BIOMEDICA

PRODUCT CATALOGUE

A complete line of specialty coagulation and diagnostic products, focused on haemostasis & thrombosis diagnostic solutions for human and animal health.

Distributed by:

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HELPING PEOPLE LIVE BETTER LIVES

Choose BioMedica Diagnostics for:

CUSTOM REAGENT FORMULATION for conventional, and point-of-care instrument platforms

BULK INTERMEDIATE CONCENTRATES Custom adjustment and final manufacturing by a third party

OEM PRODUCTS AND MANUFACTURING SERVICES

ROUTINE AND SPECIALTY COAGULATION PRODUCTS Health Canada registered, FDA 510(k) cleared and/or CE marked

BioMedica's innovative advantages include:

- Enhanced target-oriented extraction of natural, pro-coagulant macromolecules
- Novel purification, and localized concentration of pro-coagulant components
- Novel artificial reconstitution of macromolecular diagnostic complexes
- Optimization of tertiary structure orientation for maximum biological reactivity
- Custom regulation of pro-coagulant activity for point-of-care and viscoelastic based platforms
- Custom reagent optimization for existing and new platforms
- Custom control and calibrator development
- Single-serve reagent systems for point-of-care application
- Development of novel detection reagents for thrombophilia and hypercoagulability.
- Synthetic molecular mimics of enzymatic (Chromogenic) and immune specific substrates
- Enhanced photometric signaling of specific molecular diagnostic interactions for increased chromogenic assay sensitivity

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ANTICOAGULANT THERAPY

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Shown above: 832 ACTICHROME® Heparin (Anti-FXa), Activity Assay

The role of anticoagulant therapies is to block the activity of coagulation factors. Anticoagulant agents may block specific targets in the coagulation cascade.

Approved anticoagulants for clinical use in the acute setting of acute coronary syndrome (ACS)/percutaneous coronary interventions (PCI) patients are classified according to their mechanism of action. Thrombin inhibitors are the most commonly used and are classified as indirect and direct thrombin inhibitors.

Anti-X inhibitors are also available, although their use is limited in patients undergoing PCI. Blockade of coagulation factors is pivotal as they are associated with enhanced platelet reactivity, thus increasing thrombotic risk.

ACTICHROME® Heparin (Anti-FIIa) REF: 820 IVD

ACTICHROME® Heparin (Anti-FIIa) is an amidolytic chromogenic assay intended for the quantitative determination of therapeutic heparin in human plasma via the measurement of factor IIa (thrombin) activity.

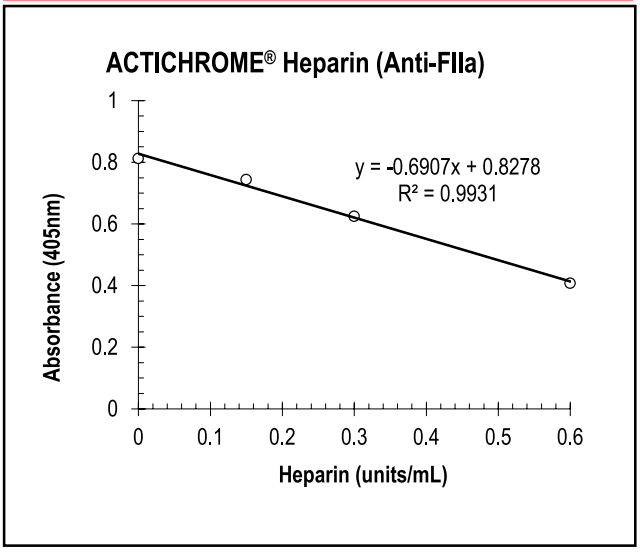
The inhibitory effect of antithrombin III (AT-III) on Factor IIa (thrombin), Factor Xa, and other coagulation serine proteases in plasma is increased several thousand-fold by heparin. This inhibition accounts for the anticoagulant effect of heparin. Assaying plasma heparin levels by the measurement of their anti-factor IIa activity is a necessary tool for monitoring the efficacy of heparin treatment efficacy. Low molecular weight heparin (LMWH) preparations appear to catalyze the reaction between thrombin (FIIa) and AT-III less readily than the reaction between factor Xa and AT-III. Unfractionated heparin (UFH) catalyzes both reactions equally.

ACTICHROME Heparin (Anti-FIIa) is a three stage assay. First, plasmas containing heparin incubate with human antithrombin III forming a heparin-ATIII complex. Second, thrombin is added which is inhibited by the heparin-ATIII complex. Last, the residual thrombin activity hydrolyzes SPECTROZYME® TH, a thrombin specific chromogenic substrate. As both thrombin and antithrombin III are in excess, the residual thrombin activity measured is inversely proportional to the heparin concentration in the plasma.

REAGENTS

- 6 Vials of Bovine Thrombin Reagent, 2 mL (lyophilized)
- 6 Vials of Human Antithrombin III Reagent, 5 mL (lyophilized)
- 6 Vials of SPECTROZYME® TH, 2 mL (lyophilized)

RESULTS/REPRESENTATIVE STANDARD CURVE



SPECIFICATIONS

SAMPLES	Citrate collected plasma
SAMPLE PREPARATION	1:16 dilution in Human Anti-Thrombin III Reagent
SAMPLE VOLUME	25 µL of diluted plasma
TOTAL ASSAY TIME	10 minutes
STANDARD RANGE	0 – 0.6 Units/mL
LOWER LIMIT OF DETECTION	N.D.
PRECISION	Intra-assay CV < 10.8% Inter-assay CV < 9.6%
NUMBER OF TESTS	120

RELATED PRODUCTS

ACTICHROME® Heparin (Anti-FXa) REF 832 .....Pg 6
IMUBIND™ Platelet Factor 4 ELISA REF 634 .....Pg 7

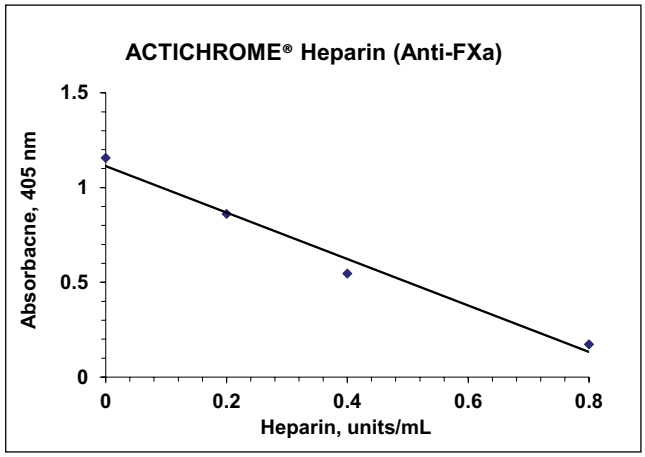
ACTICHROME® Heparin (Anti-FXa) REF: 832 IVD

ACTICHROME® Heparin (Anti-FXa) is an amidolytic chromogenic assay intended for the quantitative determination of therapeutic heparin in human plasma via the measurement of Factor Xa activity.

The inhibitory effect of antithrombin III (AT-III) on Factor IIa (thrombin), Factor Xa, and other coagulation serine proteases in plasma is increased several thousand-fold by heparin. This inhibition accounts for the anticoagulant effect of heparin. Assaying plasma heparin levels by the measurement of their anti-Factor Xa activity is a necessary tool for monitoring the efficacy of heparin treatment efficacy. Low molecular weight heparin (LMWH) preparations appear to catalyze the reaction between thrombin (FIIa) and AT-III less readily than the reaction between Factor Xa and AT-III. Unfractionated heparin (UFH) catalyzes both reactions equally.

ACTICHROME Heparin (Anti-FXa) is a three stage assay. First, plasmas containing heparin incubate with human antithrombin III forming a heparin-ATIII complex. Second, Factor Xa is added which is inhibited by the heparin-ATIII complex. Last, the residual Factor Xa activity hydrolyzes SPECTROZYME® FXa, a Factor Xa specific chromogenic substrate. As both Factor Xa and antithrombin III are in excess, the residual Factor Xa activity measured is inversely proportional to the heparin concentration in the plasma.

RESULTS/REPRESENTATIVE STANDARD CURVE



SPECIFICATIONS

SAMPLES	Citrate collected plasma
SAMPLE PREPARATION	No dilution
SAMPLE VOLUME	25 µL of diluted plasma
TOTAL ASSAY TIME	15 minutes
STANDARD RANGE	0 – 0.8 Units/mL
LOWER LIMIT OF DETECTION	N.D.
PRECISION	Intra-assay CV < 5.1% Inter-assay CV < 9.3%
NUMBER OF TESTS	200

REAGENTS

- 4 Vials of Bovine Factor Xa Reagent, 5 mL (lyophilized)
- 4 Vials of Human Antithrombin III Reagent, 5 mL (lyophilized)
- 4 Vials of SPECTROZYME® FXa, 5 mL (lyophilized)

RELATED PRODUCTS

ACTICHROME® Heparin (Anti-FIIa) REF 820 ..... Pg 5
IMUBIND™ Platelet Factor 4 ELISA REF 634 ..... Pg 7

IMUCLONE™ Platelet Factor 4 ELISA REF: 634 RUO

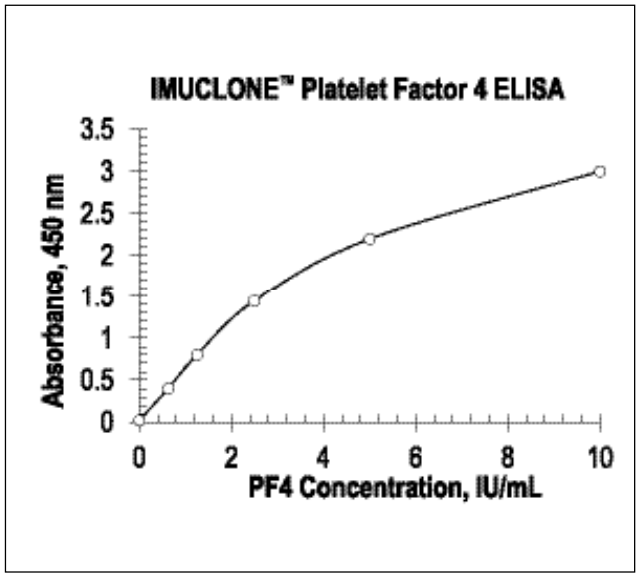
The IMUCLONE™ Platelet Factor 4 ELISA is an enzyme-linked immunosorbent assay for measuring human Platelet Factor 4 in platelet depleted plasma, or in any biological fluid where Platelet Factor 4 may be present.

Platelet Factor 4 (PF4) is a 70 amino acid (molecular weight of 7,800) protein released from the alpha-granules of activated platelets complexed with platelet proteoglycan. Upon release, the half-life of PF4 is very short, less than 5 minutes, as it quickly binds to endothelial cell glycosaminoglycans where it is stored. Its major physiologic role appears to be the neutralization of heparin-like molecules on the endothelial surface of blood vessels. PF4 possesses a powerful anti-heparin activity, binding to heparin with a high affinity, where 1 mg of PF4 will inhibit 27 IU of heparin. This anti-heparin activity translates to lower antithrombin III activity which promotes coagulation. The PF4 concentration in normal human plasma is less than 10 IU/mL. Heparin administration causes PF4 to be released from its endothelial cell storage sites, greatly increasing its concentration in blood.

REAGENTS

96 Microwell Plate pre-coated with anti-Human PF4 IgG plus storage bag with desiccant
2 Vials of PF4 Sample Diluent, 50 mL
3 Vials of PF4 Standard, 2 mL (lyophilized)
1 Vial of PF4 Plasma Control I, High, 0.5 mL (lyophilized)
1 Vial of PF4 Plasma Control II, Low, 0.5 mL (lyophilized)
3 Vials of Anti-Human PF4-HRP Immunoconjugate, 7.5 mL (lyophilized)
1 Vial of Conjugate Diluent, 25 mL
1 Vial of Wash Solution (20X concentrate), 50 mL
1 Vial of TMB Substrate, 25 mL
1 Vial of Stop Solution, 0.45 M Sulfuric Acid, 6 mL

RESULTS/REPRESENTATIVE STANDARD CURVE



SPECIFICATIONS

SAMPLES	CTAD (citrate, theophylline, adenosine, dipyridamole) or ETP (EDTA, theophylline, prostaglandin E1) collected plasma
SAMPLE PREPARATION	1:2, 1:5 (or higher) dilution
SAMPLE VOLUME	200 µL of diluted sample
TOTAL ASSAY TIME	3 hours
STANDARD RANGE	0 – 10 IU/mL (10 ng/mL)
PRECISION	Intra-assay CV = N.D. Inter-assay CV = N.D.
NUMBER OF TESTS	96

RELATED PRODUCTS

ACTICHROME® Heparin (Anti-FIIa) REF 820 .....Pg 5
ACTICHROME® Heparin (Anti-FXa) REF 832 .....Pg 6

FEMTELLE® uPA/PAI-1 ELISA **REF: 899** **CE**

CANCER PROGNOSIS

FEMTELLE® is intended for the quantitative measurement of human Urokinase-type Plasminogen Activator (uPA) and human Plasminogen Activator Inhibitor Type-1 (PAI-1) in detergent extracts of breast tumor tissue.

uPA and PAI-1 are clinically validated independent prognostic markers in breast cancer and have reached the highest Level of Evidence (LoE-1) according to the "Tumor Marker Utility System".

SPECIFICATIONS

SAMPLES	Detergent extracts of tumor tissue
SAMPLE PREPARATION	1:20 dilution in sample buffer
SAMPLE VOLUME	100 µL of diluted sample
TOTAL ASSAY TIME	2½ days, including detergent extraction
STANDARD RANGE PAI-1	0 – 10 ng/mL
LOWER LIMIT OF DETECTION, PAI-1	0.125 ng/mL
PRECISION, PAI-1	Intra-assay CV = 6.7% Inter-assay CV = 4.7%
STANDARD RANGE, UPA	0 – 1.0 ng/mL
LOWER LIMIT OF DETECTION, UPA	0.025 ng/mL
PRECISION	Intra-assay CV < 4.7% Inter-assay CV < 3.9%
NUMBER OF TESTS	96

REAGENTS

- 96 Anti-human PAI-1 IgG coated microwells
- 96 Anti-human uPA IgG coated microwells
- 6 Vials of PAI-1 Standards, 0-10 ng/mL, lyophilized
- 6 Vials of uPA Standards, 0-1.0 ng/mL, lyophilized
- 2 Vials of Detection Antibody, biotinylated anti-human PAI-1, lyophilized
- 2 Vials of Detection Antibody, biotinylated anti-human uPA, lyophilized
- 1 Vial of PAI-1 Enzyme Conjugate, Streptavidin-Horseradish Peroxidase, 60 µL
- 1 Vial of uPA Enzyme Conjugate, Streptavidin-Horseradish Peroxidase, 60 µL
- 2 Vials of Enzyme Conjugate Diluent, 20 mL, lyophilized
- 2 Vials of Substrate, TMB, 11 mL
- 2 Vials of Detergent, 25% Triton X-100, 12 mL
- 2 Packets of TBS Buffer, pH 9.6, powder
- 4 Packets of PBS Buffer, pH 7.4, powder

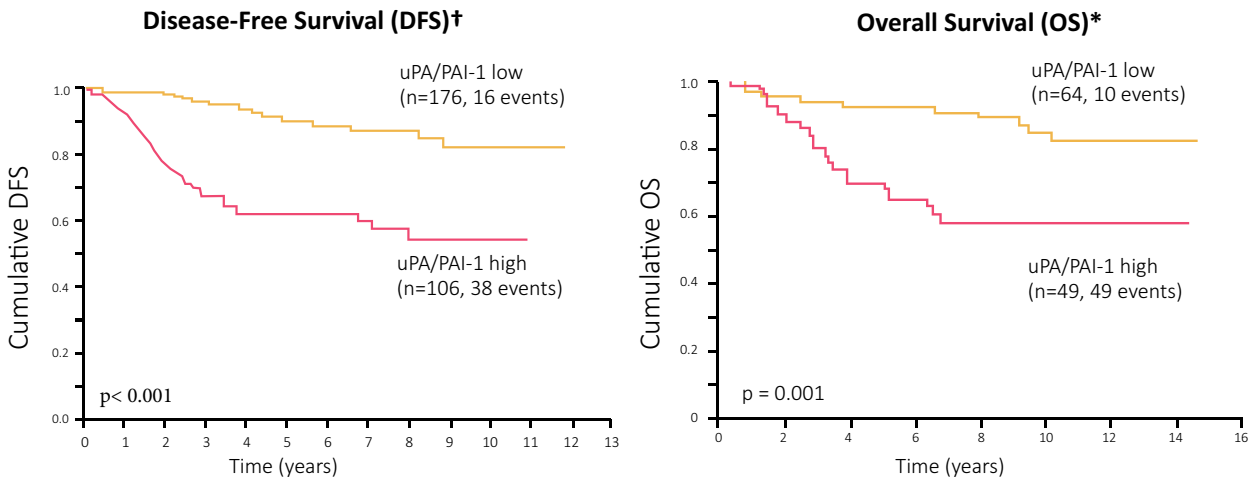
Not for sale in the USA/Canada

FEMTELLE® uPA/PAI-1 ELISA REF: 899 CE

Prospective, randomized multi-center clinical trials as well as retrospective meta-analyzes have shown that measurement of both uPA and PAI-1 levels in extracts of breast cancer tumor tissue can help to assess the risk of disease recurrence. FEMTELLE results are useful for the following indications:

1. Prognosis for breast cancer patients who are either at low or high risk for disease recurrence following surgery. A low level of both uPA and PAI-1, below the established cutoff value of 3 ng uPA/mg of total protein and 14 ng of PAI-1/mg total protein, places the patient in the low-risk category for disease recurrence. A high level of uPA and/or PAI-1, above the respective cut-off values, correlate with a significantly shortened Disease Free Survival (DFS) and reduced Overall Survival (OS) as compared to patients with tumor tissue containing low levels.
2. Prediction: It has been proposed that uPA and PAI-1 levels may be used to predict patient response to adjuvant chemotherapy. Clinical trials suggest that breast cancer patients with low uPA and PAI-1 are unlikely to benefit from adjuvant chemotherapy, whereas those patients with high uPA and PAI-1 levels are more likely to benefit from adjuvant chemotherapy.

Combined uPA and PAI-1 levels from breast tumor extracts are prognostic for disease-free survival and overall survival in patients with lymph node-negative breast cancer



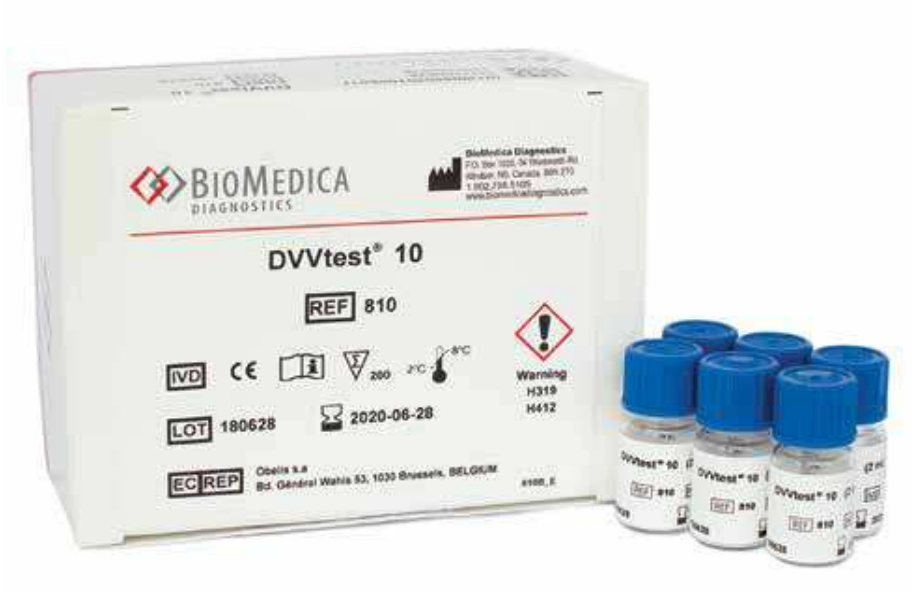
Adapted from: †Harbeck N, Kates RE, and Schmitt M. J Clin Oncol. 2002;20:1000-1007; and, *Zemzoum I, Kates RE, Ross JS, et al. J Clin Oncol. 2003;21:1022-1028.

Results from FEMTELLE should be used in conjunction with information available from clinical and other diagnostic procedures in the management of breast cancer disease.

Not for sale in the USA/Canada


PTHS
Your Logo Here
Cat. # PTHS-02ML-8AB
Storage 2 to 8°C
2 mL
BioMedica Diagnostics

ANTIPHOSPHOLIPID SYNDROME



Shown Above: 810 DVVTEST®

PRODUCT	PG
810/825	14
815/815L	15
824	18
816A/816N	16

Antiphospholipid Syndrome (APS) is an autoimmune, hypercoagulable state caused by antiphospholipid antibodies interfering with the clot formation. APS leads to both arterial and venous thromboses as well as pregnancy related complications such as miscarriage, stillbirth, preterm delivery and severe preeclampsia.

The diagnostic criteria for APS consist of one clinical event (i.e. thrombosis or pregnancy complication) and two antibody blood tests spaced at least three months apart that confirm the presence of either lupus anticoagulants or anti-β2-glycoprotein-I antibodies. As β2-glycoprotein-I antibodies are a subset of anti-cardiolipin antibodies, an anti-cardiolipin assay can be performed as a less specific substitute.

DVVtest®

REF: 810 | REF: 825 **IVD**

DVVtest® is a dilute Russell's Viper Venom Time (dRVVT) test intended for the determination of Lupus Anticoagulants (LA) in human plasma. The assay is for in vitro diagnostic use.

The identification of Lupus Anticoagulants (LA) in plasma is a diagnostic hallmark of the Antiphospholipid Syndrome (APS), an autoimmune disorder clinically characterized by arterial and venous thrombosis, recurrent spontaneous fetal loss, thrombocytopenia and neurological disorders. Lupus Anticoagulants are immunoglobulins of the IgG, IgM and IgA isotypes that prolong one or more of the in vitro phospholipid-dependent coagulation tests: Activated partial thromboplastin time (aPTT), Dilute prothrombin time (dPT), Textarin time or dRVVT. LA autoantibodies are specifically directed against a variety of phospholipid binding proteins including β2-glycoprotein I (β2GPI), prothrombin, and annexin V which are complexed to various anionic phospholipids (e.g. cardiolipin, phosphatidylinositol and phosphatidylserine).

The International Society for Thrombosis and Haemostasis, Scientific Subcommittee Criteria on Lupus Anticoagulants and Phospholipid-dependent Antibodies has recommended that LA be diagnosed using coagulation-based screening tests and a confirmatory test containing a high phospholipid concentration. DVVtest is the primary screening diagnostic test for LA with DVVconfirm serving as its companion high phospholipid-containing test to confirm the diagnosis of LA.

The DVVtest reagent contains Factor X activator isolated from Russell's Viper Venom that directly activates Factor X to Factor Xa in the presence of phospholipids and calcium. Factor Xa activates prothrombin to thrombin, which converts fibrinogen to fibrin leading to detectable clot formation in plasma. This direct activation of Factor X bypasses the contact and intrinsic pathways in the coagulation cascade, thereby excluding interference from deficiencies of Factors VIII, IX, XI and XII, or their respective inhibitors. A positive DVVtest is indicated by a significant prolongation of the phospholipid-dependent clotting time. If a patient is suspected to have LA, the DVVtest may also be performed on samples with a normal APTT as the formulation of the reagent increases the test's sensitivity and specificity to LA.

REAGENTS

10 Vials of DVVtest Reagent, 2.0 mL, lyophilized (REF 810)
10 Vials of DVVtest Reagent, 5.0 mL, lyophilized (REF 825)

SPECIFICATIONS

SAMPLES	Citrate collected plasma
SAMPLE PREPARATION	Neat
SAMPLE VOLUME	100 µL of plasma
TOTAL ASSAY TIME	< 5 minutes
STANDARD RANGE	0 – 100%
LOWER LIMIT OF DETECTION	4.6 IU/mL
SENSITIVITY	100%, used in conjunction with DVVconfirm
SPECIFICITY	97.9%, used in conjunction with DVVconfirm
PRECISION	Intra-assay CV ≤ N.D. Inter-assay CV < 6.5%
NUMBER OF TESTS	200 for REF 810 500 for REF 825

RELATED PRODUCTS

DVVconfirm® ..... REF 815, REF 815L ..... Pg. 13
ACTICLOT® dPT™ ..... REF 824 ..... Pg. 14
LAtrol™ Abnormal Control Plasma ..... REF 816A ..... Pg. 15
LAtrol™ Normal Control Plasma ..... REF 816N ..... Pg. 15

DVVconfirm® REF 815 | REF 815L IVD

DVVconfirm® is the high phospholipid containing coagulation reagent to be used in conjunction with DVVtest to confirm the presence of Lupus Anticoagulants (LA) in human plasma.

The identification of Lupus Anticoagulants (LA) in plasma is a diagnostic hallmark of the Antiphospholipid Syndrome (APS), an autoimmune disorder clinically characterized by arterial and venous thrombosis, recurrent spontaneous fetal loss, thrombocytopenia and neurological disorders. Lupus Anticoagulants are immunoglobulins of the IgG, IgM and IgA isotypes that prolong one or more of the in vitro phospholipid-dependent coagulation tests: Activated partial thromboplastin time (aPTT), dilute prothrombin time (dPT), Textarin time or dRVVT. LA autoantibodies are specifically directed against a variety of phospholipid binding proteins including β2-glycoprotein I (β2GPI), prothrombin, and annexin V which are complexed to various anionic phospholipids (e.g. cardiolipin, phosphatidylinositol and phosphatidylserine).

The International Society for Thrombosis and Haemostasis, Scientific Subcommittee Criteria on Lupus Anticoagulants and Phospholipid-dependent Antibodies has recommended that LA be diagnosed using coagulation-based screening tests and a confirmatory test containing a high phospholipid concentration. DVVtest is the primary screening diagnostic test for LA with DVVconfirm serving as its companion high phospholipid-containing test to confirm the diagnosis of LA.

Like DVVtest, DVVconfirm reagent is formulated with Factor X activator isolated from Russell's Viper Venom that directly activates Factor X to Factor Xa in the presence of phospholipids and calcium, and a high concentration of phospholipids. The clotting time of a plasma containing LA should be significantly shorter with DVVconfirm as compared to DVVtest. The presence of LA in plasma samples is confirmed when the ratio of the DVVtest clotting time to the DVVconfirm clotting time is greater than the range of the laboratory's normal reference DVVtest/ DVVconfirm Ratio.

REAGENTS

10 Vials of DVVtest Reagent, 1.0 mL, lyophilized (REF 815)
10 Vials of DVVtest Reagent, 2.0 mL, lyophilized (REF 815L)

RELATED PRODUCTS

DVVtest®	REF 810 | REF 825	Pg. 12
ACTICLOT® dPT™	REF 824	Pg. 14
LAtrol™ Abnormal Control Plasma	REF 816A	Pg. 15
LAtrol™ Normal Control Plasma	REF 816N	Pg. 15

SPECIFICATIONS

SAMPLES	Citrate collected plasma
SAMPLE PREPARATION	Neat
SAMPLE VOLUME	100 µL of plasma
TOTAL ASSAY TIME	< 5 minutes
STANDARD RANGE	0 – 100%
SENSITIVITY	100%, used in conjunction with DVVtest
SPECIFICITY	97.9%, used in conjunction with DVVtest
PRECISION	Intra-assay CV < 4.7% Inter-assay CV < 3.9%
NUMBER OF TESTS	100 for REF 815 200 for REF 815L

ACTICLOT® dPT™ Dilute Prothrombin Time Test REF: 824 IVD

Clinical studies show that a dilute prothrombin time test is an effective LA coagulation assay and can identify LA that are not detected by other tests such as a lupus-sensitive APTT and a dilute Russell's Viper Venom test. ACTICLOT dPT is a fully integrated dilute prothrombin time test for screening and confirming the presence of phospholipid-dependent LA autoantibodies. The screening protocol utilizes an activator reagent that contains a unique formulation of relipidated recombinant human tissue factor and calcium. The use of recombinant tissue factor in the formulation of the dPT test improves the test's performance. In the confirmatory protocol, a uniquely formulated phospholipid reagent is used to demonstrate the phospholipid-dependent nature of the LA detected in samples that tested positive in the screening protocol.

Clotting is initiated by activating the extrinsic coagulation pathway with tissue factor in the presence of calcium ions. Tissue Factor binds to Factor VIIa resulting in the activation of Factor IX and Factor X. The subsequent conversion of prothrombin to thrombin by Factor Xa initiates clot formation by cleaving fibrinogen to fibrin. Activation of the tissue factor pathway bypasses the intrinsic (contact) pathway and excludes any interference from deficiencies of Factor XII.

REAGENTS

6 Vials of dPT Activator, 2 mL, lyophilized
3 Vials of LA Phospholipids, 2 mL, lyophilized
3 Vials of LA Buffer, 3 mL, lyophilized

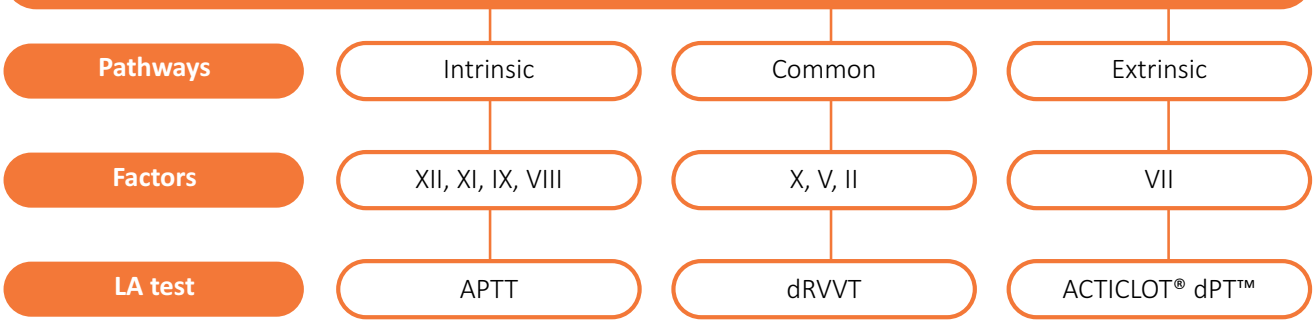
RELATED PRODUCTS

DVVtest®	REF 810, REF 825	Pg. 12
DVVconfirm®	REF 815, 815L	Pg. 13
LAtrol™ Abnormal Control Plasma	REF 816A	Pg. 15
LAtrol™ Normal Control Plasma	REF 816N	Pg. 15

SPECIFICATIONS

SAMPLES	Citrate collected plasma
SAMPLE PREPARATION	Neat
SAMPLE VOLUME	100 µL of plasma
TOTAL ASSAY TIME	< 5 minutes
NORMAL CLOT TIME	33 – 43 seconds
SENSITIVITY	100%
SPECIFICITY	91%
PRECISION	Intra-assay CV < 4% Inter-assay CV < 5%
NUMBER OF TESTS	240 tests (120 screen/120 confirm)

Lupus Anticoagulation Testing Relationship to Coagulation Pathways



CLSI guideline H60-A, Laboratory Testing for the Lupus Anticoagulant; Approved Guideline

LAtrol™ LA Control Plasmas — REF 816A | REF 816N — IVD

The LAtrol™ Abnormal Control (REF 816A) and LAtrol™ Normal Control (REF 816N) plasmas have been developed for use as part of daily quality control procedures for Lupus Anticoagulant (LA) testing. These control plasmas are designed to be used with ACTICLOT® dPT™ (REF 824), DVVtest® (REF 810/825), and DVVconfirm® (REF 815/815L).

LAtrol Abnormal Control is a lyophilized preparation of a Lupus Anticoagulant plasma which has been determined to be positive for LA in accordance with the revised criteria of the International Society for Thrombosis and Haemostasis, Scientific and Standardization Committee's (SSC) on Lupus Anticoagulant detection.

LAtrol Normal Control is a lyophilized preparation of a multi-donor normal plasma pool. This normal plasma may also be used in mixing studies to determine the presence of inhibitors or factor deficiencies in patient plasmas that test positive using DVVtest and ACTICLOT dPT.

Source plasmas for these products are processed in a manner consistent with established procedures to ensure that the plasma is platelet-poor.

AVAILABLE AS

REF	PACKAGING
816A	10 x 0.5 mL vials
816N	10 x 1.0 mL vials

REAGENTS

10 Vials of plasma, 0.5 mL, lyophilized (REF 816A)
10 Vials of plasma, 1.0 mL, lyophilized (REF 816N)

SPECIFICATIONS

PRECISION WHEN USED WITH DVVTEST / DVVCONFIRM	Intra-assay CV < 2% Inter-assay CV < 5%
PRECISION WHEN USED WITH ACTICLOT dPT	Intra-assay CV < 4% Inter-assay CV < 5%

RELATED PRODUCTS

DVVtest® REF 810, REF 825 .....Pg. 12
DVVconfirm® REF 815, REF 815L .....Pg. 13
ACTICLOT® dPT™ REF 824.....Pg. 14

BLEEDING PROFILES

SCCA - 180 Special Coagulation Control Abnormal

Bleeding profiles are screening tests (Activated Partial Thromboplastin Time, Prothrombin Time, Thrombin Time, Fibrinogen, D-dimer) designed to detect abnormal blood clotting. Based on the pathways of the coagulation cascade, the test results when interpreted together are used to identify deficiencies and defects in coagulation factors, the presence of inhibitors to coagulation factors, the effectiveness of blood-thinning medications, hereditary conditions, severe infections and liver problems.

The bleeding profile may also be performed to confirm normal blood clotting prior to a surgical procedure.

QuikCoag® APTT-EA

IVD

QuikCoag APTT-EA (Ellagic Acid) reagent is an in vitro diagnostic assay intended for use in determining activated partial thromboplastin time (APTT) and coagulation factor assays that are based on a modified APTT. Used as a general screening test for the detection of coagulation abnormalities in the intrinsic (contact) pathway, the APTT is sensitive to deficiencies or abnormalities of Factors VIII, IX, XI, XII, X, and II, prekallikrein, high molecular weight kininogen (HMWK), and fibrinogen. It is also sensitive to inhibitors of blood coagulation such as lupus inhibitor and fibrin/fibrinogen degradation products. The APTT is the most widely used method for monitoring intravenous heparin anticoagulation therapy.

The capacity of blood to form a fibrin clot by way of the intrinsic hemostatic pathway requires coagulation Factors I, II, V, VIII, IX, X, XI and XII, platelet lipids and calcium. The assay is performed by the addition of a suspension of rabbit brain cephalin with a surface activator.

- Ready-to-use liquid format
- Tissue based reagent
- May be used on any open system
- Stable for three years from the date of manufacture when properly stored in the original container at 2° to 8°C
- Insensitive to Heparin up to 0.5 IU/mL
- Unique Device Identifiers (UDI) with scannable and human readable bar codes on the box and vial labels
- OEM options available

AVAILABLE AS

REF	PACKAGING
C.BMD.APTT-04ML	10 x 4 mL vials
C.BMD.APTT-10ML	10 x 10 mL vials

RELATED PRODUCTS

QuikCoag Calcium Chloride REF C.BMD.CACL2-04ML.....Pg 22
REF C.BMD.CACL2-10ML.....Pg 22

QuikCoag® PT-HS

IVD

The QuikCoag PT-HS reagent is an in vitro diagnostic assay intended for use in performing the one stage prothrombin time (PT) test and assays which are based on a modified prothrombin time. The PT test is the method of choice for monitoring oral anticoagulation therapy and is a fundamental screening test for acquired or inherited bleeding disorders.

During oral anti-coagulation therapy, the activity of vitamin K-dependant clotting Factors (II, VII, IX, X, Protein C and Protein S) is reduced and PT time is increased. The test is used for quantitative determination of blood clotting factors in the extrinsic (Tissue Factor) and common pathways (II, V and X) of coagulation. The capacity of blood to form a fibrin clot via the extrinsic hemostatic pathway requires thromboplastin, calcium, Factors I, II, V, VII and X. The QuikCoag PT-HS reagent provides a source of tissue thromboplastin and calcium that specifically activate Factor VII in the extrinsic coagulation pathway. The factors involved in the intrinsic coagulation pathway are bypassed, therefore deficiencies of intrinsic pathway factors (VIII, IX and XII) are not detected using the PT test.

- Target ISI value range of 0.90 – 1.50, with a specific ISI assigned to each lot
- Convenient lyophilized format
- Rabbit brain based reagent
- May be used on any open system
- Lyophilized reagent is stable for three years from the date of manufacture when properly stored in the original container at 2° to 8°C. Reconstituted reagent is stable for five days when properly stored in the original container at 2° to 8°C
- Unique Device Identifiers (UDI) with scannable and human readable bar codes on the box and vial labels
- OEM options available

AVAILABLE AS

REF	PACKAGING
C.BMD.PTHS-02ML-8A	10 x 2 mL vials
C.BMD.PTHS-04ML-8A	10 x 4 mL vials
C.BMD.PTHS-1-ML-8A	10 x 10 mL vials

QuikCoag® Fibrinogen

CE, Health Canada Registered

QuikCoag™ Fibrinogen is an in vitro diagnostic assay intended for quantitative determination of fibrinogen in plasma. Thrombin converts soluble fibrinogen into insoluble fibrin, which when cross-linked becomes the fibrin clot as the last step in the coagulation cascade. A Clauss based assay, QuikCoag Fibrinogen measures the rate of fibrinogen to fibrin conversion in the presence of excess thrombin. When diluted plasma is clotted with excess thrombin, the fibrinogen level is inversely proportional to the clotting time. A calibration curve is prepared from a fibrinogen reference and plotted on log-log paper. This calibration curve is used to determine the fibrinogen concentration in the test sample.

Fibrinogen is an acute-phase reactant protein in that the concentration rises sharply in response to various physiological stimuli such as tissue inflammation or injury. High fibrinogen levels are associated with atherosclerotic cardiovascular disease, the occurrence of myocardial infarction and stroke, cancers of the breast, kidney and stomach, and inflammatory disorders such as rheumatoid arthritis. Reduced fibrinogen levels are prevalent in liver disease, prostate cancer, lung disease, bone marrow lesions, malnourishment, and disseminated intravascular coagulation.

- Ready-to-use liquid format
- Clauss-based method
- May be used on any open system
- Stable for three years from the date of manufacture when properly stored in the original container at 2° to 8°C
- Unique Device Identifiers (UDI) with scannable and human-readable bar codes on the box and vial labels
- OEM options available

AVAILABLE AS

REF	PACKAGING
CC.BMD.FIBR-02ML	100 tests (includes Fibrinogen Reagent, Imidazole Buffer, Fibrinogen Normal Control)
C.BMD.FIBR-02ML-8A	10 x 2 mL vials (Fibrinogen Reagent Only)

RELATED PRODUCTS

QuikCoag IMIDAZOLE Buffer REF C.BMD.IMID-125ML-B .....Pg 22

QuikCoag® Thrombin Time

CE, Health Canada Registered

QuikCoag Thrombin is a thrombin reagent (bovine) for use in the determination of the Thrombin Time (TT) in human plasma. The TT assay is based on the ability of thrombin to catalyze the polymerization of fibrinogen into a fibrin clot. Following the cleavage of fibrinopeptides A and B from the amino-terminal ends of the alpha and beta chains of fibrinogen by thrombin, the resulting fibrin monomers ultimately polymerize into a fibrin clot.

The TT assay is a qualitative screening assay used to detect abnormalities in this phase of coagulation. The assay is performed by adding a known quantity of low concentration thrombin reagent to the sample and measuring the time required for clot formation to occur. Abnormalities affecting this stage of coagulation include quantitative and qualitative alterations in fibrinogen, increased fibrinolytic activity causing variations in Fibrin Degradation Products (FDP), and interferences with fibrinogen polymerization. The TT assay is also sensitive to heparin and other circulating antithrombins.

AVAILABLE AS

REF	PACKAGING
C.BMD.TT-01ML	10 x 1 mL vials

- Convenient lyophilized format
- May be used on any open system
- Stable for three years from the date of manufacture when properly stored in the original container at 2° to 8°C. Reconstituted reagent is stable for seven days when properly stored at 2° to 8°C and 30 days at -20°C
- Unique Device Identifiers (UDI) with scannable and human-readable bar codes on the box and vial labels
- OEM options available

QuikCoag® Calcium Chloride

IVD

QuikCoag Calcium Chloride is a reagent for use in the in vitro determination of prothrombin time (PT) test, activated partial thromboplastin time (APTT) and recalcification (plasma clotting) time, as well as various coagulation factor assays.

- Ready-to-use liquid format
- Stable for three years from date of manufacture when stored in the original container at 2 to 8°C
- Unique Device Identifiers with scannable and human-readable bar codes on box and vial labels
- OEM and customized options available

AVAILABLE AS

REF	PACKAGING
C.BMD.CACL2-04ML	10 x 4 mL vials
C.BMD.CACL2-10ML	10 x 10 mL vials

RELATED PRODUCTS

QuikCoag APTT-EA	REF C.BMD.APTT-04ML.....Pg 18 REF C.BMD.APTT-10ML.....Pg 18

QuikCoag® Imidazole Buffer

CE, Health Canada Registered

QuikCoag Imidazole Buffer is intended for use in conjunction with QuikCoag Fibrinogen. It is used to dilute the plasma samples prior to doing the fibrinogen testing. QuikCoag Imidazole Buffer is a liquid preparation containing imidazole, sodium chloride and sodium azide.

AVAILABLE AS

REF	PACKAGING
C.BMD.IMID-125ML-B	1 x 125 mL bottle

RELATED PRODUCTS

QuikCoag Fibrinogen	REF C.BMD.FIBR-02ML-8A.....Pg 20

QuikCoag® Controls

IVD

QuikCoag Routine Controls are intended for use for quality assurance of in vitro diagnostic coagulation tests. The controls are suitable for use in the one-stage prothrombin time (PT) test and in the activated partial thromboplastin time (APTT) test. Controls are available at three levels:

QuikCoag Control Level 1 (Normal)	for use as a normal coagulation time control
QuikCoag Control Level 2 (Low Abnormal)	for use as a moderately elevated coagulation time control
QuikCoag Control Level 3 (High Abnormal)	for use as a highly elevated coagulation time control

- Human plasma-based controls
- Convenient lyophilized format
- Available in standard 1.0 mL fill volumes
- Stable for three years from the date of manufacture when properly stored in the original vial at 2° to 8°C
- Stable for six hours following reconstitution when stored in the original vial at 2° to 8°C
- Unique Device Identifiers (UDI) with scannable and human readable bar codes on the box and vial labels
- OEM options available

AVAILABLE AS

REF	PACKAGING
C.BMD.CON1-01ML-8A	10 x 1 mL vials
C.BMD.CON2-01ML-8A	10 x 1 mL vials
C.BMD.CON3-01ML-8A	10 x 1 mL vials

RELATED PRODUCTS

QuikCoag APTT-EA REF C.BMD.APTT-04ML .....Pg 18
QuikCoag PT-HS REF C.BMD.PTHS-02ML-8A .....Pg 19

Special Coagulation Controls (18 Parameter) CE

Special Coagulation Controls are intended to be used as unassayed controls for monitoring the performance of special and routine coagulation assays on analyzers in a clinical setting. The controls are to be tested in the same manner as freshly drawn citrated patient plasma. The controls are available within the normal and abnormal ranges and suitable for use in eighteen (18) parameters.

- Convenient lyophilized format
- Lyophilized controls are stable until the stated expiration date when properly stored in the original vial at 2° to 8°C
- Reconstituted controls are for eight hours at room temperature
- OEM options available

COAGULATION TEST	NORMAL CONTROL TARGET RANGE	ABNORMAL CONTROL TARGET RANGE
PROTHROMBIN TIME	10.0 – 14.0 seconds	18.0 – 26.0 seconds
ACTIVATED PARTIAL THROMBIN TIME	23.0 – 35.0 seconds	50.0 – 70.0 seconds
THROMBIN TIME	13.0 – 19.0 second	22.0 – 35.0 seconds
FIBRINOGEN CONCENTRATION	200 – 400 mg/dL	< 200 mg/dL
FACTOR II ACTIVITY	> 60%	≤ 60%
FACTOR V ACTIVITY	> 60%	≤ 60%
FACTOR VII ACTIVITY	> 60%	≤ 60%
FACTOR VIII ACTIVITY	> 60%	≤ 60%
FACTOR IX ACTIVITY	> 60%	≤ 60%
FACTOR X ACTIVITY	> 60%	≤ 60%
FACTOR XI ACTIVITY	> 60%	≤ 60%
FACTOR XII ACTIVITY	> 60%	≤ 60%
FACTOR XIII ACTIVITY	> 60%	≤ 60%
PROTEIN S ACTIVITY	> 60%	≤ 60%
PROTEIN C ACTIVITY	> 60%	≤ 60%
ANTITHROMBIN III ACTIVITY	> 60%	≤ 60%
PLASMINOGEN ACTIVITY	> 60%	≤ 60%
ALPHA2-ANTIPLASMIN ACTIVITY	> 60%	≤ 60%

AVAILABLE AS

REF	PACKAGING
SCCN-180 (Normal Control)	10 x 1.0 mL vials

REF	PACKAGING
SCCA-180 (Abnormal Control)	10 x 1.0 mL vials

Routine Coagulation Controls (4 Parameter) CE

Routine Coagulation Controls are intended to be used as unassayed controls for monitoring the performance of routine coagulation assays on analyzers in a clinical setting. The controls are to be tested in the same manner as freshly drawn citrated patient plasma. The controls are available within the normal and abnormal ranges and suitable for use in four (4) parameters.

- Convenient lyophilized format
- Lyophilized controls are stable until the stated expiration date when properly stored in the original vial at 2° to 8°C
- Reconstituted controls are for eight hours at room temperature
- OEM options available

COAGULATION TEST	NORMAL CONTROL TARGET RANGE	ABNORMAL CONTROL TARGET RANGE
PROTHROMBIN TIME	10.0 – 14.0 seconds	18.0 – 26.0 seconds
ACTIVATED PARTIAL THROMBIN TIME	23.0 – 35.0 seconds	50.0 – 70.0 seconds
THROMBIN TIME	13.0 – 19.0 second	22.0 – 35.0 seconds
FIBRINOGEN CONCENTRATION	200 – 400 mg/dL	< 200 mg/dL

AVAILABLE AS

REF	PACKAGING
RCCN-040 (Normal Control)	10 x 1.0 mL vials
RCCA-040 (Abnormal Control)	10 x 1.0 mL vials

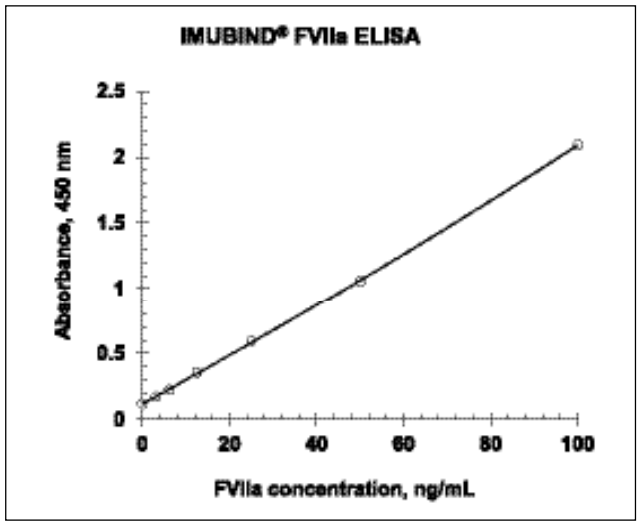
IMUBIND® Factor VIIa ELISA

REF 827 **RUO**

The IMUBIND® Factor VIIa ELISA is an enzyme-linked immunoassay for the quantitation of activated human Factor VII (FVIIa) in plasma as well as in cell culture supernatants. The ELISA detects FVIIa as well as FVIIa complexed with Tissue Factor (TF/FVIIa). The assay is For Research Use Only, not for use in diagnostic procedures.

Factor VII (FVII) is the first zymogen of the extrinsic pathway of blood coagulation. Activation of FVII occurs via cleavage of the proenzyme by proteases (e.g. Factors IXa, Xa, XIIa and thrombin). Factor VII is also subject to auto-activation by Factor VIIa (FVIIa). When FVIIa complexes with Tissue Factor, an enhanced enzymatic complex is formed that rapidly promotes coagulation.

RESULTS/REPRESENTATIVE STANDARD CURVE



REAGENTS

96 Anti-Human FVII/FVIIa IgG coated microwells with acetate cover sheet
96 microwell plate, uncoated
2 Vials of FVIIa Standard, 200 ng/mL, lyophilized
1 Vial of FVII Deficient Plasma, 300 µL, lyophilized
1 Vial of FVIIa Inhibitor, 160 µL, lyophilized
1 Vial of Assay Diluent, 22 mL, lyophilized
1 Vial of Reference Plasma, 300 µL, lyophilized
1 Vial of Stabilizer, 3.5 mL, lyophilized
1 Vial of Enzyme Conjugate, Streptavidin-Horseradish peroxidase, 120 µL
1 Vial of Substrate, TMB, 11 mL
1 Packet of Wash Buffer, PBS with 0.05% Tween 20, 1 Liter, powder

SPECIFICATIONS

SAMPLES	Citrate or EDTA collected plasma, cell culture supernatants
SAMPLE PREPARATION	Neat
SAMPLE VOLUME	12.5 µL of plasma
TOTAL ASSAY TIME	3 hours
STANDARD RANGE	0 – 100 ng/mL
LOWER LIMIT OF DETECTION	200 ng/mL
SPECIFICITY	< 5 ng/mL
PRECISION	Intra-assay CV = N.D. Inter-assay CV = N.D.
NUMBER OF TESTS	96

RELATED PRODUCTS

IMUBIND® Tissue Factor REF 845 .....Pg. 43
ACTICHROME® TF REF 846 .....Pg. 48

VON WILLEBRAND DISEASE

Shown Above: 828 IMUBIND vWF ELISA

Von Willebrand disease (VWD), one of the most common inherited bleeding disorders, is characterized by excessive mucosal bleeding and abnormally low levels of high molecular weight von Willebrand Factor (VWF) activity. Following an evaluation of the personal and family history, comprehensive laboratory testing is required to identify specific defects and correctly type VWD patients as recommended by the International Society of Thrombosis and Haemostasis.

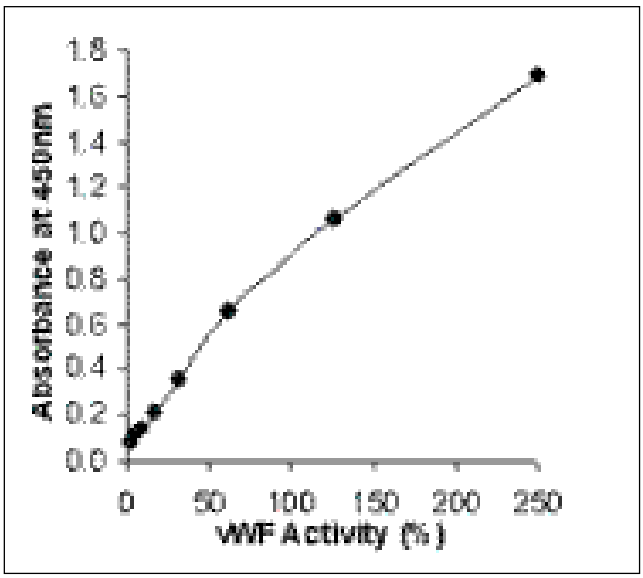
Guided by results of initial haemostasis testing: CBC with Platelet Count, Activated Partial Thromboplastin Time (APTT), and Prothrombin Time (PT), further laboratory testing on VWF status may confirm the presence of the disorder.

IMUBIND® vWF Activity ELISA REF: 885 IVD

The IMUBIND® vWF Activity ELISA is a quantitative direct enzyme-linked immunosorbent assay (ELISA) for the detection of von Willebrand Factor (vWF) activity in citrated human plasma. It is intended for the assessment of vWF activity in patients where this is deemed useful in the diagnostic process, particularly as an aid in the differential classification of von Willebrand's disease (vWD).

Von Willebrand Factor (vWF) is a complex multimeric adhesive glycoprotein synthesized by endothelial cells and megakaryocytes. It functions as an adhesive protein in haemostasis, binding to collagen and mediating platelet adhesion to the sub-endothelium, playing a role in platelet-platelet interaction, and as a carrier/stabilizer protein for the Factor VIII (FVIII:C).

RESULTS/REPRESENTATIVE STANDARD CURVE



RELATED PRODUCTS

IMUBIND® vWF ELISA REF 828 .....Pg 29
QuikCoag APTT-EA REF C.BMD.APTT-04ML.....Pg 18

In its mildest form, von Willebrand disease is the most common bleeding disorder with a reported frequency of 1 in 100. Classifications of the disease are based upon clinical observation, patient history and laboratory analysis such as bleeding times, vWF protein levels and vWF activity levels. The differential diagnosis of the two predominant classes of the disease, Type 1 and Type 2 is important as clinical management varies with type.

REAGENTS

96 Anti-Human vWF IgG Coated Microwells with an acetate cover sheet
2 Vials of vWF Calibrator, 0.5 mL (lyophilized)
2 Vials of vWF Control 1, Normal, 0.5 mL (lyophilized)
2 Vials of vWF Control 2, Abnormal, 0.5 mL (lyophilized)
1 Vial of vWF Diluent Concentrate (5X), 25 mL
1 Vial of vWF Wash Buffer Concentrate (16X), 25 mL
1 Vial vWF Conjugate, 15 mL
1 Vial of TMB Substrate, 11 mL
1 Vial of Stop Solution, 15 mL

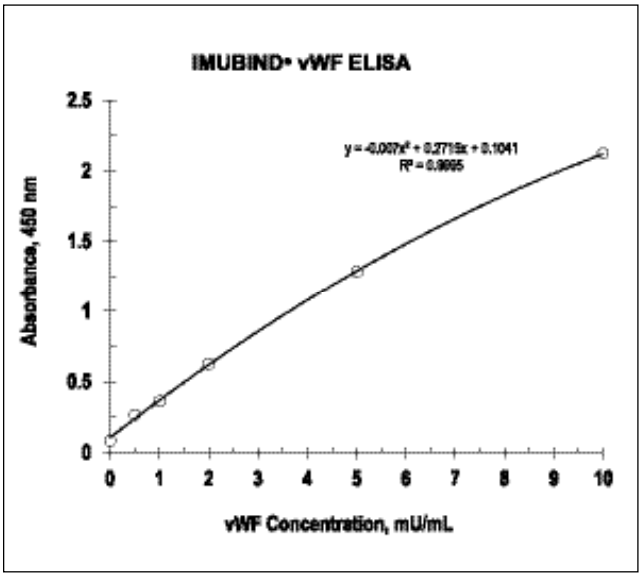
SPECIFICATIONS

SAMPLES	Citrate collected plasma
SAMPLE PREPARATION	1:20 dilution
SAMPLE VOLUME	100 µL diluted plasma
TOTAL ASSAY TIME	2½ hours
STANDARD RANGE	0 – 200% (LOT DEPENDENT)
LOWER LIMIT OF DETECTION:	1.6%
PRECISION	Intra-assay CV < 15% Inter-assay CV < 20%
NUMBER OF TESTS	96

IMUBIND® vWF ELISA REF: 828 RUO

The IMUBIND® vWF ELISA is an enzyme-linked immunoassay for the measurement of vWF antigen in human plasma. Von Willebrand Factor (vWF) is a large, multimeric protein (molecular weight of 1,000-20,000 kD) composed of repeating 270 kD subunits containing 2050 amino acid residues. It is synthesized by endothelial cells and megakaryocytes, and is present in multimeric form in the basement membrane of the subendothelium, in plasma and platelets. vWF promotes platelet adhesion to damaged endothelium and is a key component in the formation of the platelet plug and stable clot formation. Together with fibronectin and collagen, vWF functions in maintaining vessel wall integrity. vWF also functions as a carrier protein for Factor VIII, the coagulation protein absent in haemophilia A. Von Willebrand disease is a bleeding disorder characterized by decreased levels of circulating vWF protein (Type 1), a complete absence of vWF protein (Type 3), and low vWF activity (Types 2A, 2B, 2M, 2N).

RESULTS/REPRESENTATIVE STANDARD CURVE



REAGENTS

96 Anti-Human vWF IgG Coated Microwells with an acetate cover sheet
6 vials of vWF standards, 0 - 10 mU/mL (lyophilized)
1 vial of Detection Antibody, HRP-conjugated anti-human vWF, 135 µL
1 vial of Detection Antibody Diluent, 20 mL (lyophilized)
1 vial of Substrate, TMB, 11 mL
1 packet of Wash Buffer, PBS with 0.05% Tween 20, pH 7.4, 1 L (lyophilized)

SPECIFICATIONS

SAMPLES	Citrate or EDTA collected plasma
SAMPLE PREPARATION	1:100 dilution
SAMPLE VOLUME	100 µL diluted plasma
TOTAL ASSAY TIME	3 hours
STANDARD RANGE	0 – 10 mU/mL (0.01 IU/mL)
LOWER LIMIT OF DETECTION	0.1 mU/mL (1 IU/dL)
PRECISION	N.D.
NUMBER OF TESTS	96

RELATED PRODUCTS

IMUBIND® vWF Activity ELISA REF 885 .....Pg 28
QuikCoag APTT-EA REF C.BMD.APTT-04ML.....Pg 18

D-DIMER

Shown above: 800DB ActiScreen™ XL-FDP Immunoagglutination Assay

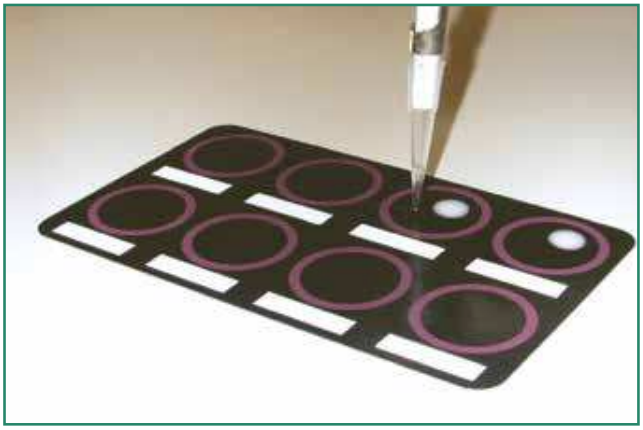
PRODUCT	PG
602	33
800DB	32
DLHK7	31

D-dimer is a cross-linked fibrin degradation product (XL-FDP), a small protein fragment present in blood after a clot is degraded during fibrinolysis.

Measuring the level of D-dimer in a patient is useful to indicate the presence of a blood clot. Therefore, levels below pre-determined cut-of thresholds may be used to rule out conditions such as Deep Vein Thrombosis (DVT), Pulmonary embolism (PE) and Stroke.

A D-dimer level may be used to help diagnose Disseminated Intravascular Coagulation (DIC) and to monitor the effectiveness of DIC treatment.

DIMERTEST® Latex REF: DLHK7 IVD



The most accurate and sensitive manual XL-FDP / D-dimer test.

DIMERTEST® Latex is an immunoagglutination assay for the rapid qualitative or semi-quantitative evaluation of derivatives of cross-linked fibrin degradation products (XL-FDP) circulating in human plasma. During blood coagulation, fibrinogen is converted to fibrin monomers by thrombin, and these fibrin monomers polymerize to form a soluble gel of non-cross-linked fibrin. This fibrin gel is then converted to cross-linked fibrin by factor XIIIa to form an insoluble fibrin clot. Generation of plasmin, the major clot-lysing enzyme, is triggered when a fibrin clot is formed. Plasmin cleaves both fibrinogen and fibrin yielding degradation products including cross-linked fibrin degradation products (XL-FDP). Only cross-linked fibrin degradation products contain the D-dimer protein, therefore XL-FDP is a specific marker of fibrinolysis.

DIMERTEST Latex utilizes latex beads coupled with the highly specific monoclonal antibody DD3B6/22. XL-FDP present in the plasma binds to the antibody coated latex beads resulting in agglutination, visible on the test card, when the XL-FDP concentration is above the lower limit of detection of the assay.

REAGENTS

1 Vial of Latex Reagent, 2.0 mL
1 Vial of Positive Control, 0.6 mL
1 Vial of Negative Control, 0.6 mL
1 Vial of Buffer, 20 mL
10 test cards, 8 tests/card
1 Pack of Stir Sticks, 60

SPECIFICATIONS

SAMPLES	Citrate collected plasma
SAMPLE PREPARATION	No dilution for the qualitative method. Serial dilutions from 1:2 to 1: 8 for the semi-quantitative method
SAMPLE VOLUME	20 µL of plasma
TOTAL ASSAY TIME	3 minutes
RANGE	200 – 3,200 ng/mL for the semi-quantitative method
LOWER LIMIT OF DETECTION	200 ng/mL
SPECIFICITY	95.3%
PRECISION	Intra-assay CV See Instructions For Use
NUMBER OF TESTS	60

RELATED PRODUCTS

IMUCLONE™ D-dimer ELISA REF 602.....Pg 33

ACTISCREEN™ XL-FDP REF 800DB 510(k), Health Canada Registered

ACTISCREEN™ XL-FDP is an immunoagglutination assay for the rapid qualitative or semi-quantitative evaluation of derivatives of cross-linked fibrin degradation products (XL-FDP) circulating in human plasma.

During blood coagulation, fibrinogen is converted to fibrin monomers by thrombin, and these fibrin monomers polymerize to form a soluble gel of non-cross-linked fibrin. This fibrin gel is then converted to cross-linked fibrin by factor XIIIa to form an insoluble fibrin clot. Generation of plasmin, the major clot-lysing enzyme, is triggered when a fibrin clot is formed. Plasmin cleaves both fibrinogen and fibrin yielding degradation products including cross-linked fibrin degradation products (XL-FDP). Only cross-linked fibrin degradation products contain the D-dimer protein, therefore XL-FDP is a specific marker of fibrinolysis.

ACTISCREEN XL-FDP utilizes latex beads coupled with the highly specific monoclonal antibody DD3B6/22. XL-FDP present in the plasma binds to the antibody coated latex beads resulting in agglutination, visible on the test card, when the XL-FDP concentration is above the lower limit of detection of the assay.

REAGENTS

1 Vial of Immunoagglutination Reagent, 2.0 mL
1 Vial of Positive Control, 0.6 mL
1 Vial of Negative Control, 0.6 mL
1 Vial of Buffer, 20 mL
10 Test Cards, 8 tests/card
1 Pack of Stir Sticks, 60

SPECIFICATIONS

SAMPLES	Citrate collected plasma
SAMPLE PREPARATION	No dilution for the qualitative method Serial dilutions from 1:2 to 1:8 for the semi-quantitative method
SAMPLE VOLUME	20 µL of plasma
TOTAL ASSAY TIME	3 minutes
RANGE	200 – 3,200 ng/mL for the semi-quantitative method
LOWER LIMIT OF DETECTION	200 ng/mL
SPECIFICITY	95.3%
PRECISION	Intra-assay CV (See Instructions For Use) Inter-assay CV (See Instructions For Use)
NUMBER OF TESTS	60

RELATED PRODUCTS

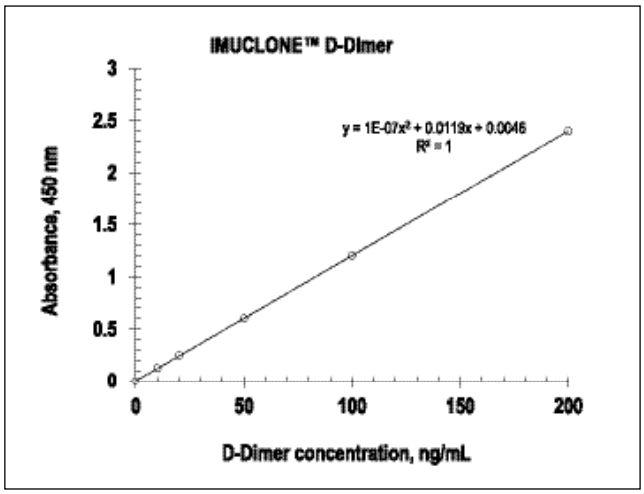
IMUCLONE™ D-dimer ELISA REF 602 .....Pg. 33

IMUCLONE™ D-dimer ELISA REF: 602 RUO

The IMUCLONE™ D-Dimer ELISA is intended for the measurement of D-dimer, crosslinked fibrin degradation product (XL-FDP), in human plasma. During early clot formation, thrombin cleaves fibrinopeptides from the fibrinogen, a soluble plasma protein, converting it into fibrin monomers. Molecular polymerization of these fibrin monomers forms a soluble fibrin gel, which is then stabilized through covalent cross-linking by FXIIIa activity to produce an insoluble fibrin clot. Fibrin clots are immediately degraded by plasmin, a fibrinolytic enzyme, the process known as fibrinolysis.

Under normal physiological conditions, excess plasmin is rapidly neutralized by alpha-2-antiplasmin within the region of the clot. Depending on the extent of fibrinolysis, a variety of XL-FDPs are generated, of which the smallest fragment is D-dimer. Therefore the presence of D-dimer indicates the sequence of events: Thrombin activation, clot formation and subsequent clot lysis.

RESULTS/REPRESENTATIVE STANDARD CURVE



REAGENTS

- 96 Well Microtest Plate pre-coated with anti-Human D-Dimer plus storage bag with desiccant
- 2 Vials of Sample Diluent, 50 mL
- 3 Vials of D-Dimer Calibrator, 2 mL (lyophilized)
- 1 Vial of D-Dimer Plasma Control I, High, 0.5 mL (lyophilized)
- 1 Vial of D-Dimer Plasma Control II, Low, 0.5 mL (lyophilized)
- 3 Vials of Anti-Human D-Dimer-HRP Immunoconjugate, 7.5 mL (lyophilized)
- 1 Vial of Conjugate Diluent, 25 mL
- 1 Vial of Wash Solution (20X concentrate), 50 mL
- 1 Vial of TMB Substrate, 25 mL
- 1 Vial of Stop Solution, 0.45 M Sulfuric Acid, 6 mL

SPECIFICATIONS

SAMPLES	Citrate collected plasma, EDTA collected plasma
SAMPLE PREPARATION	1:50 dilution
SAMPLE VOLUME	200 µL of diluted sample
TOTAL ASSAY TIME	3 hours
STANDARD RANGE	0 – 200 ng/mL
LOWER LIMIT OF DETECTION	2 – 4 ng/mL

RELATED PRODUCTS

DIMERTEST® Latex REF DLHK7 .....Pg 31

THROMBOTIC RISK MARKERS

PRODUCT	PG
101201	35
603	36
635	37
842	38
873	39
821	40
822	41
837	42
845	43
894	44
840	45
840C	45
843L	46
ACC-45	47
846	48
848	49
851	50
838	51

Shown above: 101201 SPECTROLYSE® PAI-1

For individuals with a documented thrombotic event and a family history of thrombosis, testing coagulation factors is crucial for diagnosing the condition. Deficiencies of natural anticoagulants Antithrombin III, Protein C, Protein S, and factor mutations such as Activated Protein C Resistance may lead to venous thrombosis: Superficial Venous thrombosis (SVT), Deep Venous Thrombosis (DVT) and Pulmonary Embolism (PE).

Specific coagulation factors released from the vascular endothelium, Thrombomodulin and Tissue Factor Pathway Inhibitor offer information about endothelial dysfunction. When hemostasis is disrupted because thrombi are not degraded, levels of Plasminogen and Plasminogen Activator Inhibitor Type 1 (PAI-1) may provide information to the state of the patient. The mechanisms of thrombosis in cancer patients involve a complex interaction between the tumor cell, the patient, and the hemostatic system. Tumors may activate coagulation by their expression of Tissue Factor.

SPECTROLYSE® PAI-1 REF: 101201 IVD

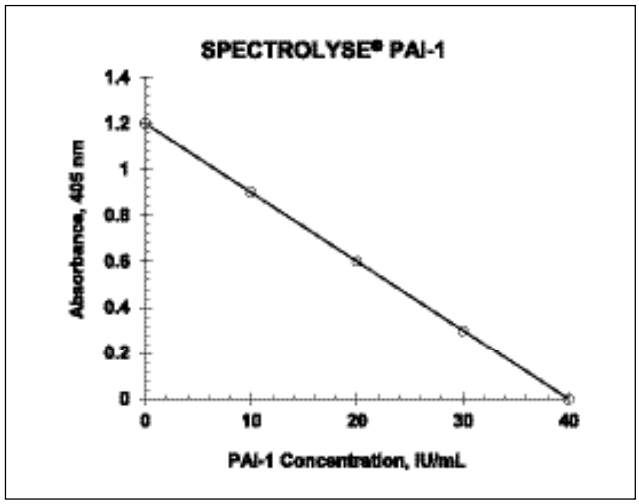
SPECTROLYSE® PAI-1 is intended for the quantitative determination of Plasminogen Activator Inhibitor Type-1 (PAI-1) activity in human plasma. The test is for in vitro diagnostic use.

As a primary regulator of fibrinolysis, PAI-1 is found in a variety of different tissues and cell types including macrophages and monocytes, hepatocytes, vascular endothelia cells, adipose tissue of the heart and lungs and platelets. Clinical interest in measuring PAI-1 in plasma is based on case studies in which levels of this serine protease inhibitor are associated with various thrombotic and fibrinolytic complications.

One unit of PAI-1 activity (IU) is defined as the amount of PAI-1 that inhibits one International Unit (IU) of human tPA. SPECTROLYSE PAI-1 is a two-stage, indirect chromogenic assay. In the first stage, a fixed amount of human tPA is added to a plasma sample and allowed to react with the PAI-1 present in the sample. Next, the sample is acidified to destroy alpha-2-antiplasmin that would otherwise interfere with the assay.

In the second stage, the residual tPA activity is measured by adding the sample to a mixture of human glu-plasminogen, poly-D-lysine and a chromogenic substrate for plasmin (PAR). The residual tPA activity in the plasma sample catalyzes the conversion of plasminogen to plasmin, which in turn hydrolyzes the chromogenic substrate. Poly-D-lysine is present as a stimulator of this tPA catalyzed conversion of plasminogen to plasmin. As the PAI-1 activity measured in the sample is based upon the residual tPA activity, the absorbance of the assayed is inversely proportional to the amount of PAI-1 activity in the sample.

RESULTS/REPRESENTATIVE STANDARD CURVE



REAGENTS

1 Vial of Imidazole Buffer pH 7.2, 10X concentrated, 3 mL
2 Vials of Plasminogen Activator Reagent (PAR)
1 Vial of 1-chain human tPA, 6000 IU/mL, lyophilized
1 Vial of tPA/PAI-1 Depleted Plasma, 1 mL, lyophilized
1 Vial of Acetate Buffer pH, 3.9, 7 mL
1 Vial of Stop Reagent, 4 mL

SPECIFICATIONS

SAMPLES	Citrate collected plasma
SAMPLE PREPARATION	50 µL of plasma, further prepared
SAMPLE VOLUME	20 µL of prepared sample
TOTAL ASSAY TIME	2 hours
STANDARD RANGE	0 – 40 IU/mL
LOWER LIMIT OF DETECTION	4.6 IU/mL
NUMBER OF TESTS	60

RELATED PRODUCTS

IMUBIND® Plasma PAI-1 ELISA REF 822 .....Pg. 41
tPA/PAI-1 Deficient Plasma REF 273 .....Pg. 59

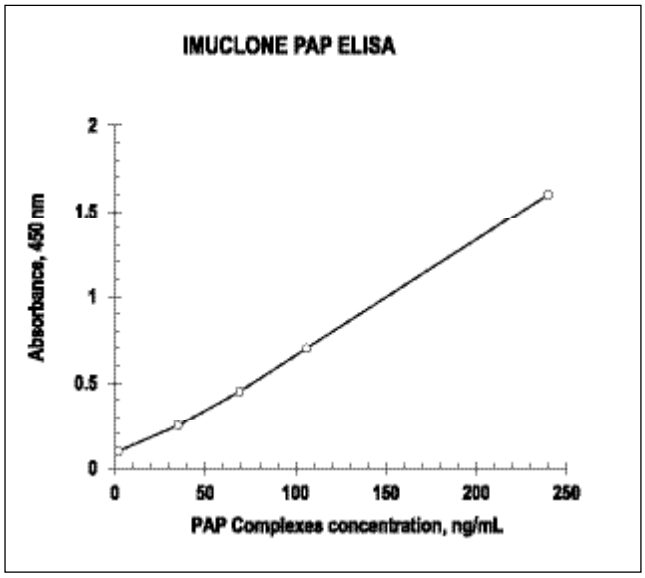
IMUCLONE™ PAP ELISA

REF: 603 **RUO**

The IMUCLONE™ PAP ELISA is intended for the measurement of plasmin/alpha-2-antiplasmin (PAP) complexes in human plasma. The assay measures only PAP complexes. It neither measures nor is affected by free plasminogen, alpha-2-antiplasmin or other plasmin complexes.

Alpha-2-antiplasmin (α-2-antiplasmin) is a single chain, 70,000 molecular weight inhibitor of plasmin which reacts rapidly with plasmin to form the inactive plasmin/alpha-2-antiplasmin complex. Synthesized by the liver, alpha-2-antiplasmin circulates in plasma at a concentration of approximately 1 µM (70 µg/mL), with 20% being cross-linked when blood clots. The formation of the PAP complex is a two-step process. First, the lysine binding sites of plasmin and the carboxyl-terminal region of alpha-2-antiplasmin form a reversible complex. In the second step, cleavage of the peptide bond of the inhibitor forms the irreversible complex. Increased PAP complex formation is accompanied by increased fibrin formation. Accordingly, a correlation between the level of fibrin split products and the level of PAP complexes exists.

RESULTS/REPRESENTATIVE STANDARD CURVE



REAGENTS

- 96 MAb Anti-Human PAP Complex IgG Coated Microwells
- 5 Vials of PAP Calibrator, 0.5 mL (lyophilized)
- 1 Vial of PAP Control, High, 0.5 mL (lyophilized)
- 1 Vial of PAP Control, Low, 0.5 mL (lyophilized)
- 1 Vial of Detection Antibody, HRP-Anti-Human Plasminogen IgG, 0.3 mL
- 1 Vial of Dilution Buffer (2.5X concentrate), 20 mL
- 2 Vials of Wash Buffer, 0.15M PBS, 0.05% Tween 20 (12.5X concentrate), 20 mL
- 1 Vial of Substrate, TMB, 12 mL
- 1 Vial of Stop Solution, 0.45 M Sulfuric Acid, 12 mL

SPECIFICATIONS

SAMPLES	Citrate collected plasma with Aprotinin (2,000 KIU/mL final concentration) and Benzamidine (20 mM final concentration). PPACK containing collection tubes are an alternative
SAMPLE PREPARATION	1:10 dilution (low PAP levels), 1:100 (high PAP levels)
SAMPLE VOLUME	100 µL of diluted sample
TOTAL ASSAY TIME	Overnight incubation
STANDARD RANGE	0 – 250 ng/mL
LOWER LIMIT OF DETECTION	N.D.
PRECISION	Intra-assay CV < 5.0% Inter-assay CV < 10.0%
NUMBER OF TESTS	96

RELATED PRODUCTS

DIMERTEST® Latex REF DLHK7 .....Pg 31
IMUCLONE™ D-dimer ELISA REF 602.....Pg 33

IMUCLONE™ FPA ELISA REF: 635 RUO

The IMUCLONE™ FPA ELISA is a competitive enzyme-linked immunosorbent assay (CELIA) for measuring human (FPA) on bentonite adsorbed human plasma or in any fluid where FPA may be present.

FPA, Fibrinopeptide A, is a 1536 D molecular weight, 16 amino acid peptide released from the amino terminus of fibrinogen A alpha chains by thrombin cleavage. Two molecules of FPA are released per molecule of fibrinogen. Elevated blood levels of FPA are indicative of excess thrombin activity.

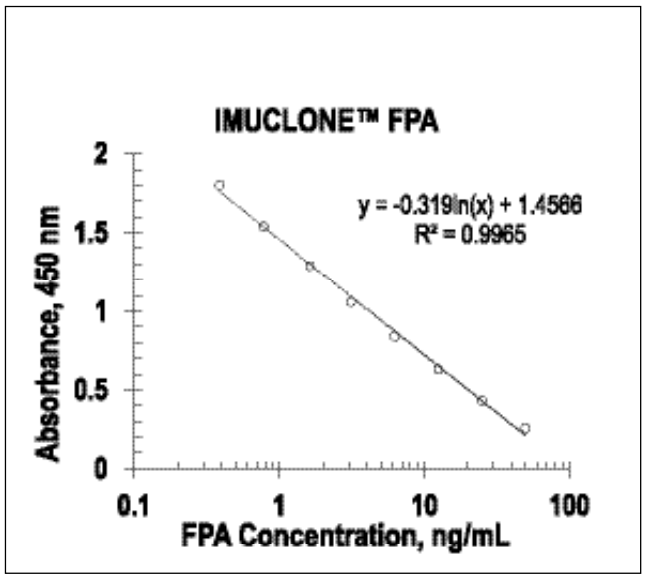
SPECIFICATIONS

SAMPLES	Special Anticoagulant collected plasma
SAMPLE PREPARATION	1:2 dilution of bentonite treated plasma
SAMPLE VOLUME	200 µL diluted plasma
TOTAL ASSAY TIME	3 hours
STANDARD RANGE	0 – 10 ng/mL
PRECISION	Intra-assay CV = N.D. Inter-assay CV = N.D.
NUMBER OF TESTS	96

RELATED PRODUCTS

IMUBIND® vWF Activity ELISA REF 885 .....Pg 28
QuikCoag APTT-EA REF C.BMD.APTT-04ML.....Pg 18

RESULTS/REPRESENTATIVE STANDARD CURVE



REAGENTS

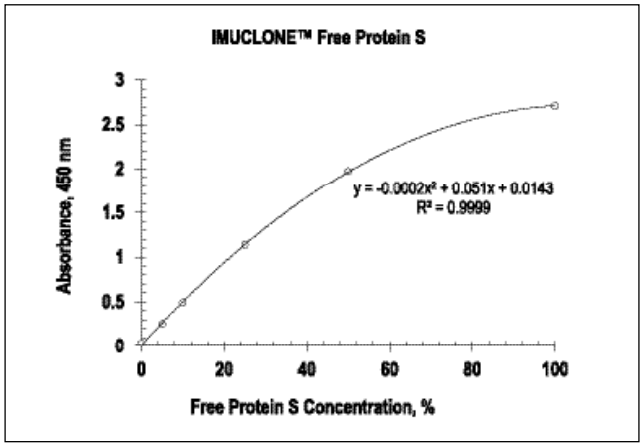
96 Microtest Plate pre-coated with human FibrinoPeptide A
1 Vial of Bentonite Suspension, ready to use, 50 mL
1 Vial of 2% Tween 20, ready to use, 5 mL
1 Vial of Sample Diluent, ready to use, 50 mL
3 Vials of FPA Calibrator, lyophilized
3 Vials of Rabbit Anti-human FPA antibodies, lyophilized
3 Vials of Anti-Rabbit IgG HRP IC (Immunoconjugate), lyophilized
1 Vial of Conjugate Diluent, ready to use, 25 mL
1 Vial Wash Solution, 20 fold concentrate, 50 mL
1 Vial of TMB Substrate (Peroxidase Substrate), 25 mL
1 Vial of Special Anticoagulant solution, ready to use, 20 mL
1 Vial of Stop Solution (0.45 M Sulfuric Acid), ready to use, 6 mL

IMUCLONE™ Free Protein S ELISA REF: 842 RUO

The IMUCLONE™ Free Protein S is a an enzyme-linked immunosorbent assay for measuring human Free Protein S (the activated Protein C cofactor) in plasma or any biological fluid where Free Protein S may be present. The assay is For Research Use Only, not for use in diagnostic procedures.

Protein S is an 80,000 D molecular weight, vitamin K dependent glycoprotein synthesized in the liver. The concentration of Protein S in normal human plasma is approximately 25 µg/mL and is found in two forms: Free Protein S comprises approximately 40% (10 µg/mL) of the total amount while approximately 60% (15 µg/mL) circulates in blood as a non-covalent complex with C4b Binding Protein (C4b-BP). Only the Free Protein S possesses anticoagulant activity as the cofactor of Activated Protein C. The balance between the Free and C4b-BP complexed forms of Protein S plays an important role as only the Free Protein S is active.

RESULTS/REPRESENTATIVE STANDARD CURVE



SPECIFICATIONS

SAMPLES	Citrate collected plasma or serum
SAMPLE PREPARATION	1:50 dilution
SAMPLE VOLUME	100 µL of diluted sample
TOTAL ASSAY TIME	1½ hours, Overnight primary incubation
STANDARD RANGE	0 – 100%
PRECISION	Intra-assay CV = N.D. Inter-assay CV = N.D.
NUMBER OF TESTS	96

REAGENTS

- 96 Microtest Plate pre-coated with Anti-(h) Free Protein S
- 2 Vials of Protein S Sample Diluent (contains calcium), ready to use, 50 mL
- 3 Vials of Plasma Protein S Calibrator, 1:50 prediluted, lyophilized
- 1 Vial of Protein S Control Plasma I, High, lyophilized
- 1 Vial of Protein S Control Plasma II, Low, lyophilized
- 3 Vials of Anti-(h)-Free PS-HRP Immunoconjugate, lyophilized
- 1 Vial of Protein S Conjugate Diluent, ready to use, 15 mL
- 1 Vial of Protein S Wash Solution, 20 fold concentrate, 50 mL
- 1 Vial of TMB Substrate (Peroxidase Substrate), ready to use, 25 mL
- 1 Vial of Stop Solution (0.45 M Sulfuric Acid), ready to use, 6 mL

RELATED PRODUCTS

ACTICLOT® Protein S REF 843L .....Pg. 46

IMUCLONE™ Total TAFI ELISA REF: 873 RUO

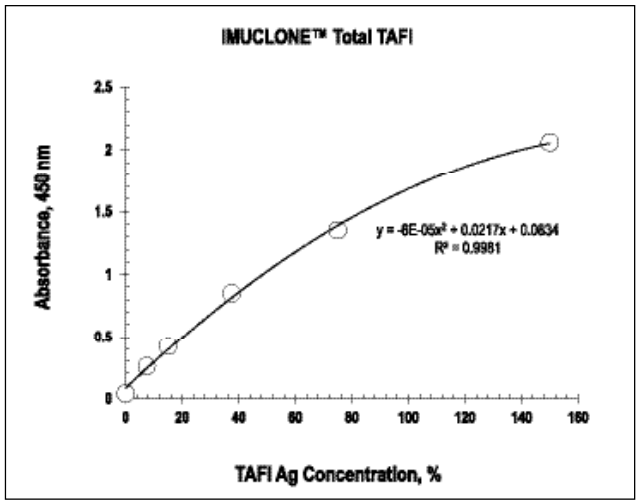
The IMUCLONE™ Total TAFI ELISA is an in vitro assay for the measurement of TAFI antigen in human plasma, or in any fluid where TAFI may be present. The assay is For Research Use Only, not for use in diagnostic procedures.

TAFI, Thrombin Activatable Fibrinolytic Inhibitor, (also known as carboxypeptidase U and plasma pro-carboxypeptidase B) is a 60,000 D molecular weight glycoprotein (proenzyme form) present in human plasma that modulates fibrinolysis in vivo. This proenzyme is converted to a 35,000 D molecular ratio active form, TAFIa, following proteolytic cleavage by the thrombin/thrombomodulin complex. TAFIa possesses carboxypeptidase activity with a preference for cleaving lysine and arginine residues from the c-terminus of proteins. Modulation of fibrinolysis occurs when TAFIa cleaves C-terminal arginine and lysine residues of partially degraded fibrin. The removal of the c-terminus arginine and lysine residues from fibrin inhibits the continued degradation of fibrin by tPA activated plasmin. TAFI may play a central role in thrombosis and fibrinolysis due to its ability to retard fibrin clot lysis.

SPECIFICATIONS

SAMPLES	Citrate or EDTA collected plasma
SAMPLE PREPARATION	1:50 dilution
SAMPLE VOLUME	200 µL of diluted sample
TOTAL ASSAY TIME	4 hours
STANDARD RANGE	0 – 160% (approximate)
PRECISION	Intra-assay CV = N.D. Inter-assay CV = N.D.
NUMBER OF TESTS	96

RESULTS/REPRESENTATIVE STANDARD CURVE



REAGENTS

96-Well Microtest Plate pre-coated with anti-Human Total TAFI
- 2 Vials of Sample Diluent-F, ready to use, 50 mL
- 3 Vials of Plasma TAFI Calibrator, lyophilized
- 1 Vial of TAFI Control I – High, lyophilized
- 1 Vial of TAFI Control II – Low, lyophilized
- 1 Vial of Conjugate Diluent, ready to use, 25 mL)
- 3 Vials of Anti-Human Total TAFI-HRP Immunoconjugate, lyophilized
- 1 Vial of Wash Solution, 20 fold concentrate, 50 mL
- 1 Vial of TMB Substrate (Peroxidase Substrate), ready to use, 25 mL
- 1 Vial of Stop Solution (0.45 M Sulfuric Acid), ready to use, 6 mL

RELATED PRODUCTS

IMUBIND® Thrombomodulin ELISA REF 837 .....Pg. 42
Human Alpha-Thrombin REF 470HT.....Pg. 58
Human Thrombomodulin REF 2374.....Pg. 58

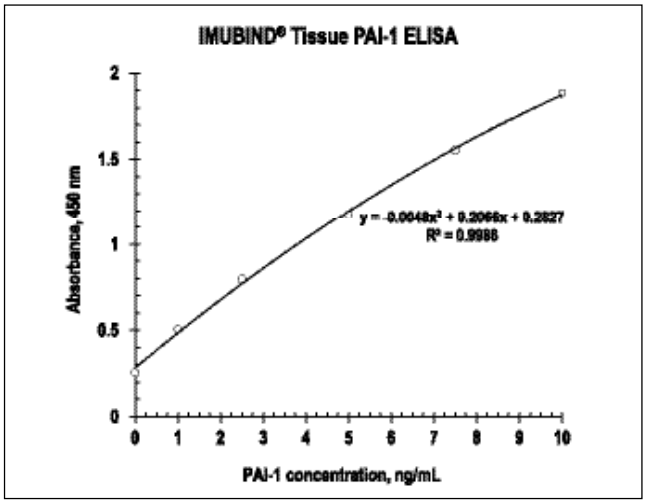
IMUBIND® Tissue PAI-1 ELISA

REF: 821 **RUO**

IMUBIND® Tissue PAI-1 ELISA is an enzyme-linked immunosorbent assay for the quantitative measurement of human Plasminogen Activator Inhibitor Type 1 (PAI-1) in tissue extracts and cell culture supernatants. The assay detects latent (inactive) and active forms of PAI-1 and PAI-1 complexes and is insensitive to Plasminogen Activator Inhibitor Type 2 (PAI-2). This assay is For Research Use Only, not for use in diagnostic procedures.

PAI-1 is a serine protease inhibitor that serves as the principal inhibitor of tissue-type plasminogen activator (tPA) and urokinase-type plasminogen activator (uPA), the activators that cleave plasminogen to form plasmin, and therefore the fibrinolytic process. As a primary regulator of fibrinolysis, PAI-1 has been found in a number of different tissues, and cell types including macrophages/monocytes, hepatocytes, vascular endothelia, adipose tissue of the heart and lungs, and in platelets.

RESULTS/REPRESENTATIVE STANDARD CURVE



SPECIFICATIONS

SAMPLES	Tissue Culture Supernatant, Detergent Extracts of Tissue
SAMPLE PREPARATION	Variable dilution for tissue culture supernatants 1:20 dilution for tissue extracts
SAMPLE VOLUME	100 µL prepared sample
TOTAL ASSAY TIME	22 hours, Overnight primary incubation
STANDARD RANGE	0 – 10 ng/mL
LOWER LIMIT OF DETECTION	0.125 ng/mL
PRECISION	Intra-assay CV = N.D. Inter-assay CV = N.D.
NUMBER OF TESTS	96

REAGENTS

96 Anti-human PAI-1 IgG coated microwells
6 Vials of PAI-1 Standards, 0-10 ng/mL, lyophilized
2 Vials of Detection Antibody, biotinylated anti-human PAI-1, lyophilized
1 Vial of Enzyme Conjugate, Streptavidin-Horseradish Peroxidase, 60 µL
1 Vial of Enzyme Conjugate Diluent, 20 mL, lyophilized
1 Vial of Substrate, TMB, 11 mL
1 Vial of Detergent, 25% Triton X-100, 12 mL
2 Packets of PBS Buffer, pH 7.4, powder

RELATED PRODUCTS

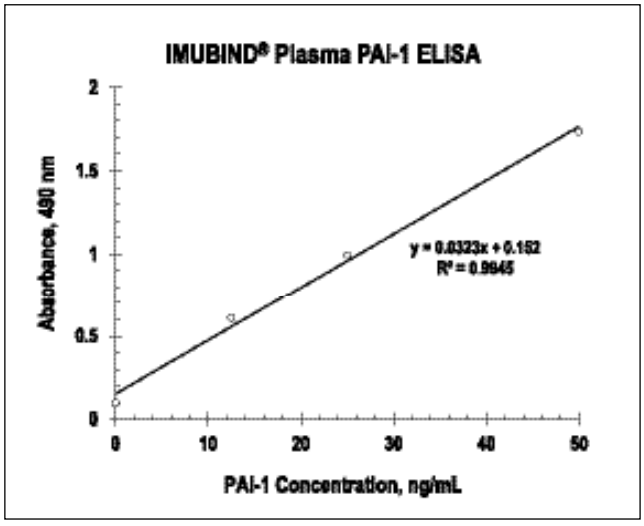
IMUBIND® uPA ELISA	REF 894	Pg. 44
SPECTROLYSE® PAI-1	REF 101201	Pg. 35
tPA/PAI-1 Deficient Plasma	REF 273	Pg. 59
Murine Monoclonal Antibody Against Human PAI-1	REF 3785	Pg. 58

IMUBIND® Plasma PAI-1 ELISA REF 822 IVD

IMUBIND® Plasma PAI-1 ELISA is an enzyme-linked immunosorbent assay for the quantitative measurement of human Plasminogen Activator Inhibitor Type-1 (PAI-1) antigen in plasma. This assay is for in vitro diagnostic use.

As a primary regulator of fibrinolysis Plasminogen Activator Inhibitor Type-1 (PAI-1), has been found in a number of different tissues, and cell types including macrophages/monocytes, hepatocytes, vascular endothelia, adipose tissue of the heart and lungs, and in platelets. The clinical interest in measuring PAI-1 in plasma is based on case studies in which levels of this serine protease inhibitor are associated with various thrombotic and fibrinolytic complications. Deficiency of PAI-1 activity is associated with bleeding disorders wherein the routine haemostatic screening tests are normal. High levels of PAI-1 activity are found in patients suffering from myocardial infarction, haemolytic uremic syndrome, and stroke. Levels of PAI-1 in the plasma of pregnant women are also correlated with gestational diabetes, reduced placental blood flow and preeclampsia. Patients with cirrhosis may also have elevated levels of PAI-1.

RESULTS/REPRESENTATIVE STANDARD CURVE



SPECIFICATIONS

SAMPLES	Citrate or EDTA collected plasma
SAMPLE PREPARATION	Neat plasma
SAMPLE VOLUME	20 µL of plasma
TOTAL ASSAY TIME	3 hours
STANDARD RANGE	0 – 50 ng/mL
LOWER LIMIT OF DETECTION	2.2 ng/mL
PRECISION	Intra-assay CV ≤ 6.6% Inter-assay CV ≤ 9.0%
NUMBER OF TESTS	96

REAGENTS

96 Monoclonal Antibody Anti-Human PAI-1 Coated Microwells
1 Vial of PET Buffer (PBS-EDTA-Tween 20, powder), 15.15 g
1 Vial of PAI-1 Standard, 50 ng/mL, lyophilized
1 Vial of PAI-1 Standard, 0 ng/mL, lyophilized
1 Vial of Detection Antibody, 200 µL, concentrate
2 Tablets of OPD Substrate, each tablet contains 10 mg of OPD-HCl

RELATED PRODUCTS

SPECTROLYSE® PAI-1 REF 101201 .....Pg. 35
tPA/PAI-1 Deficient Plasma REF 273 .....Pg. 59
IMUBIND® uPA ELISA REF 894 .....Pg. 44
Murine Monoclonal Antibody Against Human PAI-1 REF 3785 .....Pg. 58

IMUBIND® Thrombomodulin ELISA

REF: 837 **RUO**

The IMUBIND® Thrombomodulin ELISA is an enzyme linked immunosorbent assay for the measurement of thrombomodulin in human plasma, serum and cell culture supernatants. The ELISA measures whole and truncated forms of thrombomodulin as well as thrombomodulin/thrombin complexes, but is less sensitive to non-functional or degraded fragments. The assay is For Research Use Only, not for use in diagnostic procedures.

Thrombomodulin (TM) is the cell surface receptor for thrombin. When occupied, thrombomodulin converts thrombin from a procoagulant protein into the activator of Protein C. The thrombomodulin-thrombin complex enhances the catalytic activation of Protein C over 1,000 fold. Once activated Protein C (APC) has been generated, thrombomodulin acts as a major anticoagulant through its ability to inactivate various blood factors (Va, VIIIa, Xa and XIIIa). In competing for thrombin binding, thrombomodulin inhibits the proteolytic effect of thrombin in its conversion of fibrinogen to fibrin, the inactivation of Protein S and the induction of platelet aggregation. Platelets, monocytes and neutrophils contain small amounts of TM in comparison to cultured endothelial cells. TM is present in human plasma and urine in a truncated form, lacking the transmembrane and cytoplasmic domains of TM found on the cell surface. A detailed analysis of thrombomodulin circulating in human plasma revealed smaller fragments or degraded forms that are considered to possess only limited function. Plasma levels of TM have been used as a marker for in vivo endothelial cell injury.

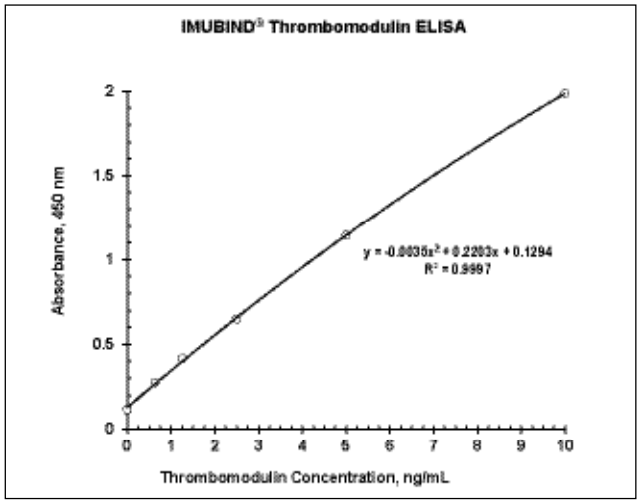
REAGENTS

- 96 Anti-Human Thrombomodulin IgG Coated Microwells
- 2 Vials of Thrombomodulin Deficient Plasma, 0.5 mL, lyophilized
- 1 Vial of Thrombomodulin Control, 1.0 mL, lyophilized
- 2 Vials of Thrombomodulin Standard, 10 ng/mL, lyophilized
- 1 Vial of Detection Antibody, HRP-Conjugated Anti-Human Thrombomodulin, 250 µL
- 1 Vial of Detection Antibody Diluent, 15 mL, lyophilized
- 2 Vials of Substrate, TMB, 11 mL
- 1 Packet of Wash Buffer, PBS Buffer with 0.05% Tween 20, pH 7.4, 1 Liter, powder

RELATED PRODUCTS

Human Thrombomodulin REF 2374 .....Pg. 58
Thrombomodulin, Rabbit REF 237 .....Pg. 58

RESULTS/REPRESENTATIVE STANDARD CURVE



SPECIFICATIONS

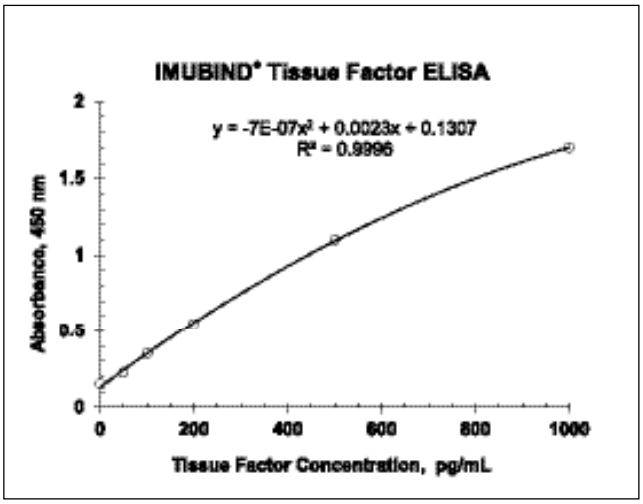
SAMPLES	Citrate collected plasma, cell lysates, cell culture supernatants
SAMPLE PREPARATION	1:4 dilution (plasma samples), 1:5 (cell culture supernatants)
SAMPLE VOLUME	200 µL of diluted sample
TOTAL ASSAY TIME	3 hours
STANDARD RANGE	0 – 10 ng/mL
LOWER LIMIT OF DETECTION	N.D.
PRECISION	Intra-assay CV = N.D. Inter-assay CV = N.D.
NUMBER OF TESTS	96

IMUBIND® Tissue Factor ELISA REF: 845 RUO

The IMUBIND® Tissue Factor ELISA is intended for the measurement of human tissue factor (TF, thromboplastin, factor III) in human plasma, tumor tissue extracts and cell culture supernatants (e.g. LPS stimulated monocytes). Tissue Factor (TF) is a 45 kD transmembrane cell surface glycoprotein known for its role in initiating coagulation. Comprised of three domains: an extracellular domain (aa 1-219), followed by a hydrophilic spanning domain (aa 220-242) and a cytoplasmic tail (aa 243-263), it functions as a receptor and cofactor for Factor VII and Factor VIIa. Tissue Factor is released into the blood stream following disruption of the endothelium. Contact between TF and blood is sufficient to initiate the extrinsic pathway of coagulation.

In vitro studies reveal that once TF complexes with Factor VII, Factor VII is efficiently activated by Factor Xa. Factor VIIa possesses little proteolytic activity by itself; only when bound to TF does it possess sufficient proteolytic activity to activate Factor IX and Factor X. The TF/FVIIa complex efficiently activates both Factor IX and Factor IX, thus initiating both the intrinsic and extrinsic coagulation pathways. The extrinsic pathway is quickly dampened by Tissue Factor Pathway Inhibitor (TFPI). TFPI is the only effective inhibitor of the TF/FVIIa complex.

RESULTS/REPRESENTATIVE STANDARD CURVE



REAGENTS

- 96 Anti-Human Tissue Factor IgG Coated Microwells with an acetate cover sheet
- 6 Vials of TF Standards, 0-1000 pg/mL (lyophilized)
- 2 Vials of Detection Antibody, biotinylated anti-human TF IgG, 5.5 mL (lyophilized)
- 1 Vial of Enzyme Conjugate, Streptavidin-horseradish Peroxidase, 60 µL
- 1 Vial of Enzyme Conjugate Diluent, 20 mL (lyophilized)
- 1 Vial of Substrate, TMB, 11 mL
- 1 Packet of Wash Buffer, PBS with 0.1% Triton X-100, pH 7.4, 1 L (lyophilized)

SPECIFICATIONS

SAMPLES	Citrate collected plasma, cell lysates, tissue extracts, cell culture supernatants
SAMPLE PREPARATION	1:4 dilution (plasma samples), 1:5 (cell culture supernatants)
SAMPLE VOLUME	100 µL diluted sample
TOTAL ASSAY TIME	Overnight incubation
STANDARD RANGE	0 – 1,000 pg/mL
LOWER LIMIT OF DETECTION	10 pg/mL
PRECISION	Intra-assay CV = 4.5% Inter-assay CV = 7.5%
NUMBER OF TESTS	96

RELATED PRODUCTS

ACTICHROME® TF REF 846 .....Pg. 48
ACTICHROME® TFPI REF 848 .....Pg. 49

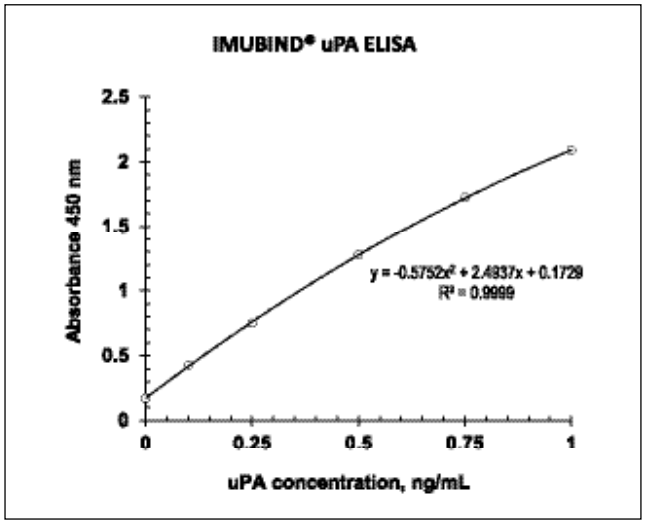
IMUBIND® uPA ELISA

REF 894 **RUO**

IMUBIND® uPA ELISA is an enzyme-linked immunoassay for the quantitative determination of human urokinase-type plasminogen activator (uPA) in tissue extracts, plasma and cell culture supernatants. Single chain uPA (sc-uPA, pro-uPA) and HMW-uPA forms of urokinase-type plasminogen activator are all recognized by the assay, as is receptor-bound uPA and uPA complexed with PAI-1 and PAI-2. This assay is For Research Use Only, not for use in diagnostic procedures.

uPA was originally isolated from human urine, it is also present in blood and in the extracellular matrix of various tissues. It is a serine protease with plasminogen serving as its primary physiological substrate. Activation of plasminogen to plasmin triggers the fibrinolytic cascade and fibrin degradation. uPA is also involved in the degradation of the extracellular tumor matrix and has been implicated in the mechanics of cell proliferation, invasion and metastasis. Secreted by tumor cells in an enzymatically inactive single-chain form, sc-uPA binds to receptors on the surface of tumor cells. Sc-uPA is converted into an enzymatically active two-chain molecule by serine proteases (plasmin, plasma kallikrein, trypsin), metalloproteases (thermolysin) or cysteine proteases (Cathepsin B and L).

RESULTS/REPRESENTATIVE STANDARD CURVE



REAGENTS

96 Anti-human uPA IgG coated microwells
6 Vials of uPA Standards, 0-1.0 ng/mL, lyophilized
2 Vials of Detection Antibody, biotinylated anti-human uPA, lyophilized
1 Vial of Enzyme Conjugate, Streptavidin-Horseradish Peroxidase, 60 µL
1 Vial of Enzyme Conjugate Diluent, 20 mL, lyophilized
1 Vial of Substrate, TMB, 11 mL
1 Vial of Detergent, 25% Triton X-100, 12 mL
2 Packets of PBS Buffer, pH 7.4, powder

SPECIFICATIONS

SAMPLES	Tissue Culture Supernatant, Detergent Extracts of Tissue
SAMPLE PREPARATION	Variable dilution for tissue culture supernatants 1:20 dilution for plasma 1:20 dilution for tissue extracts
SAMPLE VOLUME	100 µL of prepared sample
TOTAL ASSAY TIME	22 hours, overnight primary incubation
STANDARD RANGE	0 – 1.0 ng/mL
LOWER LIMIT OF DETECTION	0.025 ng/mL
PRECISION	Intra-assay CV = N.D. Inter-assay CV = N.D.
NUMBER OF TESTS	96

RELATED PRODUCTS

IMUBIND® Tissue PAI-1 ELISA REF 821 .....Pg. 40
IMUBIND® Plasma PAI-1 ELISA REF 822 .....Pg. 41

ACTICLOT® Protein C Resistance REF 840 | 840C IVD

ACTICLOT® Protein C Resistance is a plasma based functional assay for the determination of resistance to activated protein C caused by the Factor V Leiden mutation (FV:Q506). The assay is for in-vitro diagnostic use.

Activated Protein C (APC) resistance is the most frequent hereditary defect associated with deep vein thrombosis. Over 95% of the APC resistance phenotype can be explained by the Factor V Leiden mutation. This defect is caused by point mutation in the factor V gene resulting in a replacement of the amino acid Arg 506 by a Gln residue. The heterozygous defect is associated with a 5 to 10 fold increased thrombotic risk, the homozygous defect is associated with a 50 to 100 fold increased thrombosis risk. There are two possibilities of detecting factor V (FV) Leiden: plasma based functional assays identifying the phenotype expression of the defect or genotype determination performed by PCR technology.

ACTICLOT® Protein C Resistance differs from other functional APC resistance tests by acting specifically on the prothrombinase complex level. It is based on a FVa-dependent prothrombin activator isolated from snake venom. Specificity of the assay is enhanced by eliminating interference by factors upstream of the coagulation cascade, as the assay is not dependent on the presence of calcium. Interference from unfractionated heparin, low-molecular weight heparin and pentasaccharide in the blood sample is precluded by inclusion of a heparin inhibitor. Clot times of plasma samples in the presence of APC and in the absence of APC are recorded and the ratio calculated. Differentiation of homozygous, heterozygous and negative samples is based on the typical ratio ranges measured with genotyped patient plasma samples.

REAGENTS

- 3 Vials of APC + RVV-V Reagent, 2.0 mL, lyophilized
- 3 Vials of RVV-V Reagent, 2.0 mL, lyophilized
- 3 Vials of PTA Reagent, 4.0 mL, lyophilized
- 3 Vials of Dilution Plasma, 2.0 mL, lyophilized

SPECIFICATIONS

SAMPLES	Citrate collected plasma
SAMPLE PREPARATION	Neat
SAMPLE VOLUME	30 µL of plasma
TOTAL ASSAY TIME	5 minutes
SENSITIVITY	100%
SPECIFICITY	100%
PRECISION	Inter-assay CV < 5.0%
NUMBER OF TESTS	120

RELATED PRODUCTS

ACTICLOT® Activated Protein C Resistance Control Plasma REF 840C.....Pg. 45
ACTICLOT® C REF ACC-45 .....Pg. 47
ACTICLOT® Protein S REF 843L .....Pg. 46

ACTICLOT® Protein S

REF: 843L **IVD**

ACTICLOT® Protein S is a functional clotting assay intended for the quantitative determination of Protein S activity in human plasma. The assay is for in vitro diagnostic use. Protein S is a Vitamin K-dependent primarily synthesized in the liver, but also in the endothelium and possibly in megakaryocytes. It functions as a cofactor for activated Protein C (APC), mediating APC in its ability to inhibit Factor Va in the prothrombinase complex. Therefore, there is an association between Protein S deficiencies and thrombotic events.

DEFICIENCY TYPE	TOTAL PROTEIN S	FREE PROTEIN S	PROTEIN S ACTIVITY
I	∇[b]	∇	∇
II	⇔[a]	⇔	∇
III	⇔	∇	∇

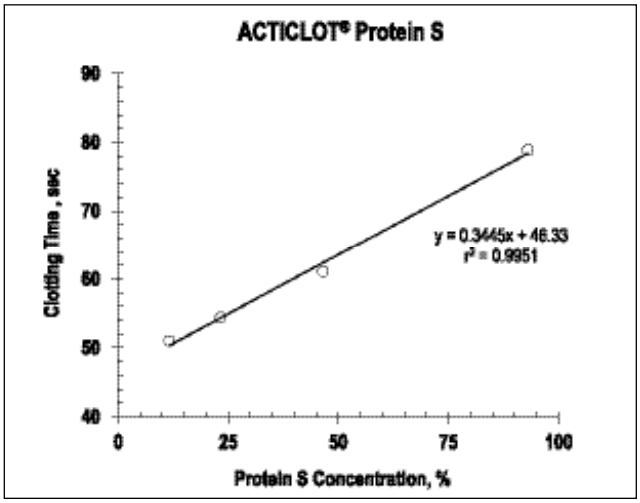
⇔ = Normal
∇ = Is at a reduced level

In the assay, dilutions of patient plasma are mixed with Protein S deficient plasma. A reagent containing factor Xa, activated Protein C and phospholipids is added to the mixture. Following a 5-minute incubation period, calcium chloride is added to initiate clot formation. Under these conditions, the prolongation of the clotting time is directly proportional to the concentration of Protein S in the patient plasma.

REAGENTS

4 Vials of ACTICLOT Activator Reagent, 1 mL, lyophilized
4 Vials of Protein S Deficient Plasma, 1 mL, lyophilized
2 Vials of Protein S Control Plasma, 0.5 mL, lyophilized
2 Vials of Sample Dilution Buffer, 2.5 mL,10X Concentrate

RESULTS/REPRESENTATIVE STANDARD CURVE



SPECIFICATIONS

SAMPLES	Citrate collected plasma
SAMPLE PREPARATION	1:10 dilution
SAMPLE VOLUME	100 µL of diluted plasma (50 µL when using automated analyzers)
TOTAL ASSAY TIME	10 minutes
STANDARD RANGE	0 – 100%
LOWER LIMIT OF DETECTION	N. D.
PRECISION	Intra-assay CV = N.D. Inter-assay CV = N.D.
NUMBER OF TESTS	40 (increased when using automated analyzers)

RELATED PRODUCTS

Protein S Deficient Plasma ..... REF 843LDP ..... Pg. 59
ACTICLOT® C ..... REF ACC-45 ..... Pg. 47
IMUBIND™ Free Protein S ELISA ..... REF 842 ..... Pg. 38
ACTICLOT® Activated Protein C Resistance ..... REF 840 ..... Pg. 45

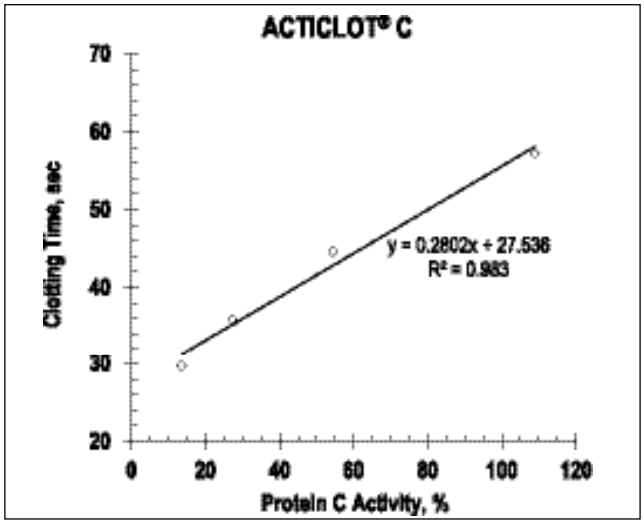
ACTICLOT® C

REF ACC-45 **510(k), Health Canada Registered**

ACTICLOT® C is a functional clotting assay intended for the quantitative determination of Protein C activity in human plasma. The assay is for in vitro diagnostic use. Protein C is a vitamin K-dependent anticoagulant protein that normally circulates in plasma as an inactive zymogen. It is activated when it binds to thrombin in the thrombin-thrombomodulin complex on the surface of endothelial cells. Following activation and release from the cell surface, Protein C exerts its anticoagulant effect by inactivating Factor Va and its ability to form the prothrombinase complex and generate thrombin. Due to the anticoagulant effects of Protein C, people with Protein C deficiency, or who possess Activated Protein C Resistance, are at increased risk for suffering from a thrombotic event.

The venom of the copperhead snake Agkistrodon contortrix is a rapid activator of Protein C. Under the assay conditions of ACTICLOT C, the ACTICLOT Activator, formulated with the venom from Agkistrodon contortrix, converts human Protein C to its active protease within 5 minutes. The activator reagent is formulated to activate both Protein C and the contact factors of the intrinsic pathway. Using this reagent, the clotting time of normal plasma is very long, greater than 100 seconds, while the clotting time of a Protein C deficient plasma is essentially the same as the clotting time of an APTT test, approximately 30 - 40 seconds. When an unknown test plasma is mixed with Protein C deficient plasma, the Protein C level is proportional to the prolongation of the clotting time.

RESULTS/REPRESENTATIVE STANDARD CURVE



SPECIFICATIONS

SAMPLES	Citrate collected plasma
SAMPLE PREPARATION	1:10 dilution
SAMPLE VOLUME	100 µL of diluted plasma (50 µL when using automated analyzers)
TOTAL ASSAY TIME	10 minutes
STANDARD RANGE	0 – 100%
LOWER LIMIT OF DETECTION	N. D.
PRECISION	Intra-assay CV < 4.7% Inter-assay CV < 3.9%
NUMBER OF TESTS	45 (increased when using automated analyzers)

REAGENTS

3 Vials of ACTICLOT Activator, 1.5 mL, lyophilized
3 Vials of Protein C Deficient Plasma, 1.5 mL, lyophilized
3 Vials of Protein C Control Plasma, 0.5 mL, lyophilized
3 Vials of Dilution Buffer, 5 mL, 10X concentrate

RELATED PRODUCTS

Protein C Deficient Plasma	REF ACC-45DP .....Pg. 59
ACTICLOT® Protein C Reisistance	REF 840.....Pg. 45
ACTICLOT® Protein S	REF 843L.....Pg. 46
IMUBIND® Thrombomodulin ELISA	REF 837.....Pg. 42

ACTICHROME® TF

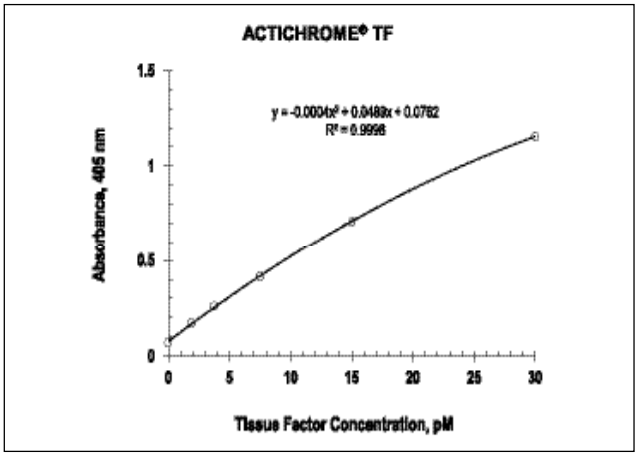
REF: 846 **RUO**

The ACTICHROME® TF is a chromogenic assay intended for the measurement of human Tissue Factor procoagulant activity in human plasma and cell lysates. Tissue Factor (TF) is a 45 kD transmembrane cell surface glycoprotein known for its role in initiating coagulation. Comprised of three domains: an extracellular domain (aa 1-219), followed by a hydrophilic spanning domain (aa 220-242) and a cytoplasmic tail (aa 243-263), it functions as a receptor and cofactor for Factor VII (FVII) and Factor VIIa (FVIIa). Tissue Factor is released into the blood stream following disruption of the endothelium. Contact between TF and blood is sufficient to initiate the extrinsic pathway of coagulation.

In vitro studies reveal that once TF complexes with FVII, FVII is efficiently activated by Factor Xa (FXa). Factor VIIa possesses little proteolytic activity by itself; only when bound to TF does it possess sufficient proteolytic activity to activate Factor IX and Factor X. The TF/FVIIa complex efficiently activates both Factor IX and Factor IX, thus initiating both the intrinsic and extrinsic coagulation pathways. The extrinsic pathway is quickly dampened by Tissue Factor Pathway Inhibitor (TFPI). TFPI is the only effective inhibitor of the TF/FVIIa complex.

ACTICHROME TF measures the activity of human Tissue Factor via a two stage assay. In the first stage, Tissue Factor in the sample complexes with human Factor VIIa to generate the TF/FVIIa complex and convert human Factor X to Factor Xa. In the second stage, Factor Xa cleaves SPECTROZYME® FXa, a highly specific chromogenic substrate for Factor Xa. The cleaved substrate releases a para-nitroaniline (pNA) chromophore into the reaction solution. The solution absorbance is read at 405 nm and compared to those values obtained from a standard curve generated using known amounts of human Tissue Factor.

RESULTS/REPRESENTATIVE STANDARD CURVE



REAGENTS

- 2 Vials of Human Factor VIIa (lyophilized)
- 2 Vials of Human Factor X (lyophilized)
- 2 Vials of SPECTROZYME® FXa, 5 µmoles (lyophilized)
- 1 Vial of Relipidated Human Tissue Factor, 500 pM (lyophilized)
- 2 Vials of TF/TFPI Depleted Plasma, 0.5 mL (lyophilized)
- 1 Vial of Assay Buffer (10X concentrate), 5 mL

SPECIFICATIONS

SAMPLES	Citrate collected plasma, cell lysates
SAMPLE PREPARATION	No dilution
SAMPLE VOLUME	25 µL
TOTAL ASSAY TIME	1 hour
STANDARD RANGE	0 – 30 PM
LOWER LIMIT OF DETECTION	~ 2 PM
PRECISION	N.D.
NUMBER OF TESTS	100

RELATED PRODUCTS

IMUBIND® Tissue Factor ELISA REF 845 .....Pg 43
ACTICHROME® TFPI REF 848 .....Pg 49

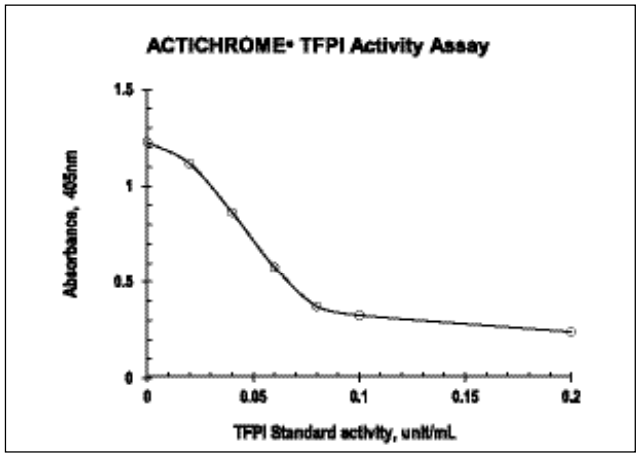
ACTICHROME® TFPI REF: 848 RUO

The ACTICHROME® TFPI is a chromogenic assay intended for the measurement of Tissue Factor Pathway Inhibitor (TFPI) activity in human plasma where TFPI exhibits an inhibitory effect on the Tissue Factor/FVIIa complex. TFPI circulates in human plasma as complexes with LDL, HDL and VLDL and can be found in several forms: a 36,000 D molecule, a 43,000 D molecule and as truncated moieties. Approximately 10% of the total amount of TFPI is carried by platelets, which release TFPI once they are activated by thrombin. At the site of a wound, where platelets aggregate, elevated levels of TFPI are present. Based on the initial isolation of the inhibitor, it was found that TFPI inhibits Tissue Factor (TF) procoagulant activity; i.e., the TF/FVIIa complex, and directly inhibits Factor Xa by binding at or near its serine active site.

The inhibitory mechanism of TFPI is a two-step process. In the first step TFPI binds to Factor Xa via its Kunitz-2 domain, followed by a second step in which the TFPI/FXa complex binds to the TF/FVIIa complex via its Kunitz-1 domain, forming an inactive quaternary TFPI/FXa/TF/FVIIa complex. The direct inhibition of Factor Xa is based on a 1:1 stoichiometry and is not calcium dependent. Furthermore, Factor Xa inhibition does not rely solely on TFPI binding through its Kunitz-2 domain. The C-terminal region of TFPI is required for a high affinity binding between TFPI and Factor Xa and the subsequent Factor Xa inhibition. It has been found that TFPI is released into blood following administration of heparin and that heparin enhances TFPI inhibition of Factor Xa.

ACTICHROME TFPI measures the ability of TFPI to inhibit the catalytic activity of the TF/FVIIa complex as it activates Factor X to Factor Xa. It is a two stage assay. In the first stage, samples incubate with TF/FVIIa and the residual TF/VIIa activity converts FX to FXa. In the second stage, the FXa activity generated cleaves SPECTROZYME® FXa, a highly specific chromogenic substrate for Factor Xa. The cleaved substrate releases a para-nitroaniline (pNA) chromophore into the reaction solution. The solution absorbance is read at 405 nm and compared to those values obtained from a standard curve constructed using known TFPI activity levels.

RESULTS/REPRESENTATIVE STANDARD CURVE



REAGENTS & SPECIFICATIONS

1 Vial of Relipidated Tissue Factor, 50 ng (lyophilized)
1 Vial of Human Factor VIIa Reagent (lyophilized)
1 Vial of Human Factor X, 25 µg (lyophilized)
1 Vial of SPECTROZYME® FXa, 5 µmoles (lyophilized)
1 Vial of TFPI Standard, 0.2 unit/mL (lyophilized)
2 Vials of TFPI Depleted Plasma, 0.5 mL (lyophilized)
1 Vial of TFPI Reference Plasma, 0.5 mL (lyophilized)
1 Vial of Assay Buffer (5X concentrate), 5 mL

SAMPLES	Citrate collected plasma
SAMPLE PREPARATION	1:20 dilution
SAMPLE VOLUME	20 µL diluted sample
TOTAL ASSAY TIME	1.5 hours
STANDARD RANGE	0 – 0.2 U/mL)
LOWER LIMIT OF DETECTION	N.D.
PRECISION	N.D.
NUMBER OF TESTS	100

RELATED PRODUCTS

IMUBIND® Tissue Factor ELISA REF 845 .....Pg 43
ACTICHROME® TF REF 846 .....Pg 48

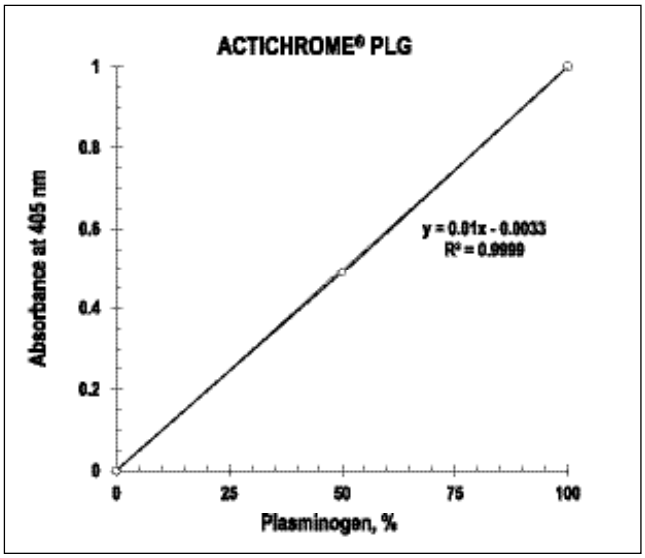
ACTICHROME® PLG REF: 851 RUO

ACTICHROME® PLG is intended for the measurement of plasminogen in human plasma. The assay is For Research Use Only, not for use in diagnostic procedures.

Plasminogen is synthesized in the liver as an 88,000 D molecular weight single chain glycoprotein, circulating in plasma at a concentration of approximately 200 µg/mL. The conversion of plasminogen to plasmin occurs via a variety of mechanisms yielding an 83,000 D two chain protease.

A complex is formed between plasminogen and streptokinase in the presence of excess streptokinase. This plasminogen-streptokinase complex possesses plasmin activity that can be measured using SPECTROZYME® PL, a highly specific chromogenic substrate for thrombin.

RESULTS/REPRESENTATIVE STANDARD CURVE



SPECIFICATIONS

SAMPLES	Citrate collected plasma
SAMPLE PREPARATION	1:6 dilution
SAMPLE VOLUME	200 µL of diluted plasma
TOTAL ASSAY TIME	10 minutes
STANDARD RANGE	0 – 100%
LOWER LIMIT OF DETECTION	N.D.
PRECISION	Intra-assay CV = N.D. Inter-assay CV = N.D.
NUMBER OF TESTS	40 (increased using automated analyzers)

REAGENTS

- 4 Vials of Streptokinase Reagent, 2 mL, lyophilized
- 4 Vials of SPECTROZYME® PL, 2 mL, lyophilized
- 4 Vials of Dilution Buffer, 5 mL, 10X concentrate

RELATED PRODUCTS

Plasminogen, Glu type, Human REF 400, REF 410.....Pg. 58
Plasminogen, Bovine REF 416.....Pg. 58

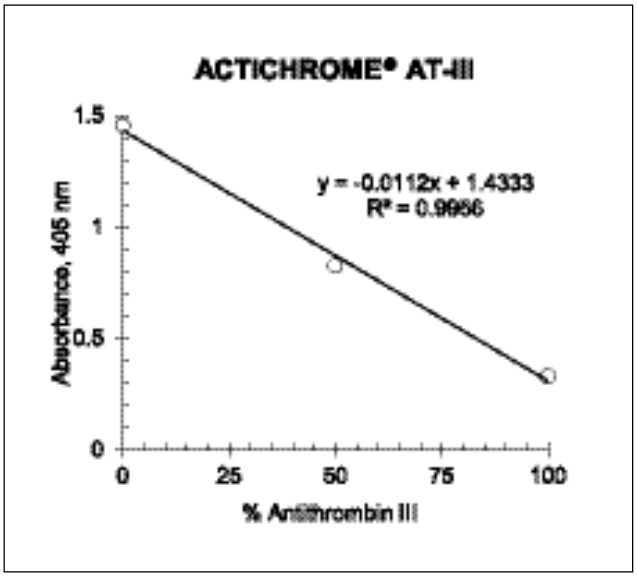
ACTICHROME® AT-III REF: 838 510(K) Health Canada Registered

ACTICHROME® AT-III is an amidolytic chromogenic assay intended for the quantitative determination of antithrombin III in human plasma. Antithrombin III (AT-III) is an inhibitor of plasma serine proteases, including thrombin. AT-III levels of 30-60% of normal may be observed in patients with hereditary AT-III deficiency. Pathological conditions associated with acquired ATIII deficiency include liver disease, DIC, nephrotic syndrome, pulmonary embolism, stroke and thrombophlebitis.

AT-III inhibition of thrombin is slow under normal conditions, however, the rate of inhibition can be enhanced several thousand- fold in the presence of heparin (heparin cofactor activity). Heparin Cofactor II is another rapid heparin-dependent thrombin inhibitor in human plasma. Heparin Cofactor II can interfere with AT-III measurements especially at high heparin concentrations (2 USP units/mL). To impart specificity to antithrombin III, ACTICHROME AT-III utilizes a lower final heparin concentration (1 USP units/mL) where heparin-enhanced inactivation of thrombin by heparin cofactor II is negligible. In addition, human heparin cofactor II reacts more readily with human thrombin than with bovine thrombin, thus further specificity for antithrombin III is imparted by the use of bovine thrombin.

ACTICHROME AT-III is a two-stage assay. In the first stage, thrombin is added to a diluted plasma sample in the presence of excess heparin. In the second stage, residual thrombin activity is measured using SPECTROZYME® TH, a highly specific with thrombin chromogenic substrate. The residual thrombin activity is inversely proportional to the antithrombin III concentration in the plasma.

RESULTS/REPRESENTATIVE STANDARD CURVE



REAGENTS

6 Vials of Bovine Thrombin Reagent, 2 mL (lyophilized)
6 Vials of SPECTROZYME® TH, 2 mL (lyophilized)
6 Vials of Assay Buffer, 5 mL (10X concentrate)

SPECIFICATIONS

SAMPLES	Citrate collected plasma
SAMPLE PREPARATION	1:41 dilution in Assay Buffer
SAMPLE VOLUME	200 µL of diluted plasma
TOTAL ASSAY TIME	6 minutes
STANDARD RANGE	0 – 100%
LOWER LIMIT OF DETECTION	10%
SPECIFICITY	95.3%
PRECISION	Intra-assay CV < 4.4% Inter-assay CV < 6.4%
NUMBER OF TESTS	60 (increased using automated analyzers)

RELATED PRODUCTS

ACTICHROME® Heparin (Anti-FIIa) REF: 820 .....Pg. 5
ACTICHROME® Heparin (Anti-FXa) REF: 832 .....Pg. 6

THROMBOTIC THROMBOCYTOPENIA PURPURA

PRODUCT	PG
812	53
813	54
814	55

Shown above: 812ACTIFLUOR® ADAMTS13 Activity Assay

Thrombotic Thrombocytopenic Purpura (TTP) is a severe, occlusive, microvascular "thrombotic microangiopathy" characterized by low platelet count, microvascular thrombi, red cell fragmentation, central nervous system disorders and renal complications.

ADAMTS13, also known as von Willebrand Factor (vWF) cleaving protease, is a zinc metalloproteinase that cleaves ultra large (UL) vWF multimers within the A2 region of vWF. The UL-vWF multimers bind to receptors on platelets inducing platelet aggregation and formation of intravascular microthrombi.

Studies have shown that low levels of ADAMTS13 activity are strongly associated with a diagnosis of TTP. Assessing the ADAMTS13 protein levels and the presence of ADAMTS13 autoantibodies presents a comprehensive overview of the patient, identifying the patient's condition as congenital versus acquired TTP.

ACTIFLUOR™ ADAMTS13 Activity Assay

REF: 812 **CE, Health Canada Registered***
REF: 812RUO **RUO**

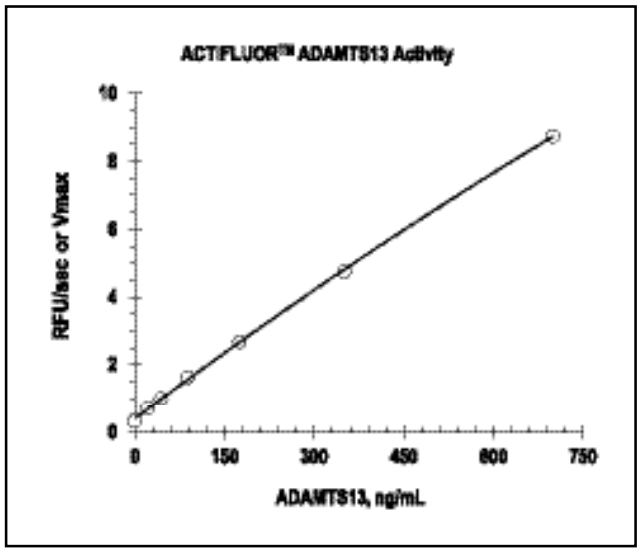
The ACTIFLUOR™ ADAMTS13 Activity assay is a fluorescence resonance energy transfer (FRET) assay for the measurement of ADAMTS13 in human plasma. ADAMTS13, also known as von Willebrand Factor (vWF) cleaving protease, is a zinc metalloproteinase that cleaves ultra large vWF multimers (UL-vWF) at the Tyr(1605)-Met(1606) bond located in the A2 region of vWF. Studies have shown that low levels of ADAMTS13 activity are associated with Thrombotic Thrombocytopenia Purpura (TTP), a life-threatening hematological condition characterized by low platelet count, microvascular thrombi, red cell fragmentation, CNS and renal complications. An ADAMTS13 activity level below 5% of normal leads to an accumulation of UL-vWF multimers in plasma which bind to receptors on platelets inducing platelet aggregation and formation of intravascular microthrombi.

Congenital TTP is a rare heritable disorder caused by mutations within the ADAMTS13 gene which result in the production of non-functional ADAMTS13 protein. The acquired form of TTP is an autoimmune-like disorder caused by the development of autoantibodies to ADAMTS13 that inhibit enzyme activity. Measurement of the ADAMTS13 activity level is useful in the differential diagnosis of patients with TTP from other thrombocytopenic conditions such as hemolytic uremic syndrome (HUS) and idiopathic thrombocytopenic purpura (ITP).

REAGENTS

48 Fluorescence Microwells (white)
2 Vials of ADAMTS13 Standard, 250 µL (lyophilized)
1 Vial of ADAMTS13 Positive Control, 150 µL (lyophilized)
1 Vial of DMSO, 0.5 mL
1 Vial of ALEXA488-VWF86 FRET Substrate, 300 µL (lyophilized)
2 Vials of Assay Buffer, 10 mL (lyophilized)
3 Vials of ADAMTS13 Inactivated Plasma, 0.5 mL (lyophilized)

RESULTS/REPRESENTATIVE STANDARD CURVE



SPECIFICATIONS

SAMPLES	Citrate collected plasma only
SAMPLE PREPARATION	1:2 dilution
SAMPLE VOLUME	20 µL diluted plasma
TOTAL ASSAY TIME	1 hour
STANDARD RANGE	0 – 750 ng/mL
PRECISION	Intra-assay CV = 4.1% Inter-assay CV = 4.4%
NUMBER OF TESTS	48

RELATED PRODUCTS

IMUBIND® ADAMTS13 ELISA REF 813 .....Pg 54
IMUBIND® ADMTS13 Autoantibody ELISA REF 814.....Pg 55

Not for sale in USA

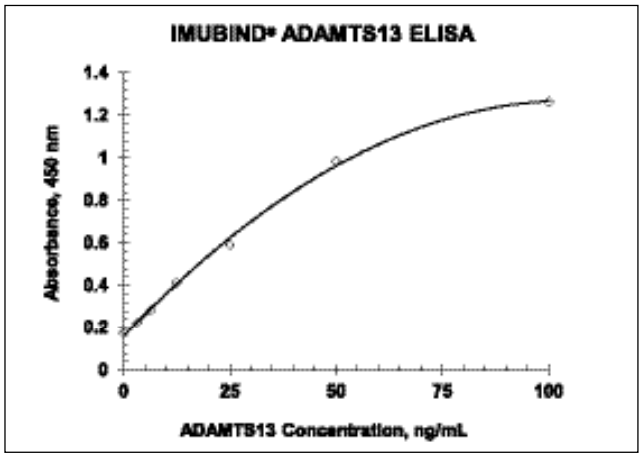
IMUBIND® ADAMTS13 ELISA

REF: 813 **CE, Health Canada Registered***
REF: 813RUO **RUO**

The IMUBIND® ADAMTS13 ELISA is intended for the measurement of ADAMTS13 protein in human plasma. ADAMTS13, also known as von Willebrand Factor (vWF) cleaving protease, is a zinc metalloproteinase that cleaves ultra large vWF multimers (UL-vWF) at the Tyr(1605)-Met(1606) bond located in the A2 region of vWF. Studies have shown that low levels of ADAMTS13 protein activity are associated with Thrombotic Thrombocytopenia Purpura (TTP), a life-threatening hemato- logical condition characterized by low platelet count, microvascular thrombi, red cell fragmentation, CNS and renal complications. An ADAMTS13 activity level below 5% of normal leads to an accumulation of UL-vWF multimers in plasma which bind to receptors on platelets inducing platelet aggregation and formation of intravascular microthrombi.

Congenital TTP is a rare heritable disorder caused by mutations within the ADAMTS13 gene which result in the production of non-functional ADAMTS13 protein. The acquired form of TTP is an autoimmune-like disorder caused by the development of autoantibodies to ADAMTS13 that inhibit enzyme activity. Measurement of the ADAMTS13 protein level is useful in the differential diagnosis of patients with TTP from other thrombocytopenic conditions such as hemolytic uremic syndrome (HUS) and idiopathic thrombocytopenic purpura (ITP).

RESULTS/REPRESENTATIVE STANDARD CURVE



REAGENTS

96 MAb Anti-Human ADAMTS13 Coated Microwells with acetate cover sheet
3 vials of Assay Buffer, 15 mL (lyophilized)
2 vials of ADAMTS13 Standard, 100 ng/mL, 0.6 mL (lyophilized)
2 vials of Positive Control, 0.25 mL (lyophilized)
1 vial of Detection Antibody, biotinylated rabbit anti-human ADAMTS13 IgG, 120 µL
1 vial of Enzyme Conjugate, SA-HRP, 120 µL
1 vial of Substrate, TMB, 11 mL
1 packet of Wash Buffer, PBS with 0.05% Tween 20, pH 7.4, 1 L (lyophilized)

SPECIFICATIONS

SAMPLES	Citrate collected plasma only
SAMPLE PREPARATION	1:20 dilution
SAMPLE VOLUME	100 µL diluted plasma
ASSAY TIME	4 hours
STANDARD RANGE	0 – 100 ng/mL
PRECISION	Intra-assay CV = 4.0% Inter-assay CV = 7.3%
NUMBER OF TESTS	96

RELATED PRODUCTS

ACTIFLUOR™ ADAMTS13 Activity REF 812 ..... Pg 53
IMUBIND® ADAMTS13 Autoantibody ELISA REF 814 ..... Pg 55

Not for sale in USA

IMUBIND® ADAMTS13 Autoantibody ELISA

REF: 814 **CE, Health Canada Registered***
REF: 814RUO **RUO**

The IMUBIND® ADAMTS13 Autoantibody ELISA is intended for the measurement of ADAMTS13 IgG autoantibodies in human plasma. ADAMTS13, also known as von Willebrand Factor (vWF) cleaving protease, is a zinc metalloproteinase that cleaves ultra large vWF multimers (UL-vWF) at the Tyr(1605)-Met(1606) bond located in the A2 region of vWF. Studies have shown that low levels of ADAMTS13 activity are associated with Thrombotic Thrombocytopenia Purpura (TTP), a life-threatening hematological condition characterized by low platelet count, microvascular thrombi, red cell fragmentation, CNS and renal complications. An ADAMTS13 activity level below 5% of normal leads to an accumulation of UL-vWF multimers in plasma which bind to receptors on platelets inducing platelet aggregation and formation of intravascular microthrombi.

Congenital TTP is a rare heritable disorder caused by mutations within the ADAMTS13 gene which result in the production of non-functional ADAMTS13 protein. The acquired form of TTP is an autoimmune-like disorder caused by the development of autoantibodies to ADAMTS13 that inhibit enzyme activity. Measurement of the ADAMTS13 autoantibody level is useful in the differential diagnosis of patients with congenital TTP and acquired TTP, from other thrombocytopenic conditions such as hemolytic uremic syndrome (HUS) and idiopathic thrombocytopenic purpura (ITP), which dictates the course of therapy.

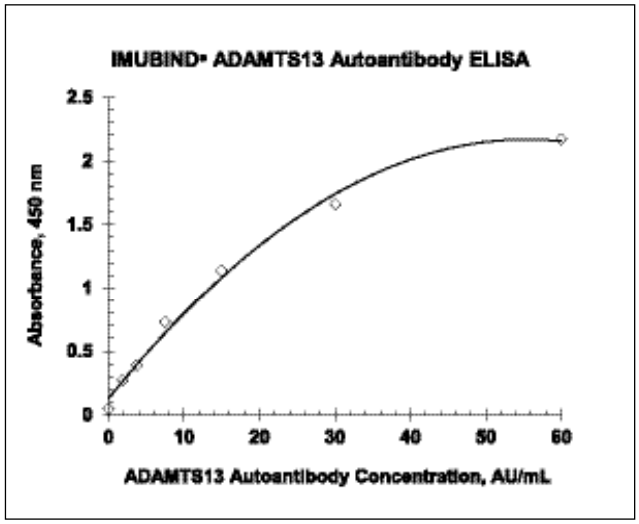
REAGENTS

96 ADAMTS13 coated microwells, with acetate cover sheet
2 Vials of Assay Buffer, 15 mL (lyophilized)
2 Vials of Plasma Standard, 60 AU/mL, 0.45 mL (lyophilized)
2 Vials of Positive Control, 0.35 mL (lyophilized)
1 Vial of Detection Antibody, goat anti-human IgG-HRP, 140 µL
1 Vial of Substrate, TMB, 11 mL
1 Packet of Wash Buffer, PBS w/0.05% Tween 20, pH 7.4, 1 Liter (lyophilized)

SPECIFICATIONS

SAMPLES	Citrate collected plasma only
SAMPLE PREPARATION	1:20 dilution
SAMPLE VOLUME	100 µL diluted plasma
TOTAL ASSAY TIME	4.5 hours
STANDARD RANGE	0 – 60 AU/mL
PRECISION	Intra-assay CV < 6%
NUMBER OF TESTS	96

RESULTS/REPRESENTATIVE STANDARD CURVE



RELATED PRODUCTS

ACTIFLUOR™ ADAMTS13 Activity REF 812 .....Pg. 53
IMUBIND® ADAMTS13 ELISA REF 813 .....Pg. 54

Not for sale in USA

REACTIVE WITH C1 ESTERASE					
PRODUCT NAME	DESCRIPTION	MOLECULAR FORMULA	MOLECULAR WEIGHT	VIAL SIZE	REF
SPECTROZYME® C1-E	Chromogenic substrate reactivw with C1-esterase	CH3CO-Lys(Cbo)-Gly-Arg-pNA.AcOH	715.8 g/mole	25 mg	767
REACTIVE WITH FACTOR IXA					
PRODUCT NAME	DESCRIPTION	MOLECULAR FORMULA	MOLECULAR WEIGHT	VIAL SIZE	REF
SPECTROZYME® FIXa	Chromogenic substrate for the amidolytic assay of Factor IXa	CH3SO2-D-CHG-Gly-Arg-pNA.AcOH	628.7 g/mole	10 µmoles	299
SPECTROFLUOR™ FIXa	Fluorgenic substrate for the amidolytic assay of Factor IXa	CH3SO2-D-CHG-Gly-Arg-AMC·AcOH	665.8 g/mole	10 µmole vial	299F
				50 µmole vial	299FL
REACTIVE WITH FACTOR XA					
PRODUCT NAME	DESCRIPTION	MOLECULAR FORMULA	MOLECULAR WEIGHT	VIAL SIZE	REF
SPECTROZYME® FXa	Chromogenic substrate for the amidolytic assay of Factor Xa	CH3O-CO-D-CHG-Gly-Arg-pNA.AcOH	608.7 g/mole	5 µmole vial	222
				50 µmole vial	222L
				0.5 gram vial	222B
SPECTROFLUOR™ FXa	Fluorogenic substrate for the amidolytic assay of Factor Xa	CH3SO2-D-CHA-Gly-Arg-AMC·AcOH	679.8 g/mole	10 µmole vial	222F
REACTIVE WITH LIMULUS AMOEBOCYTE LYSATE (LAL)					
PRODUCT NAME	DESCRIPTION	MOLECULAR FORMULA	MOLECULAR WEIGHT	VIAL SIZE	REF
SPECTROZYME® LAL	Chromogenic substrate for assaying the presence of gram-negative bacterial endotoxins	CH3O-CO-D-CHA-Gly-Arg-pNA•AcOH	622.7 g/mole	100 µmole vial	200/086

REACTIVE WITH PLASMIN					
PRODUCT NAME	DESCRIPTION	MOLECULAR FORMULA	MOLECULAR WEIGHT	VIAL SIZE	REF
SPECTROZYME® PL	Chromogenic substrate for the amidolytic assay of Plasmin	H-D-Nle-CHA-Lys-pNA.2AcOH	652.8 g/mole	50 µmole vial	251L
REACTIVE WITH PROTEIN C					
PRODUCT NAME	DESCRIPTION	MOLECULAR FORMULA	MOLECULAR WEIGHT	VIAL SIZE	REF
SPECTROZYME® PCa	Chromogenic substrate for the amidolytic assay of Activated Protein C	H-D-Lys (γ-Cbo)-Pro-Arg-pNA.2AcOH	773.8 g/mole	10 µmole vial	336
REACTIVE WITH THROMBIN					
PRODUCT NAME	DESCRIPTION	MOLECULAR FORMULA	MOLECULAR WEIGHT	VIAL SIZE	REF
SPECTROZYME® TH	Chromogenic substrate for the amidolytic assay of Thrombin	H-D-CHA-Ala-Arg-pNA.2AcOH	638.7 g/mole	5 µmole vial	238
				50 µmoles	238L
				0.5 grams	238B
REACTIVE WITH TISSUE PLASMINOGEN ACTIVATOR					
PRODUCT NAME	DESCRIPTION	MOLECULAR FORMULA	MOLECULAR WEIGHT	VIAL SIZE	REF
SPECTROZYME® tPA	Chromogenic substrate for the amidolytic assay of tPA	CH3SO2-D-CHA-Gly-Arg-pNA·AcOH	642.7 g/mole	0.5 gram vial	444B

PRODUCT NAME	CLONE ID	HOST	ISOTYPE	APPLICATIONS	SIZE	REF
Factor Va, Human					50 µg	405
Factor VIIa, Human, Recombinant					1.0 mg	407REC/N
ANTIBODIES						
Murine MAb Against Human FVIIa	IIH2	Mouse	IgG1		200 µg	2282
Murine MAb Against Human Factor VIII	ESH-8	Mouse	IgG2a	IHC, IP	0.5 mg	ESH-8
Factor IXa, Human					500 µg	449B
Factor X, Human					80 µg	527
Factor Xa, Human					80 µg	526
Factor XIa, Human					50 µg	4011A
Factor XIIa, Human					0.5 mg	412HA
ANTIBODIES						
Murine MAb Against Human Fibrin	α-Fib Beta	Mouse	IgG1	IHC	0.5 mg	350
Murine MAb Against Gla (Gamma-Carboxyglutamyl) Amino Acid	M3B	Mouse	IgG2b	IP, WB	0.5 mg	3570
Murine MAb Against Human Growth Hormone Receptor	263	Mouse	IgG1	IHC, INH, IP	1 mg	7263B
Kallikrein, Human					1 mg	473
Plasmin, Human					2 mg	411
Plasminogen, Glu type, Human					5 mg	400
Plasminogen, Glu type, Human					1 mg	410
Plasminogen, Bovine					1 mg	416
ANTIBODY						
Murine MAb Against Human PAI-1		Mouse	IgG1	IHC, INH, WB	0.5 mg	3785
Streptokinase					10,000,000 IU	155
Thrombin, Alpha, Human					2,500 IU	470HT
Thrombomodulin, Human, Recombinant					10 µg	2374
Thrombomodulin, Rabbit					30 units	237
Tissue Factor, Human, recombinant					25 µg	4500
Tissue Factor, Human, recombinant, re-lipidated					250 ng	4500L/B
ANTIBODIES						
Goat Anti-Human Tissue Factor IgG	Polyclonal	Goat	IgG	IHC, WB	1 mg	4501
Murine MAb Against Human Tissue Factor		Mouse	IgG1	FC, IHC, IP, WB	0.5 mg	4503
Murine MAb Against Human Tissue Factor, FITC Conjugated	VIC7	Mouse	IgG1	IF, FC	50 µg	4507CJ
Murine MAb Against Human Tissue Factor, FITC Conjugated	VD8	Mouse	IgG1	IF, FC	50 µg	4508CJ
Murine MAb Against Human Tissue Factor	IIID8	Mouse	IgG1	IHC, INH, WB	0.5 mg	4509
Rabbit Anti-Mouse Tissue Factor IgG	Polyclonal	Rabbit	IgG		250 µg	4515
Tissue Factor Pathway Inhibitor (TFPI), Human, Recombinant					1 mg	4900B
Urokinase (uPA), human					100,000 IU	128
von Willebrand Factor (vWF), human, FVIII free					100 µg	2042

FC = Flow Cytometry
IF = Immunofluorescence
IHC = Immunohistochemistry
INH = Inhibitory
IP = Immunoprecipitation
WB = Western Blo

PRODUCT NAME	CERTIFICATION	SIZE	REF
Activated Protein C Resistance		3 x 1.0 mL Normal	840C
		3 x 1.0 mL Factor V	
		Leiden Heterozygous	
HEMOSTASIS	**CERTIFICATION**	**SIZE**	**REF**
QuikCoag Control Level 1 Normal	IVD	10 x 1.0 mL	C.BMD.CON1-01ML-8A
QuikCoag Control Level 2 Low Abnormal	IVD	10 x 1.0 mL	C.BMD.CON2-01ML-8A
QuikCoag Control Level 3 High Abnormal	IVD	10 x 1.0 mL	C.BMD.CON3-01ML-8A
QuikCoag Fibrinogen Control Abnormal	CE Mark		
	Health Canada	10 x 1.0 mL	C.BMD.FIBL-01ML-8A
QuikCoag Fibrinogen Control Normal	CE Mark		
	Health Canada	10 x 1.0 mL	C.BMD.FIBN-01ML-8A
QuikCoag Multi-Parmater Control Level 1 Normal	Health Canada	10 x 1.0 mL	C.BMD.CON1/3P-01ML-8A
QuikCoag Multi-Paramater Control Level 2 Abnormal	Health Canada	10 x 1.0 mL	C.BMD.CON2/3P-01ML-8A
Routine Coagulation Control Abnormal	CE Mark	10 x 1.0 mL	RCCA-040
Routine Coagulation Control Normal	CE Mark	10 x 1.0 mL	RCCN-040
Special Coagulation Control Abnormal	CE Mark	10 x 1.0 mL	SCCA-180
Special Coagulation Control Normal	CE Mark	10 x 1.0 mL	SCCN-180
LUPUS ANTICOAGULANT	**CERTIFICATION**	**SIZE**	**REF**
LAtrol™ Abnormal Control Plasma	IVD	10 x 0.5 mL	816A
LAtrol™ Normal Control Plasma	IVD	10 x 1.0 mL	816N
FACTOR DEFICIENT PLASMAS	**CERTIFICATION**	**SIZE**	**REF**
Antithrombin III	RUO	0.5 mL	203
Factor VIII	RUO	10 x 1.0 mL	268
Protein C	IVD	1.5 mL	ACC-45DP
Protein S	IVD	1.0 mL	843LDP
Tissue Factor Pathway Inhibitor (TFPI)	RUO	0.5 mL	848DP
tPA/PAI-1	RUO	1.0 mL	273

BIOMEDICA
DIAGNOSTICS

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