

### Method Name

Only orderable as part of a profile or reflex. For more information see:

ALUPP / Lupus Anticoagulant Profile, Plasma

ALBLD / Bleeding Diathesis Profile, Limited, Plasma

AATHR / Thrombophilia Profile, Plasma

APROL / Prolonged Clot Time Profile, Plasma

ADIC / Disseminated Intravascular Coagulation/Intravascular Coagulation and Fibrinolysis (DIC/ICF) Profile, Plasma  
Optical Clot-Based

### NY State Available

Yes

## Specimen

### Specimen Type

Plasma Na Cit

### Necessary Information

Heparin or Coumadin therapy should be noted.

### Specimen Required

Only orderable as part of a profile or reflex. For more information see:

ALUPP / Lupus Anticoagulant Profile, Plasma

ALBLD / Bleeding Diathesis Profile, Limited, Plasma

AATHR / Thrombophilia Profile, Plasma

APROL / Prolonged Clot Time Profile, Plasma

ADIC / Disseminated Intravascular Coagulation/Intravascular Coagulation and Fibrinolysis (DIC/ICF) Profile, Plasma

### Reject Due To

Gross hemolysis    Reject

Gross lipemia      Reject

Gross icterus      Reject

### Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
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Plasma Na Cit	Frozen (preferred)	14 days	
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## Clinical & Interpretive

### Clinical Information

This assay is used to monitor oral anticoagulant therapy to maintain a patient in a safe therapeutic range.

In the absence of oral anticoagulant therapy, a prolonged prothrombin time indicates deficiency of one or more factors (I, II, V, VII, or X) or the presence of a coagulation inhibitor.

The prothrombin time is also reported as the INR (International Normalized Ratio), based on the ISI (International Sensitivity Index) assigned to the thromboplastin and coagulometer. This assay is used for monitoring "stable" oral anticoagulation. A mixing test of patient and normal plasma (1:2) can be performed, if indicated, to differentiate coagulation factor deficiency from inhibition.

### Reference Values

Only orderable as part of a profile or reflex. For more information see:

ALUPP / Lupus Anticoagulant Profile, Plasma

ALBLD / Bleeding Diathesis Profile, Limited, Plasma

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ADIC / Disseminated Intravascular Coagulation/Intravascular Coagulation and Fibrinolysis (DIC/ICF) Profile, Plasma

PROTHROMBIN TIME

9.4-12.5 seconds

INTERNATIONAL NORMALIZED RATIO (INR)

0.9-1.1

Standard intensity warfarin therapeutic range: 2.0-3.0

High intensity warfarin therapeutic range: 2.5-3.5

### Interpretation

Prolongation of the prothrombin time (PT) can occur as a result of deficiency of one or more coagulation factors (acquired or congenital in origin), or the presence of an inhibitor of coagulation such as heparin, a lupus anticoagulant, a "nonspecific" inhibitor such as a monoclonal immunoglobulin, or a specific coagulation factor inhibitor.

PT mixing study, using equal volume patient and normal pool plasma, may be performed on specimens with a prolonged PT to assist in differentiating coagulation factor deficiencies from coagulation inhibitors. Correction of the PT mix to within the normal reference range usually indicates a coagulation factor deficiency (normal plasma in the mixture ensures at least 50% activity of all coagulation factors). If the prolonged PT is due to an inhibitor (eg, specific coagulation factor inhibitor, lupus anticoagulant, heparin), the PT mix typically fails to correct a prolonged PT. However, the presence of a weak inhibitor may be missed by the PT mixing study.

Accurate interpretation of both PT and PT mixing study results may often require additional testing. For example, the thrombin time (TT) test is helpful for identifying or excluding the presence of heparin, the platelet neutralization procedure (PNP, using a modified APTT method) for identifying or excluding lupus anticoagulant, the activated partial thromboplastin (APTT) and dilute Russell viper venom time (DRVVT) for further assessment of the common procoagulant pathway, and coagulation factor assays to detect and identify deficient or abnormal factors. These assays are available as components of reflexive and interpretive testing panels in the Special Coagulation Laboratory (eg, APROL / Prolonged Clot Time Profile).

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**Cautions**

Prothrombin time (PT) mixing studies have no utility when the patient PT is normal.  
Lipemic specimens may interfere with the instrument clot detection mechanism.

**Clinical Reference**

Kamal AH; Tefferi A; Pruthi RK: How to interpret and pursue an abnormal prothrombin time, activated partial thromboplastin time, and bleeding time in adults. Mayo Clin Proc 2007 July;82(7):864-873

**Performance****Method Description**

Tissue thromboplastin (phospholipid and recombinantly-derived human tissue factor) and calcium are added to citrated plasma, bypassing the action of platelets and factors VIII, IX, XI, and XII in the intrinsic procoagulant pathway. The tissue thromboplastin-factor VII/VIIa complex activates factor X. Activated factor X (factor Xa) forms a complex with factor Va, calcium, and phospholipid to activate factor II (prothrombin) to thrombin. Thrombin then acts on fibrinogen (factor I) to form fibrin which clots, providing the assay endpoint (the "prothrombin time").(Package insert: HemosIL RecombiPlasTin 2G Instrumentation Laboratory Company, Lexington, MA, R0, 9/2007)

**PDF Report**

No

**Performing Laboratory Location**

Rochester

**Fees & Codes****Test Classification**

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

**CPT Code Information**

85610