Hemostasis reagents portfolio

Trusted hemostasis testing solutions that help you deliver consistent results and enhance patient outcomes.

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SIEMENS Healthineers

Siemens Healthineers hemostasis reagents portfolio

Siemens Healthineers history of innovation in hemostasis testing spans more than 40 years. Our assays comprise a broad selection of testing solutions to support physicians in making sound diagnostic and therapeutic decisions. The hemostasis assay portfolio ranges from standard PT and APTT testing to the breakthrough von Willebrand factor activity-testing technology in our INNOVANCE® VWF Ac Assay. The broad portfolio addresses simplified workflow through ready-to-use and liquid reagent compositions. No matter how routine or specialized your testing, we are committed to delivering new systems and reagents that meet the needs of laboratories of all sizes.

Routine testing

	Reagent name	Reagent description and ready-to-use assay features	
PT	**Thromborel® S**	Thromborel S reagent is a lyophilized human placental thromboplastin reagent. The reagent initiates clotting via the extrinsic and common pathways in a global screening test, the prothrombin time (PT). PT is a clinically important test for the detection of coagulation abnormalities and can be used for monitoring of oral anticoagulant therapy in patients receiving vitamin K antagonists. Thromborel S reagent exhibits good correlation with the WHO international reference thromboplastin preparation. With the Thromborel S reagent and the appropriate deficient plasma, it is possible to determine activity of coagulation factors II, V, VII, and X. The reagent differentiates abnormal plasmas, even in the mildly pathological range.	
PT	**Dade® Innovin®**	Dade Innovin reagent is prepared from purified recombinant human tissue factor produced in E. coli, combined with synthetic phospholipids, calcium, buffers, and stabilizers. It is highly sensitive to extrinsic factor deficiencies and oral anticoagulant-treated patient plasma samples. The sensitivity of Dade Innovin reagent is very similar the first WHO human brain reference thromboplastin. It is insensitive to therapeutic levels of heparin, which, in combination with high sensitivity to coagulation factors, makes Dade Innovin reagent ideal for monitoring oral anticoagulant therapy (vitamin K antagonist) and differentiating abnormal plasmas, even in the mildly pathological range.	✓
APTT	**Dade Actin® Activated Cephaloplastin**	Dade Actin Activated Cephaloplastin reagent has moderate sensitivity to factor deficiencies (VIII, IX, XI, and XII) in the intrinsic system. It is the ideal choice for institutions requiring a moderate screening APTT reagent for routine testing. Dade Actin Activated Cephaloplastin reagent has low-moderate heparin sensitivity, allowing the monitoring of therapy with unfractionated heparin even with high heparin dosage. It has medium sensitivity to lupus anticoagulants.	💧 ✓
APTT	**Dade Actin FS Activated PTT**	Dade Actin FS Activated PTT reagent is a highly sensitive reagent for the detection of factor deficiencies (VIII, IX, XI and XII) of the intrinsic system. With low sensitivity to lupus anticoagulants and high sensitivity to heparin, it fulfills all requirements of routine coagulation testing.	💧 ✓
APTT	**Dade Actin FSL Activated PTT**	Dade Actin FSL Activated PTT reagent exhibits increased sensitivity to lupus anticoagulants and moderate heparin sensitivity. The reagent shows good factor sensitivity to detect clinically significant deficiencies of the intrinsic system.	💧 ✓
APTT	**Pathromtin® SL**	Pathromtin SL reagent exhibits high sensitivity to heparin and factor deficiencies and medium sensitivity to lupus anticoagulants.	💧

💧 Liquid formulation, no reconstitution required. ✓ No standing time required.

State-of-the art INNOVANCE reagents help expand precision medicine through improved diagnostic accuracy.

			Instrument availability				
Reagent name	**SMN Catalog no.**	**Package size**	**BFT™ II**	**CA-660***	**CS-2500 CS-5100**	**CN-3000 CN-6000**	
Thromborel S	10446442 OUHP29 10446445 OUHP49	10 x 4 mL 10 x 10 mL	●	●	●	●	PT
Dade Innovin	10445705 B4212-40 10445706 B4212-50 10445704 B4212-100	10 x 4 mL 10 x 10 mL 12 x 20 mL	●	●	●	●	PT
Dade Actin Activated Cephaloplastin	10445709 B4218-1 10445711 B4218-2	10 x 2 mL 10 x 10 mL	●	●	●	●	APTT
Dade Actin FS Activated PTT	10445712 B4218-20 10445710 B4218-100	10 x 2 mL 10 x 10 mL	●	●	●	●	APTT
Dade Actin FSL Activated PTT	10445713 B4219-1 10445714 B4219-2	10 x 2 mL 10 x 10 mL	●	●	●	●	APTT
Pathromtin SL	10446066 OQGS29 10446067 OQGS35 10873816†	10 x 5 mL 20 x 5 mL 10 x 10 mL	●	●	●	●	APTT

**Application on the CA-620 System may vary.*
†Only available for Germany and Austria.

Routine testing (continued)

	Reagent name	Reagent description and ready-to-use assay features	
Fibrinogen	**Multifibren® U**	Multifibren U reagent is a bovine thrombin reagent used in the modified Clauss determination of fibrinogen for the detection of hereditary or acquired hypo- and hyperfibrinogenemia and dysfibrinogenemia. The reagent is insensitive to heparin up to 2.0 U/mL and has a wide measuring range of 0.80–12.00 g/L.	
	Dade Thrombin	Dade Thrombin reagent is an effective reagent for use in the determination (Clauss method) of fibrinogen in the detection of hereditary or acquired hypo- and hyperfibrinogenemia, dysfibrinogenemia, and afibrinogenemia.	✓
	Dade Fibrinogen Determination	Dade Fibrinogen Determination reagent consists of Dade Thrombin reagent, Fibrinogen Standard, and Dade Owren's Veronal Buffer for use in the determination of fibrinogen (Clauss method) in the detection of hereditary or acquired hypo- and hyperfibrinogenemia, dysfibrinogenemia, and afibrinogenemia.	✓
	N Antiserum to Human Fibrinogen	As aid to diagnosis of fibrinogen deficiency or dysfibrinogenemia in patients with bleeding or thrombotic disorders. As fibrinogen reacts as "acute-phase" protein, plasma levels increase in response to acute and chronic inflammation, like infections, trauma, surgery, acute cardiac events or cancer.	💧 ✓
Thrombin Time/Batroxobin Time	**Thromboclotin®**	Thromboclotin reagent is intended for the determination of thrombin time. The reagent is suitable for monitoring of fibrinolytic therapy, screening for disorders of fibrin formation, in suspected cases of severe fibrinogen deficiency states, and for differentiation between heparin-induced prolongation of the thrombin time and disorders of fibrinogen formation. Thrombin time is found to be prolonged not only due to disorders in fibrin polymerization, but also due to the presence of heparin. Differentiation can be achieved using Batroxobin reagent.	✓
	Test Thrombin	Test Thrombin reagent is intended for the determination of thrombin time. The reagent is suitable for screening for disorders of fibrin formation, in suspected cases of severe fibrinogen deficiency states, and for differentiation between heparin-induced prolongation of thrombin time and disorders of fibrinogen formation. Thrombin time is found to be prolonged not only due to disorders in fibrin polymerization, but also due to the presence of heparin. Differentiation can be achieved using Batroxobin reagent.	✓
	Batroxobin	Batroxobin reagent is a snake venom-based reagent intended for the determination of the batroxobin time. It is ideal for monitoring fibrinolytic therapy by determination of fibrinogen/ fibrin degradation products, diagnosis of afibrinogenemia and dysfibrinogenemia, and elucidation of prolonged thrombin times in cases of suspected presence of heparin.	
D-dimer	**INNOVANCE D-Dimer**	INNOVANCE D-Dimer Kit is a rapid, highly precise, and sensitive test system for the determination of D-dimer. It offers high diagnostic sensitivity of >98% for exclusion of VTE (venous thromboembolism). With its extended assay range, D-dimer levels can also be used for the diagnosis and monitoring of patients with disseminated intravascular coagulopathy (DIC), as well as to estimate the risk of recurrent thrombosis and pregnancy-related coagulopathies (e.g., preeclampsia and HELLP syndrome).	

💧 Liquid formulation, no reconstitution required. ✓ No standing time required.

Reagent name	SMN Catalog no.	Package size	Instrument availability				
			BFT™ II	CA-660*	CS-2500 CS-5100	CN-3000 CN-6000	
Multifibren U	10446689 OWZG19 10446691 OWZG23	10 x 2 mL 10 x 5 mL	●	●			Fibrinogen
Dade Thrombin	10445720 B4233-25 10445721 B4233-27	10 x 1 mL 10 x 5 mL		●	●	●	Fibrinogen
Dade Fibrinogen Determination	10445718 B4233-15SY	Kit		●	●	●	Fibrinogen
N Antiserum to Human Fibrinogen	10446313 OSCA09	1 x 2 mL	The ready-to-use reagents can be tested on Atellica® NEPH 630 System, BN™ II System, and other systems.				Fibrinogen
Thromboclotin	10445597 281007	10 x 10 mL	●	●	●	●	Thrombin Time/Batroxobin Time
Test Thrombin	10446598 OWHM13	10 x 5 mL	●	●	●	●	Thrombin Time/Batroxobin Time
Batroxobin	10446463 OUOV21	2 x 5 mL	●	●	●	●	Thrombin Time/Batroxobin Time
INNOVANCE D-Dimer	10445979 OPBP03 10445980 OPBP07	Small Kit Large Kit		●	●	●	D-dimer

**Application on the CA-620 System may vary.*

Bleeding Risk Management

	Reagent name	Reagent description and ready-to-use assay features	
Single Factors	**Coagulation Factor II Deficient Plasma**	Coagulation Factor II Deficient Plasma is a human plasma-based reagent for the detection of hereditary or acquired deficiencies of factor II (prothrombin). It is manufactured by immunoabsorption and contains a residual factor concentration of <1% prothrombin activity and normal levels of fibrinogen and other extrinsic clotting factors. Coagulation Factor II Deficient Plasma was designed to be used in combination with Dade Innovin or Thromborel S reagents.	
	Coagulation Factor V Deficient Plasma	Coagulation Factor V Deficient Plasma is a human plasma-based reagent for the detection of hereditary or acquired deficiencies of factor V. It is manufactured by immunoabsorption and contains a residual factor concentration of <1% factor V activity and normal levels of fibrinogen and other extrinsic clotting factors. Coagulation Factor V Deficient Plasma was designed to be used in combination with Dade Innovin or Thromborel S reagents.	
	Coagulation Factor VII Deficient Plasma	Coagulation Factor VII Deficient Plasma is a human plasma-based reagent for the detection of hereditary or acquired deficiencies of factor VII. It is manufactured by immunoabsorption and contains a residual factor concentration of <1% factor VII activity and normal levels of fibrinogen and other extrinsic clotting factors. Coagulation Factor VII Deficient Plasma was designed to be used in combination with Dade Innovin or Thromborel S reagents.	
	Coagulation Factor VIII Deficient Plasma	Coagulation Factor VIII Deficient Plasma is a human plasma-based reagent for the detection of hereditary or acquired deficiencies of factor VIII (hemophilia A). With a residual factor VIII activity of <1% and a normal concentration of remaining coagulation factors and von Willebrand factor, the reagent is ideal for the monitoring of substitution therapy. Coagulation Factor VIII Deficient Plasma was designed to be used in combination with Dade Actin, Dade Actin FS, Dade Actin FSL, or Pathromtin SL reagents.	
	Coagulation Factor IX Deficient Plasma	Coagulation Factor IX Deficient Plasma is a human plasma-based reagent for the detection of hereditary or acquired deficiencies of factor IX (hemophilia B). With a residual factor IX activity of <1% and a normal concentration of remaining coagulation factors the reagent is ideal for the monitoring of substitution therapy. Coagulation Factor IX Deficient Plasma was designed to be used in combination with Dade Actin, Dade Actin FS, Dade Actin FSL, or Pathromtin SL reagents.	
	Coagulation Factor X Deficient Plasma	Coagulation Factor X Deficient Plasma is a human plasma-based reagent for the detection of hereditary or acquired deficiencies of factor X. It is manufactured by immunoabsorption and contains a residual factor concentration of <1% factor X activity and normal levels of fibrinogen and other extrinsic clotting factors. Coagulation Factor X Deficient Plasma was designed to be used in combination with Dade Innovin or Thromborel S reagents.	
	Coagulation Factor XI Deficient Plasma	Coagulation Factor XI Deficient Plasma is a human plasma-based reagent for the detection of hereditary or acquired deficiencies of factor XI. The reagent has a residual factor concentration of <1% factor XI activity and was designed to be used in combination with Dade Actin, Dade Actin FS, Dade Actin FSL, or Pathromtin SL reagents.	
	Coagulation Factor XII Deficient Plasma	Coagulation Factor XII Deficient Plasma is a human plasma-based reagent for the detection of hereditary or acquired deficiencies of factor XII. The reagent has a residual factor concentration of <1% factor XII activity and was designed to be used in combination with Dade Actin, Dade Actin FS, Dade Actin FSL, or Pathromtin SL reagents.	
	Berichrom® Factor XIII	Berichrom FXIII Kit is a chromogenic, assay for the quantitative determination of factor XIII activity as an aid in diagnosis and monitoring of congenital or acquired FXIII deficiencies. This chromogenic activity reagent is also used for the monitoring of patients undergoing factor XIII substitution therapy.	
	Factor VIII Chromogenic Assay	Factor VIII Chromogenic assay is recommended for factor FVIII determination in therapeutic factor FVIII preparations and the detection of hereditary or acquired factor VIII deficiencies. The chromogenic method is insensitive to heparin at levels of <10 IU/mL.	
	BIOPHEN Factor IX	The BIOPHEN FIX kit is a chromogenic method for the in vitro quantitative determination of factor IX activity on citrated human plasma or therapeutic concentrates, based on an automated or manual amidolytic method.	✓
von Willebrand Factor	**INNOVANCE VWF Ac**	INNOVANCE VWF Ac Kit is a sensitive, reliable, and convenient test system for direct determination of VWF activity using the recommended VWF:GPIbM technology. That allows the assay to mimic the way in which VWF binds to glycoprotein Ib (GPIb), the major VWF receptor protein on platelets. Latex particles are coated with an antibody against GPIb, to which recombinant GPIb is added. The addition of patient plasma induces a VWF-dependent agglutination, which is detected turbidimetrically. Because the recombinant receptor protein includes two gain-of-function mutations, the assay does not require ristocetin.	💧 ✓
	BC von Willebrand	BC von Willebrand reagent provides a simple, rapid, and automated procedure for the determination of the ristocetin cofactor activity of von Willebrand factor.	
	vWF Ag	vWF Ag Kit is a quantitative, automated immunoassay used to determine the concentration of VWF in plasma. VWF antigen determination is indicated as an aid in diagnosis of congenital or acquired vWF deficiency states and for differentiation of type 1 and type 2 VWD in combination with vWF activity methods. The kit offers a wide measuring range of 2–600%.	💧

💧 Liquid formulation, no reconstitution required. ✓ No standing time required.

			Instrument availability				
Reagent name	**SMN Catalog no.**	**Package size**	**BFT *II***	**CA-660***	**CS-2500 CS-5100**	**CN-3000 CN-6000**	
Coagulation Factor II Deficient Plasma	10446330 OSGR13	3 x 1 mL	●		●	●	Single Factors
Coagulation Factor V Deficient Plasma	10446269 ORSM19	8 x 1 mL	●		●	●	
Coagulation Factor VII Deficient Plasma	10446407 OTXV13	3 x 1 mL	●	●	●	●	
Coagulation Factor VIII Deficient Plasma	10446411 OTXW17	8 x 1 mL	●	●	●	●	
Coagulation Factor IX Deficient Plasma	10446414 OTXX17	8 x 1 mL	●		●	●	
Coagulation Factor X Deficient Plasma	10446415 OTXY13	3 x 1 mL	●		●	●	
Coagulation Factor XI Deficient Plasma	10446316 OSDF13	3 x 1 mL	●		●	●	
Coagulation Factor XII Deficient Plasma	10446318 OSDG13	3 x 1 mL	●		●	●	
Berichrom Factor XIII	10446652 OWSU11	Kit			●	●	
Factor VIII Chromogenic Assay	10445729 B4238-40	Kit			●	●	
BIOPHEN Factor IX	221802 10873620	2 x 2.5 mL			●†	●†	
INNOVANCE VWF Ac	10487040 OPHL03	Kit		●	●	●	von Willebrand Factor
BC von Willebrand	10446425 OUBD37	5 x 4 mL			●	●	
vWF Ag	10445967 OPAB03	Kit		●	●	●	

**Application on the CA-620 System may vary.*
†HYPHEN BioMed application.

Bleeding Risk Management (continued)

	Reagent name	Reagent description and ready-to-use assay features
Platelet function	**INNOVANCE PFA P2Y Cartridges**	INNOVANCE PFA P2Y Cartridge is used for the detection of P2Y12 receptor blockade in patients undergoing therapy with a P2Y12 receptor blockade antagonist.
	Dade PFA Collagen/EPI Test Cartridges	Dade PFA Collagen/EPI Test Cartridge is used for the detection of platelet dysfunction; screening for intrinsic platelet defects, von Willebrand disease, or exposure to platelet inhibiting agents; presurgical screening for bleeding risk. The cartridge is sentitiv to aspirin, DDAVP and all types of von Willebrand disease (except 2N), hereditary platelet defects, and low platelet count (<150000/µL).
	Dade PFA Collagen/ADP Test Cartridges	Dade PFA Collagen/ADP Test Cartridges are used for the differentiation of aspirin effect on platelets versus other platelet dysfunctions. It is insensitive to aspirin, yet sensitive to VWD, low platelet counts, and other platelet dysfunctions.
	Dade PFA Trigger Solution	Dade PFA Trigger Solution is an isotonic buffer solution used to trigger the membrane in cartridges for PFA Systems.
Platelet aggregation	**ADP**	ADP reagent is used for screening of systemic and acquired thrombocytopathy. It is also intended for the biological monitoring of anti-platelet therapy such as aspirin, NSAIDS, thienopyridines, abciximab, or other glycoprotein IIb/IIIa (GPIIbIIIa) inhibitors.
	Epinephrine	Epinephrine reagent is used for screening of systemic or acquired thrombocytopathy as well as biological monitoring of anti-platelet therapy.
	Arachidonic Acid	Arachidonic Acid reagent is used for the measurement of platelet aggregation. Besides the diagnosis of systemic or acquired platelet dysfunction, it can be used for the biological monitoring of patients undergoing an anti-platelet therapy such as acetylsalicylic acid.
	Ristocetin	Ristocetin reagent is available for use in ristocetin-induced platelet aggregation (RIPA) tests. It is used to detect von Willebrand disease, more specifically, to highlight an increased affinity in von Willebrand factor (vWF) for GPIb in type 2B and to identify Bernard-Soulier syndrome.
	Collagen	Collagen reagent is used for the detection of constitutional or acquired thrombocytopathy. Further, it can be used for biological monitoring of anti-platelet therapy.

Thrombophilia Risk Factors

	Reagent name	Reagent description and ready-to-use assay features
Antithrombin	**INNOVANCE Antithrombin**	The quantitative, chromogenic INNOVANCE Antithrombin assay is used as aid to diagnosis/monitoring of congenital/acquired antithrombin deficiencies, and for monitoring substitution therapy. The liquid, ready-to-use assay for functional antithrombin determination is based on human factor Xa, is traceable to an international standard, provides a broad measuring range and practical automation, and has also been shown to provide excellent precision and high sensitivity for a variety of mutations.
	N Antiserum to Human Antithrombin III	The quantitative, turbidimetric asssay is used as aid to diagnosis/monitoring of congenital/acquired antithrombin (AT) deficiencies in patients at risk for or suspected to have AT deficiency. Together with an activity assay, the AT antigen assay can help differentiating antithrombin type (I or II) deficiency.[1]
	Berichrom Antithrombin III (A)	The Berichrom Antithrombin III (A) Kit is a quantitative, chromogenic activity assay for the detection of hereditary or acquired antithrombin deficiency and the monitoring of patients undergoing substitution therapy. The heparin co-factor-independent lyophilized reagent uses bovine thrombin and exhibits no interference with anti-FXa anticoagulants (e.g., rivaroxaban).
Lupus	**LA 1 Screening**	LA 1 Screening reagent contains dilute Russell's viper venom and low phospholipids for use in the simplified DRVVT as a screening test for lupus anticoagulants. The LA 1 Screening reagent was designed to be used in conjunction with the LA 2 Confirmation reagent.
	LA 2 Confirmation	LA 2 Confirmation reagent is a simplified dilute Russell's viper venom test rich in phospholipids, making it ideal for the confirmation of lupus anticoagulants. The LA 2 Confirmation reagent was designed to be used in conjunction with the LA 1 Screening reagent.

Liquid formulation, no reconstitution required. ✓ No standing time required.

			Instrument availability				
Reagent name	**SMN Catalog no.**	**Package size**	**PFA-100**	**INNOVANCE PFA-200®**	**CS-2500 CS-5100**	**CN-3000 CN-6000**	
INNOVANCE PFA P2Y Cartridges	10445700 B4170-22	1 x 20 cartridges	●	●			Platelet function
Dade PFA Collagen/EPI Test Cartridges	10445696 B4170-20	1 x 20 cartridges	●	●			
Dade PFA Collagen/ADP Test Cartridges	10445698 B4170-21	1 x 20 cartridges	●	●			
Dade PFA Trigger Solution	10445701 B4170-50	3 x 11 mL	●	●			
ADP	10873606 AG001K	3 x 0.5 mL			●†	●†	Platelet aggregation
Epinephrine	10873608 AG002K	3 x 0.5 mL			●†	●†	
Arachidonic Acid	10873610 AG003K	3 x 0.5 mL			●†	●†	
Ristocetin	10873612 AG004K	3 x 0.5 mL			●†	●†	
Collagen	10873614 AG005K	3 x 0.5 mL			●†	●†	

			Instrument availability				
Reagent name	**SMN Catalog no.**	**Package size**	**BFT *II***	**CA-660***	**CS-2500 CS-5100**	**CN-3000 CN-6000**	
INNOVANCE Antithrombin	10446014 OPFH03 10709521 OPFH11 10446015 OPFH05	Small Kit Medium Kit Large Kit		●	●	●	Antithrombin
N Antiserum to Human Antithrombin III	10873655 OSAY13 10446310 OSAY09	1 x 2 mL	The ready-to-use reagents can be tested on Atellica NEPH 630 System, BN II System, and other systems.				
Berichrom Antithrombin III (A)	10446673 OWWR17 10446672 OWWR15	Small Kit Large Kit		●	●	●	
LA 1 Screening	10446063 OQGP17	10 x 2 mL	●	●	●	●	Lupus
LA 2 Confirmation	10446064 OQGR13	10 x 1 mL	●	●	●	●	

**Application on the CA-620 System may vary.*
†HYPHEN BioMed application.

Thrombophilia Risk Factors (continued)

	Reagent name	Reagent description and ready-to-use assay features
Protein C	**Protein C**	Protein C reagent is a coagulometric reagent used for the quantitative determination of protein C activity. The reagent is suitable for the detection of hereditary or acquired protein C deficiencies.
	Berichrom Protein C	The Berichrom Protein C Kit, a chromogenic activity assay, is used for the detection of hereditary or acquired protein C deficiency types. The assay is also used for the monitoring of substitution therapy with protein C concentrates in congenital protein C deficiency. The Berichrom Protein C Kit is less susceptible to interfering substances than a clotting assay ✓
Free Protein S Ag	**Protein S Ac**	Protein S Ac reagent, a coagulometric activity reagent, is used for the quantitative detection of hereditary or acquired protein S deficiencies.
	INNOVANCE Free PS Ag	The INNOVANCE Free PS Ag Kit is an easy-to-use, highly specific and stable assay for the quantitative detection of free protein S in human plasma. It is based on monoclonal antibodies and employs polystyrene particles covalently coated with two monoclonal antibodies (mAb A and mAb B) that have high specificity for free protein S and do not bind to protein S/C4b-binding protein complexes; the high specificity also shows no major interferences, including interferences commonly incurred from rheumatoid factors and heterophilic antibodies. The ready-to-use liquid reagent provides excellent stability performance as well as precision. ◊ ✓
FV Leiden/ APC Resistance	**ProC® Global ProC Global/FV**	In combination with the factor V (FV) deficient plasma, the ProC Global/FV assay is used to diagnose the presence of coagulation FV Leiden mutation and has been shown to provide high sensitivity for a variety of mutations. A heparin neutralizer enables determination in the presence of heparin levels of up to 0.8 U/mL. Without FV deficient plasma, ProC Global assay is used for the quantitative determination of the anticoagulatory capacity of the Protein C system.
	ProC Ac R	The ProC Ac R assay is for the quantitative, Russell Viper Venom-based determination of activated protein C resistance (APCR) as aid to diagnosis and screening for congenital factor V Leiden (FVL) mutation in patients with thromboembolic disease or at risk for APCR. The reagent is insensitive to heparin and is not influenced by high levels of factor VIII.

Anticoagulant Therapy Management

	Reagent name	Reagent description and ready-to-use assay features
Anticoagulant Therapy Management	**INNOVANCE Heparin**	The INNOVANCE Heparin Kit features an in vitro diagnostic automated chromogenic assay for the quantitative determination of the activity of unfractionated heparin (UFH) and low-molecular-weight heparin (LMWH) in citrated human plasma. The assay employs ready-to-use liquid reagents and a single hybrid calibration curve for LMWH and UFH. ◊ ✓
	INNOVANCE Anti-Xa	The INNOVANCE Anti-Xa Kit is an in vitro diagnostic reagent for the quantitative, WHO-standardized determination of unfractionated heparin (UFH) and low molecular weight heparin (LMWH) activity for monitoring patients under UFH or LMWH therapy in human sodium citrated plasma by means of automated, chromogenic methods. The assay employs ready-to-use liquid reagents and a single hybrid calibration curve for UFH and LMWH. In addition, the INNOVANCE Anti-Xa reagent is an in vitro diagnostic reagent for the quantitative determination of the direct factor Xa inhibitors rivaroxaban, apixaban and edoxaban as an aid in diagnosis to detect the anticoagulant status in patients under therapy with these factor Xa inhibitors in human sodium citrated plasma by means of automated, chromogenic methods. ◊ ✓
	INNOVANCE DTI	The INNOVANCE DTI Assay is an in vitro diagnostic reagent for the quantitative determination of the direct thrombin inhibitor dabigatran concentration to aid in the detection of dabigatran and quantification of the anticoagulant status of the patient under therapy with dabigatran in human sodium citrated plasma by means of automated, chromogenic methods. The assay employs ready-to-use reagents. ◊ ✓
	Other Direct Oral Anticoagulants (Xα)	

◊ Liquid formulation, no reconstitution required. ✓ No standing time required.

			Instrument availability				
Reagent name	**SMN Catalog no.**	**Package size**	**BFT *II***	**CA-660***	**CS-2500 CS-5100**	**CN-3000 CN-6000**	
Protein C	10446185 OQYG11	Kit	●	●	●	●	Protein C
Berichrom Protein C	10446499 OUVV17 10446500 OUVV15	Small Kit Large Kit		●	●	●	Protein C
Protein S Ac	10445968 OPAP03	Kit			●	●	Free Protein S Ag
INNOVANCE Free PS Ag	10446029 OPGL03	Kit			●	●	Free Protein S Ag
ProC Global ProC Global/FV	10446101 OQLS13	Kit	●		●	●	FV Leiden/ APC Resistance
ProC Ac R	10445977 OPBC03	Kit			●	●	FV Leiden/ APC Resistance

			Instrument availability				
Reagent name	**SMN Catalog no.**	**Package size**	**BFT *II***	**CA-660***	**CS-2500 CS-5100**	**CN-3000 CN-6000**	
INNOVANCE Heparin	10873448 OPOA03	Kit		●	●	●	Anticoagulant Therapy Management
INNOVANCE Anti-Xa	10873681 OPPU05	Kit		●‡	●	●	Anticoagulant Therapy Management
INNOVANCE DTI	10873467 OPOH03	Kit			●	●	Anticoagulant Therapy Management
Other Direct Oral Anticoagulants (Xα)	—	—	Available upon request				Anticoagulant Therapy Management

**Application on the CA-620 System may vary.*
‡Heparin application only.

Fibrinolysis and Other Specialties

	Reagent name	Reagent description and ready-to-use assay features	
Plasminogen	**Berichrom Plasminogen**	Berichrom Plasminogen Kit, a chromogenic activity test system, is used for the quantitative determination of plasminogen activity and the detection of hereditary or acquired plasminogen deficiencies.	✓
	N Antiserum to Human Plasminogen	As aid to diagnosis and monitoring of congenital or acquired plasminogen deficiencies in patients at risk for or suspected to have disorders of the fibrinolysis system. Congenital plasminogen deficiency (quantitative or qualitative) is a rare autosomal transmitted disorder, going along with an increased risk for development of an ocular complication called ligneous conjunctivitis. However, decreased plasminogen concentrations can also result from diminished synthesis (liver disease) or increased consumption, e.g. DIC, and thrombolytic therapy.	💧 ✓
α2-Antiplasmin	**Berichrom α2-Antiplasmin**	Berichrom α2-Antiplasmin Kit is used for the determination of α2-antiplasmin and the detection of hereditary or acquired α2-antiplasmin deficiencies. This chromogenic activity assay is also applicable for the assessment of thrombolytic therapy.	
Thrombin-antithrombin Complex	**Enzygnost TAT micro**	Enzygnost TAT micro is an ELISA assay for thrombin-antithrombin complex determination. The reagent is used for the diagnosis of hypercoagulability (e.g., in DIC).	
Prothrombin Fragment F1+2	**Enzygnost F 1+2 (monoclonal)**	Enzygnost F 1+2 (monoclonal) is an ELISA assay for prothrombin fragment 1 and 2 determination. The reagent is used for the diagnosis of hyper- and hypocoagulable states.	
C1-Inhibitor	**Berichrom C1-Inhibitor**	Berichrom C1-Inhibitor Kit is WHO-standardized and used for the quantitative determination of C1-inhibitor (C1-INH) activity as an aid to diagnosis of congenital or acquired C1-INH deficiencies in patients at risk for or suspected to have C1-INH deficiency, e.g., for the differentiation of bradykinin vs. histamin-mediated angioedema. It aids in the diagnosis of hereditary angioneurotic edema. Results are available within 9 minutes.	✓
	N Antiserum to Human C1-Inhibitor	As aid to diagnosis of congenital or acquired C1-Inhibitor deficiencies in patients at risk for or suspected to have C1-Inhibitor deficiency. Under conditions of C1-INH deficiency, uncontrolled activation of the contact system leads to overproduction of bradykinin, a potent vasoactive peptide thought to be the primary mediator of angioedema in hereditary angioedema (HAE, or Quincke's edema), an autosomal dominant genetic disorder. Acquired C1-INH deficiency goes along with the same symptoms of angioedema.	💧 ✓

💧 Liquid formulation, no reconstitution required. ✓ No standing time required.

			Instrument availability				
Reagent name	**SMN Catalog no.**	**Package size**	**BFT II**	**CA-660***	**CS-2500 CS-5100**	**CN-3000 CN-6000**	
Berichrom Plasminogen	10446431 OUCA17	Kit			●	●	Plasminogen
N Antiserum to Human Plasminogen	10446314 OSCB09	1 x 2 mL	The ready-to-use reagents can be tested on Atellica NEPH 630 System, BN II System, and other systems.				
Berichrom α2-Antiplasmin	10446427 OUBU15	Kit			●	●	α2-Antiplasmin
Enzygnost TAT micro	10446632 OWMG15	Kit	ELISA				Thrombin-antithrombin Complex
Enzygnost F 1+2 (monoclonal)	10445978 OPBD03	Kit	ELISA				Prothrombin Fragment F1+2
Berichrom C1-Inhibitor	10446446 OUIA15	Kit			●	●	C1-Inhibitor
N Antiserum to Human C1-Inhibitor	10446049 OQEY09	1 x 2 mL	The ready-to-use reagents can be tested on Atellica NEPH 630 System, BN II System, and other systems.				

**Application on the CA-620 System may vary.*

Controls

	Reagent name	Reagent description and ready-to-use assay features
Controls	**Control Plasma N**	Control Plasma N is a citrated normal human plasma pool. Control Plasma N is an assayed control used for the assessment of precision and analytical deviation of various analytes in the normal range.
	Control Plasma P	Control Plasma P is a citrated human plasma pool. Control Plasma P is an assayed control used for the assessment of precision and analytical deviation of various analytes in the pathological range.
	Dade Ci-Trol® 1, 2, and 3 Controls	Dade Ci-Trol Level 1, 2, and 3 Controls are citrated human plasma-based and intended for use as accuracy controls in the normal, mid, and upper therapeutic ranges for routine assays. The controls provide assigned values for the respective available analytes.
	Dade Ci-Trol Coagulation Control Level 1, 2, and 3	Dade Ci-Trol Coagulation Control Level 1, 2, and 3 Controls are citrated human plasma based and intended for use as accuracy controls in the normal, mid, and upper therapeutic ranges for routine assays. They are intended for use as unassigned controls.
	Dade Data-Fi Abnormal Fibrinogen Control Plasma	Dade Data-Fi Abnormal Fibrinogen Control Plasma is a control derived from human plasma. It is used to assess accuracy and precision of Dade Fibrinogen Determination reagents in the low range.
	LA Control Low	LA Control Low is a low-positive control for lupus anticoagulant clotting assays using LA 1 Screening and LA 2 Confirmation reagents.
	LA Control High	LA Control High is a high-positive control for lupus anticoagulant clotting assays using LA 1 Screening and LA 2 Confirmation reagents.
	ProC Control Plasma	ProC Control Plasma is an assayed intralaboratory control to estimate precision and analytical deviation of the ProC line of tests in the pathological range.
	Dade Ci-Trol Heparin Control, Low	Dade Ci-Trol Heparin Control, Low is a low-level control using the activated partial thromboplastin time.
	Dade Ci-Trol Heparin Control, High	Dade Ci-Trol Heparin Control, High is a high-level control using the activated partial thromboplastin time.
	INNOVANCE D-Dimer Controls	INNOVANCE D-Dimer Controls 1 and 2 are assayed controls for the assessment of precision and analytical bias in the normal and pathological range for the determination of D-dimer with INNOVANCE D-Dimer assay.
	INNOVANCE Heparin UF Control 1	INNOVANCE Heparin UF Control 1 is used for quality control of INNOVANCE Heparin/INNOVANCE Anti-Xa assays for the quantitative determination of unfractionated heparin (UFH) in citrated human plasma. Concentration of heparin ~0.3 IU/mL.
	INNOVANCE Heparin UF Control 2	INNOVANCE Heparin UF Control 2 is used for quality control of INNOVANCE Heparin/INNOVANCE Anti-Xa assays for the quantitative determination of unfractionated heparin (UFH) in citrated human plasma. Concentration of heparin ~0.7 IU/mL.
	INNOVANCE Heparin LMW Control 1	INNOVANCE Heparin LMW Control 1 is used for quality control of INNOVANCE Heparin/INNOVANCE Anti-Xa assays for the quantitative determination of low-molecular-weight heparin (LMWH) in citrated human plasma. Concentration of heparin ~0.4 IU/mL.
	INNOVANCE Heparin LMW Control 2	INNOVANCE Heparin LMW Control 2 is used for quality control of INNOVANCE Heparin/INNOVANCE Anti-Xa assays for the quantitative determination of low-molecular-weight heparin (LMWH) in citrated human plasma. Concentration of heparin ~1.0 IU/mL.

Liquid formulation, no reconstitution required. ✓ No standing time required.

			Instrument availability			
Reagent name	**SMN Catalog no.**	**Package size**	**BFT II**	**CA-660***	**CS-2500 CS-5100**	**CN-3000 CN-6000**
Control Plasma N	10446234 ORKE41	10 x 1 mL	●	●	●	●
Control Plasma P	10446471 OUPZ17	10 x 1 mL	●	●	●	●
Dade Ci-Trol 1, 2, and 3 Controls	10445601 291070 10445602 291071 10445603 291072	10 x 1 mL 10 x 1 mL 10 x 1 mL	●	●	●	●
Dade Ci-Trol Coagulation Control Level 1, 2, and 3	10445731 B4244-10 10445732 B4244-20 10445733 B4244-30	20 x 1 mL 20 x 1 mL 20 x 1 mL	●	●	●	●
Dade Data-Fi Abnormal Fibrinogen Control Plasma	10445719 B4233-22	10 x 1 mL		●	●	●
LA Control Low	10446154 OQWE11	6 x 1 mL	●	●	●	●
LA Control High	10446153 OQWD11	6 x 1 mL	●	●	●	●
ProC Control Plasma	10446096 OQKE17	6 x 1 mL	●		●	●
Dade Ci-Trol Heparin Control, Low	10445715 B4224-50	10 x 1 mL		●		
Dade Ci-Trol Heparin Control, High	10445716 B4224-60	10 x 1 mL		●		
INNOVANCE D-Dimer Controls	10446005 OPDY03	2 x 5 x 1 mL		●	●	●
INNOVANCE Heparin UF Control 1	10873452 OPOC03	5 x 1 mL		●	●	●
INNOVANCE Heparin UF Control 2	10873451 OPOD03	5 x 1 mL		●	●	●
INNOVANCE Heparin LMW Control 1	10873449 OPOE03	5 x 1 mL		●	●	●
INNOVANCE Heparin LMW Control 2	10873450 OPOF03	5 x 1 mL		●	●	●

Controls

**Application on the CA-620 System may vary.*

Controls continued

	Reagent name	Reagent description
Controls	**INNOVANCE Rivaroxaban Controls**	INNOVANCE Rivaroxaban Controls are used for quality control of INNOVANCE Anti-Xa assay for the quantitative determination of rivaroxaban in citrated human plasma. Includes two levels of rivaroxaban controls: Control 1 ~70 ng/mL; Control 2 ~260 ng/mL.
	INNOVANCE Apixaban Controls	INNOVANCE Apixaban Controls are used for quality control of INNOVANCE Anti-Xa assay for the quantitative determination of apixaban in citrated human plasma. Includes two levels of apixaban controls: Control 1 ~70 ng/mL; Control 2 ~260 ng/mL.
	INNOVANCE Edoxaban Controls	INNOVANCE Edoxaban Controls are used for quality control of INNOVANCE Anti-Xa assay for the quantitative determination of edoxaban in citrated human plasma. Includes two levels of edoxaban controls: Control 1 ~45 ng/mL; Control 2 ~260 ng/mL.
	Dabigatran Controls	Dabigatran Controls are used as assayed controls for INNOVANCE DTI assay for the quantification of dabigatran in human citrated plasma. Concentration of dabigatran: Control L ~65 ng/mL; Control H ~250 ng/mL.
	N/T Protein Control PY	N/T Protein Control PY is used for control of accuracy and precision in the immunochemical determination of fibrinogen, antithrombin III, plasminogen, and C1-Inhibitor on the Atellica NEPH 630, BN ProSpec®, or BN II systems.
Standards and Calibrators	**Standard Human Plasma**	Standard Human Plasma is citrated normal human pooled plasma intended for the calibration of various coagulation and fibrinolysis assays. Standard human plasma is calibrated against the respective WHO standard, where available.
	PT-Multi Calibrator	The PT-Multi Calibrator comprises a set of six plasmas intended for the direct calibration of prothrombin time (PT) in INR and % of norm. The calibrators are also suitable for the determination of a local ISI value. The single plasma levels have calibrated values for Innovin and Thromborel S reagents on each individual instrument.
	Fibrinogen Calibrator	The Fibrinogen Calibrator Kit comprises a set of six plasmas used to prepare reference curves for the fibrinogen assay by the modified Clauss method using Multifibren U reagent. (Fibrinogen levels 1–6 have a range of approximately 0.6–9.0 g/L.)
	INNOVANCE Heparin Calibrator	For calibration of the INNOVANCE Heparin/INNOVANCE Anti-Xa assays for the quantitative determination of the activity of unfractionated heparin (UFH) and low-molecular-weight heparin (LMWH) in citrated human plasma using a hybrid calibration curve. The calibrators are traceable to the WHO Standards for LMWH and UFH.
	INNOVANCE Rivaroxaban Standards	INNOVANCE Rivaroxaban Standards are used for calibration of INNOVANCE Anti-Xa assay for the quantitative determination of the concentration of rivaroxaban in citrated human plasma. The Standards set consists of a Standard 0 without rivaroxaban and a Standard 1 with ~420 ng/mL rivaroxaban.
	INNOVANCE Apixaban Standards	INNOVANCE Apixaban Standards are used for calibration of INNOVANCE Anti-Xa assay for the quantitative determination of the concentration of apixaban in citrated human plasma. The Standards set consists of a Standard 0 without apixaban and a Standard 1 with ~420 ng/mL apixaban.
	INNOVANCE Edoxaban Standards	INNOVANCE Edoxaban Standards are used for calibration of INNOVANCE Anti-Xa assay for the quantitative determination of the concentration of edoxaban in citrated human plasma. The Standards set consists of a Standard 0 without edoxaban and a Standard 1 with ~420 ng/mL edoxaban.
	Dabigatran Standards	Dabigatran Standards are used for the calibration of INNOVANCE DTI assay for the quantification of dabigatran in human citrated plasma. The Standards set consists of a Dabigatran Standard 0 and Dabigatran Standard 1 with a >500 ng/mL dabigatran.
	N Protein Standard PY	N Protein Standard PY is used for the establishment of reference curves for the immunochemical determination of fibrinogen, antithrombin III, plasminogen, and C1-inhibitor on the Atellica NEPH 630, BN ProSpec, or BN II systems.

			Instrument availability				
Reagent name	**SMN Catalog no.**	**Package size**	**BFT *II***	**CA-660***	**CS-2500 CS-5100**	**CN-3000 CN-6000**	
INNOVANCE Rivaroxaban Controls	10873676 OPPS03	2 x 5 x 1 mL			●	●	Controls
INNOVANCE Apixaban Controls	10873672 OPPV03	2 x 5 x 1 mL			●	●	
INNOVANCE Edoxaban controls	10873784	2 x 5 x 1 mL			●	●	
Dabigatran Controls	10873470 OPOK03	2 x 5 x 1 mL			●	●	
N/T Protein Control PY	10446655 OWSY13	3 x 1 mL	The ready-to-use reagents can be tested on Atellica NEPH 630 System, BN II System, and other systems.				
Standard Human Plasma	10446238 ORKL17	10 x 1 mL	●	●	●	●	Standards and Calibrators
PT-Multi Calibrator	10445969 OPAT03	6 x 1 mL	●	●	●	●	
Fibrinogen Calibrator	10446148 OQVK11	6 x 1 mL	●	●			
INNOVANCE Heparin Calibrator	10873453 OPOB03	5 x 1 x 1 mL		●	●	●	
INNOVANCE Rivaroxaban Standards	10873677 OPPT03	2 x 2 x 1 mL			●	●	
INNOVANCE Apixaban Standards	10873673 OPPW03	2 x 2 x 1mL			●	●	
INNOVANCE Edoxaban Standards	10873783	2 x 2 x 1mL			●	●	
Dabigatran Standards	10873471 OPOL03	2 x 3 x 1 mL			●	●	
N Protein Standard PY	10446449 OUI13	3 x 1 mL	The ready-to-use reagents can be tested on Atellica NEPH 630 System, BN II System, and other systems.				

**Application on the CA-620 System may vary.*

Supplementary

	Reagent name	Reagent description and ready-to-use assay features
Supplementary	**Calcium Chloride Solution**	Calcium Chloride Solution is used as a supplementary reagent for various coagulation tests.
	Dade Hepzyme®	Dade Hepzyme reagent is used as a heparin neutralizer in plasma to rule out heparin contamination in coagulation testing.
	Dade Owren's Veronal Buffer	Owren's Veronal Buffer is a dilution buffer for coagulation testing.
	INNOVANCE D-Dimer Diluent	INNOVANCE D-Dimer Diluent is a liquid used for dilution of samples with elevated D-dimer concentrations when running the INNOVANCE D-Dimer Assay.
	Imidazole Buffer Solution	Imidazole Buffer Solution is used as a supplementary reagent for various coagulation assays that run on the BFT II System.
	Kaolin Suspension	Kaolin Suspension is used as a supplementary reagent for various assays for the BFT II System.

Liquid formulation, no reconstitution required. ✓ No standing time required.

			Instrument availability				
Reagent name	**SMN Catalog no.**	**Package size**	**BFT II**	**CA-660***	**CS-2500 CS-5100**	**CN-3000 CN-6000**	
Calcium Chloride Solution	10446232 ORHO37	10 x 15 mL	●	●	●	●	Supplementary
Dade Hepzyme	10445730 B4240-10	10 x 1 mL	●	●	●	●	
Dade Owren's Veronal Buffer	10445724 B4234-25	10 x 15 mL		●	●	●	
INNOVANCE D-Dimer Diluent	10487039 OPBR03	10 x 5 mL		●	●	●	
Imidazole Buffer Solution	10446032 OQAA33	6 x 15 mL	●				
Kaolin Suspension	10446033 OQAB42	1 x 50 mL	●				

**Application on the CA-620 System may vary.*

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**Personalization of diagnosis, therapy selection and monitoring, aftercare, and managing health.*

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Reference:

1. Van Cott E, Orlando C, Moore GW, Cooper PC, Meijer P, Marlar R. Recommendations for clinical laboratory testing for antithrombin deficiency; communication from the SSC of the ISTH. J Thromb Haemost. 2020;18:17-22.

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