

# Hemostasis reagents portfolio

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

siemens-healthineers.com/hemostasis



## 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. While innovative testing solutions with LOCI® technology enable labs to stay at the cutting-edge of clinical advancements in hemostasis testing, 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.

	Reagent name	Reagent description and ready-to-use assay features		SMN Catalog no.	Package size
Td	Thromborel® S	Thromborel S reagent is prepared from human placental tissue factor combined with calcium chloride and stabilizers. The reagent contains minimal residual clotting factors, such as prothrombin or factors VII or X, for clear definition of factor deficiencies and steep factor assay curves. Because of its high sensitivity to these coagulation factors, the reagent is suitable for monitoring oral anticoagulant therapy.  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 reagen differentiates abnormal plasmas, even in the mildly pathological range.	10446442 OUHP29 10446445 OUHP49	10 x for 4 mL 10 x for 10 mL	
d	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 to that of the 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 and differentiating abnormal plasmas, even in the mildly pathological range.	<b>~</b>	10445705 B4212-40 10445706 B4212-50 10445704 B4212-100	10 x for 4 mL 10 x for 10 mL 12 x for 20 mL
	Dade Actin® Activated Cephaloplastin	for institutions requiring a moderate screening APTT reagent for routine testing.		10445709 B4218-1 10445711 B4218-2	10 x 2 mL 10 x 10 mL
АРТТ	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 moderate sensitivity to lupus anticoagulants and high sensitivity to heparin, it fulfills all requirements of routine coagulation testing.	<b>\( \lambda \)</b>	10445712 B4218-20 10445710 B4218-100	10 x 2 mL 10 x 10 mL
A	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.		10445713 B4219-1 10445714 B4219-2	10 x 2 mL 10 x 10 mL
	Pathromtin® SL	Pathromtin SL reagent exhibits high sensitivity to lupus anticoagulants, factor deficiencies, and heparin.	٥	10446066 OQGS29 10446067 OQGS35	10 x 5 mL 20 x 5 mL

<sup>△</sup> 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			
		Sys	stems and analyz	ers	Sysmex® systems			
	Reagent name	Atellica® COAG 360	BCS® XP	BFT™ <i>II</i>	CA-660*	CS-2500 CS-5100	CN-3000 CN-6000	
PT	Thromborel S	•	•	•	•	•	•	
	Dade Innovin	•	•	•	•	•	•	
	Dade Actin Activated Cephaloplastin		•	•	•	•	•	
APTT	Dade Actin FS Activated PTT	•	•	•	•	•	•	
Ā	Dade Actin FSL Activated PTT	•	•	•	•	•	•	
	Pathromtin SL	•	•	•	•	•	•	

<sup>\*</sup>Application on the Sysmex CA-620 System may vary.

	Reagent name	Reagent description and ready-to-use assay features	SMN Catalog no.	Package size
	Multifibren® U	Multifibren U reagent is a bovine thrombin reagent used in the modified Clauss determination of fibringen for the detection of hereditary or acquired hypo- and hyperfibringenemia	OWZG19	10 x for 2 mL
		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.	10446691 OWZG23	10 x for 5 mL
	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-	10445720 B4233-25	10 x for 1 mL
Fibrinogen		and hyperfibrinogenemia, dysfibrinogenemia, and afibrinogenemia. The reagent offers long stability after reconstitution.	10445721 B4233-27	10 x for 5 mL
Fibri	Dade Fibrinogen Determination	The 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. The reagent offers long stability after reconstitution.	10445718 B4233-15SY	Kit
	N Antiserum to Human Fibrinogen	Elevated concentrations of fibrinogen in plasma are to be expected in inflammatory processes, after major trauma or surgery ("acute-phase protein"), and also occur with metastasizing tumours. Diminished plasma levels of fibrinogen can occur in consumption coagulopathies, e.g., disseminated intravascular coagulation (DIC), primary hyperfibrinolysis, hepatic insufficiency, and genetic deficiency.	10873654 OSCA13	1 x 2 mL
	BC Thrombin	BC Thrombin reagent is used for the determination of thrombin time. It 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	10446636 OWNA11	Kit
Thrombin Time/Batroxobin Time	Thromboclotin®	achieved using Batroxobin reagent.  Thromboclotin reagent is intended for the determination of thrombin time in citrated human plasma. 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.	10445597 281007	10 x for 10 mL
Thrombin T	Test Thrombin	Test Thrombin reagent is intended for the determination of thrombin time in citrated human plasma. 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 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.	10446598 OWHM13	10 x for 5 mL
	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 fibrinoge fibrin degradation products, diagnosis of afibrinogenemia and dysfibrinogenemia, and elucidation of prolonged thrombin times in cases of suspected presence of heparin.	n/ 10446463 OUOV21	2 x for 5 mL

 $<sup>\</sup>bigwedge$  Liquid formulation, no reconstitution required.  $\checkmark$  No standing time required.

				Instrument	availability		
		Sys	stems and analyz	ers		Sysmex systems	
	Reagent name	Atellica COAG 360	BCS XP	BFT II	CA-660*	CS-2500 CS-5100	CN-3000 CN-6000
	Multifibren U	•	•	•	•		
Fibrinogen	Dade Thrombin	•			•	•	•
	Dade Fibrinogen Determination				•	•	•
	N Antiserum to Human Fibrinogen	•					
	BC Thrombin		•				
Thrombin Time/Batroxobin Time	Thromboclotin		•	•	•	•	•
Thrombin T	Test Thrombin	•		•	•	•	•
	Batroxobin	•	•	•	•	•	•

<sup>\*</sup>Application on the Sysmex CA-620 System may vary.

	Reagent name	Reagent description and ready-to-use assay features	SMN Catalog no.	Package size
	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.	10446330 OSGR13	3 x for 1 mL
	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.	10446269 ORSM19	8 x for 1 mL
	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.	10446407 OTXV13	3 x for 1 mL
	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 activity of <1%, 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.	10446411 OTXW17	8 x for 1 mL
Single Factors	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 activity of <1%, 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.	10446414 OTXX17	8 x for 1 mL
Single	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.	10446415 OTXY13	3 x for 1 mL
	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.	10446316 OSDF13	3 x for 1 mL
	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.	10446318 OSDG13	3 x for 1 mL
	Berichrom® Factor XIII	The Berichrom Factor XIII Kit is a chromogenic, quantitative assay for the detection of hereditary or acquired factor XIII deficiencies. The chromogenic activity reagent is also used for the monitoring of patients undergoing factor XIII substitution therapy.	10446652 OWSU11	Kit
	Factor VIII Chromogenic Assay	The 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.	10445729 B4238-40	Kit
	BIOPHEN	The BIOPHEN FIX kit is a chromogenic method for the in vitro quantitative determination of Factor IX activity on citrated human plasma or therapeutic	221802 10873620	2 x 2.5 mL
	Factor IX	concentrates, based on an automated or manual amidolytic method.	221806 10873622	2 x 6 mL

<sup>✓</sup> No standing time required.

		Instrument availability						
		Sys	tems and analyze	ers		Sysmex systems		
	Reagent name	Atellica COAG 360	BCS XP	BFT II	CA-660*	CS-2500 CS-5100	CN-3000 CN-6000	
	Coagulation Factor II Deficient Plasma	•	•	•		•	•	
	Coagulation Factor V Deficient Plasma	•	•	•		•	•	
	Coagulation Factor VII Deficient Plasma	•	•	•	•	•	•	
	Coagulation Factor VIII Deficient Plasma	•	•	•	•	•	•	
	Coagulation Factor IX Deficient Plasma	•	•	•		•	•	
ח	Coagulation Factor X Deficient Plasma	•	•	•		•	•	
	Coagulation Factor XI Deficient Plasma	•	•	•		•	•	
	Coagulation Factor XII Deficient Plasma	•	•	•		•	•	
	Berichrom Factor XIII	•	•			•	•	
	Factor VIII Chromogenic Assay	•	•			•	•	
	BIOPHEN Factor IX	•				•	•	

 $<sup>{\</sup>rm *Application\ on\ the\ Sysmex\ CA-620\ System\ may\ vary}.$ 

	Reagent name	Reagent description and ready-to-use assay features		SMN Catalog no.	Package size
nd Factor	INNOVANCE VWF Ac	The INNOVANCE VWF Ac Kit is a sensitive, reliable, and convenient test system for direct determination of VWF activity. It employs an advanced new technology that allows the assay to mimic the way in which VWF binds to glycoprotein lb (GPlb), the major VWF receptor protein on platelets. Latex particles are coated with an antibody against GPlb, to which recombinant GPlb 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.	<b>\( </b>	10487040 OPHL03	Kit
von Willebrand Factor	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. The reagent, which provides a rapid measurement time, is sensitive to types 1, 2, and 3 of von Willebrand discount (except VWD 2N) and is the recommended screening method for von Willebrand disease.		10446425 OUBD37	5 x for 4 mL
	vWF Ag	vWF Ag Kit contains is a quantitative, automated immunoassay used to determine the differentiation of quantitative versus qualitative von Willebrand factor deficiencies. It is sensitive to type 1 and 3 VWF deficiencies and offers a wide measuring range of 2–600%.	٥	10445967 OPAB03	Kit
	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.	<b>~</b>	10446063 OQGP17	10 x for 2 mL
	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.	<b>~</b>	10446064 OQGR13	10 x for 1 mL
	ProC® Global ProC Global/FV	ProC Global Kit is a coagulometric screening reagent for the protein C pathway. It provides a determination of the anticoagulatory capacity of the protein C system. The heparininsensitive reagent is useful in screening individuals affected by thrombophilia. ProC Glo Kit is sensitive to deficiencies of factor V Leiden and proteins C and S, certain lupus anticoagulants, and high factor VIII levels.		10446101 OQLS13	Kit
	ProC Ac R	The ProC Ac R Kit, a dilute Russell's viper venom test with a sensitivity and specificity of >99 screens for APC resistance due to the presence of factor V Leiden in patient samples. The reagent is insensitive to heparin and is not influenced by high levels of factor VIII.	9%,	10445977 OPBC03	Kit
Thrombophilia	INNOVANCE Free PS Ag	The INNOVANCE Free PS Ag Kit is an easy-to-use, highly specific, and stable test 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.	<b>\( \)</b>	10446029 OPGL03	Kit
_	Protein S Ac	Protein S Ac reagent, a coagulometric activity reagent, is used for the detection of herecor acquired protein S deficiencies.	ditary	10445968 OPAP03	Kit
	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.		10446185 OQYG11	Kit
	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.	<b>~</b>	10446499 OUVV17 10446500 OUVV15	Small Kit Large Kit
	INNOVANCE Antithrombin	The INNOVANCE Antithrombin Kit is an automated chromogenic assay for the quantitative determination of functional antithrombin. The human factor Xa-based reagent has minimal interference with heparin cofactor II and thrombin inhibitors such as hirudin. The ready-to-use liquid reagents provide excellent precision and reliability.	<b>\rightarrow</b>	10446014 OPFH03 10709521 OPFH11	Small Kit Medium Kit
				10446015 OPFH05	Large Kit

 $<sup>\</sup>bigwedge$  Liquid formulation, no reconstitution required.  $\checkmark$  No standing time required.

		Instrument availability					
		Sys	tems and analyz	ers		Sysmex systems	
	Reagent name	Atellica COAG 360	BCS XP	BFT II	CA-660*	CS-2500 CS-5100	CN-3000 CN-6000
nd Factor	INNOVANCE VWF Ac	•	•		•	•	•
von Willebrand Factor	BC von Willebrand		•			•	•
	vWF Ag	•	•		•	•	•
	LA 1 Screening	•	•	•	•	•	•
	LA 2 Confirmation	•	•	•	•	•	•
	ProC Global ProC Global/FV	•	•	•		•	•
	ProC Ac R	•	•			•	•
Thrombophilia	INNOVANCE Free PS Ag	•	•			•	•
두	Protein S Ac	•†	•			•	•
	Protein C	•	•	•	•	•	•
	Berichrom Protein C	•	•		•	•	•
	INNOVANCE Antithrombin	•	•		•	•	•

<sup>\*</sup>Application on the Sysmex CA-620 System may vary. †Siemens Healthineers application is under development.

	Reagent name	Reagent description and ready-to-use assay features		SMN Catalog no.	Package size
ohilia	N Antiserum to Human Antithrombin III	Immunoassay (antigen) for the quantitative determination of antithrombin in human plasma. Together with an activity assay, an antigen assay for antithrombin can help differentiating antithrombin type (I or II) deficiency.	2	10873655 OSAY13	1 x 2 mL
Thrombophilia	Berichrom Antithrombin III (A)	The Berichrom Antithrombin III (A) Kit is a chromogenic activity assay for the detection of hereditary or acquired antithrombin deficiency and monitoring of patients undergoing substitution therapy. The heparin co-factor-independent lyophilized reagent uses bovine	10446673 OWWR17	Small Kit	
·	,		10446672 OWWR15	Large Kit	
	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.		10873448 OPOA03	Kit
Anticoagulant Therapy Management	INNOVANCE Anti-Xa	The INNOVANCE Anti-Xa reagent 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 LMWH and UFH. In addition, the INNOVANCE Anti-Xa reagent is an in vitro diagnostic reagent for the quantitative determination of the direct factor Xa inhibitors rivaroxaban and apixaban 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.		10873681 OPPU05	Kit
Anticoag	INNOVANCE DTI	The INNOVANCE DTI Kit features a competitive chromogenic assay for in vitro quantitative measurement of direct thrombin inhibitors. Direct thrombin inhibitors are measured in human citrated plasma with an automated method to aid in the detection of their pharmacodynamic and pharmacokinetic effects and the anticoagulant status of the patient. The assay employs ready-to-use reagents and can be used with standards and controls for Dabigatran testing.		10873467 ОРОН03	Kit
	Other Direct Oral Anticoagulants (Xa)				
	Berichrom α2-Antiplasmin	Berichrom $\alpha 2$ -Antiplasmin Kit is used for the determination of $\alpha 2$ -Antiplasmin and the detection of hereditary or acquired $\alpha 2$ -Antiplasmin deficiencies. The chromogenic activity assay is also applicable for the monitoring of fibrinolytic therapy.	,	10446427 OUBU15	Kit
Fibrinolysis	Berichrom Plasminogen	Berichrom Plasminogen Kit, a chromogenic activity test system, is used for the determination of plasminogen and the detection of hereditary or acquired plasminogen deficiencies.		10446431 OUCA17	Kit
Fibrii	N Antiserum to Human Plasminogen	Immunoassay (antigen) for the quantitative determination of plasminogen in human plasma. Elevated plasminogen levels may occur in patients with prostate carcinoma, while diminished values can be expected to occur in cases of hepatic insufficiency, in the respiratory distress syndrome of the newborn and in therapeutic fibrinolysis treatment. Measurement of the concentration (antigen) and activity helps to identify the exact type of deficiency.		10873656 OSCB13	1 x 2 mL
D-Dimer Hypercoagulability	INNOVANCE D-Dimer	The 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 be used for the diagnosis and monitoring of patients with disseminated intravascular coagulopathy (DIC), as well as for the monitoring of anticoagulation treatment and pregnancy-related coagulopathies (e.g., preeclampsia and HELLP syndrome).		10445979 OPBP03 10445980 OPBP07	Small Kit Large Kit

 $<sup>\</sup>bigwedge$  Liquid formulation, no reconstitution required.  $\checkmark$  No standing time required.

		Instrument availability							
		Sys	tems and analyz	ers		Sysmex systems			
	Reagent name	Atellica COAG 360	BCS XP	BFT II	CA-660*	CS-2500 CS-5100	CN-3000 CN-6000		
philia	N Antiserum to Human Antithrombin III	•							
Thrombophilia	Berichrom Antithrombin III (A)	•	•		•	•	•		
	INNOVANCE Heparin	•	•		•	•	•		
Anticoagulant Therapy Management	INNOVANCE Anti-Xa	•	•		•	•	•		
Anticoagu	INNOVANCE DTI	•	•			•	•		
	Other Direct Oral Anticoagulants (Xα)	Available upon request							
	Berichrom α2-Antiplasmin	•	•			•	•		
Fibrinolysis	Berichrom Plasminogen	•	•			•	•		
Fibri	N Antiserum to Human Plasminogen	•							
D-Dimer Hypercoagulability	INNOVANCE D-Dimer	•	•		•	•	•		

<sup>\*</sup>Application on the Sysmex CA-620 System may vary. ‡Heparin application only.

	Reagent name	Reagent description	SMN Catalog no.	Package size
	Control Plasma N	Control Plasma N is citrated normal human pooled plasma. Control Plasma N is used for the assessment of the precision and analytical deviation of various analytes in the normal range. This control provides assigned values for the respective available analytes.	10446234 ORKE41	10 x for 1 mL
	Control Plasma P	Control Plasma P is citrated human plasma. Control Plasma P is a precision and accuracy control intended to monitor the performance of various parameters in the pathological range. The control provides assigned values for the respective available analytes.	10446471 OUPZ17	10 x for 1 mL
	Dade Ci-Trol® 1, 2, and 3 Controls	Dade Ci-Trol Level 1, 2, and 3 Controls are intended for use as precision and accuracy controls in the normal, mid, and upper therapeutic ranges for the routine assays. The controls provide assigned values for the respective available analytes.	10445601 291070 10445602 291071 10445603 291072	10 x for 1 mL 10 x for 1 mL 10 x for 1 mL
slo	Dade Ci-Trol Coagulation Control Level 1, 2, and 3	Dade Ci-Trol Coagulation Control Level 1, 2, and 3 Controls are composed of citrated human pooled plasma. They are intended for use as unassigned controls in the normal, mid, and upper therapeutic ranges.	10445731 B4244-10 10445732 B4244-20 10445733 B4244-30	20 x for 1 mL 20 x for 1 mL 20 x for 1 mL
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.	10445719 B4233-22	10 x for 1 mL
	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.	10446154 OQWE11	6 x for 1 mL
	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.	10446153 OQWD11	6 x for 1 mL
	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.	10446096 OQKE17	6 x for 1 mL
	Dade Ci-Trol Heparin Control, Low	Dade Ci-Trol Heparin Control, Low is a low-level control using the activated partial thromboplastin time (APTT).	10445715 B4224-50	10 x for 1 mL
	Dade Ci-Trol Heparin Control, High	Dade Ci-Trol Heparin Control, High is a high-level control using the activated partial thromboplastin time (APTT).	10445716 B4224-60	10 x for 1 mL
	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 the INNOVANCE D-Dimer Assay.	10446005 OPDY03	2 x 5 x for 1 mL



		Instrument availability						
		Sys	tems and analyze	ers		Sysmex systems		
	Reagent name	Atellica COAG 360	BCS XP	BFT II	CA-660*	CS-2500 CS-5100	CN-3000 CN-6000	
	Control Plasma N	•	•	•	•	•	•	
	Control Plasma P	•	•	•	•	•	•	
	Dade Ci-Trol 1, 2, and 3 Controls	•	•	•	•	•	•	
S	Dade Ci-Trol Coagulation Control Level 1, 2, and 3	•	•	•	•	•	•	
Controls	Dade Data-Fi Abnormal Fibrinogen Control Plasma	•			•	•	•	
	LA Control Low	•	•	•	•	•	•	
	LA Control High	•	•	•	•	•	•	
	ProC Control Plasma	•	•	•		•	•	
	Dade Ci-Trol Heparin Control, Low		•		•			
	Dade Ci-Trol Heparin Control, High		•		•			
	INNOVANCE D-Dimer Controls	•	•		•	•	•	

 $<sup>{\</sup>rm *Application\ on\ the\ Sysmex\ CA-620\ System\ may\ vary}.$ 





	Reagent name	Reagent description	SMN Catalog no.	Package size
Controls	INNOVANCE Heparin UF Control 1	INNOVANCE Heparin UF Control 1 is used for quality control of the 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.	10873452 OPOC03	5 x for 1 mL
	INNOVANCE Heparin UF Control 2	INNOVANCE Heparin UF Control 2 is used for quality control of the 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.	10873451 OPOD03	5 x for 1 mL
	INNOVANCE Heparin LMW Control 1	INNOVANCE Heparin LMW Control 1 is used for quality control of the 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.	10873449 OPOE03	5 x for 1 mL
	INNOVANCE Heparin LMW Control 2	INNOVANCE Heparin LMW Control 2 is used for quality control of the 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.	10873450 OPOF03	5 x for 1 mL
	INNOVANCE Rivaroxaban Controls	INNOVANCE Rivaroxaban Controls are used for quality control of the INNOVANCE Anti-Xa assay for the quantitative determination of rivaroxaban in citrated human plasma. Including two levels of rivaroxaban controls, Control 1 ~70 ng/mL; Control 2 ~250 ng/mL.	10873676 OPPS03	2 x 5 x for 1 mL
	INNOVANCE Apixaban Controls	INNOVANCE Apixaban Controls are used for quality control of the INNOVANCE Anti-Xa assay for the quantitative determination of apixaban in citrated human plasma. Including two levels of apixaban controls, Control 1 ~70 ng/mL; Control 2 ~250 ng/mL.	10873672 OPPV03	2 x 5 x for 1 mL
	Dabigatran Controls	Dabigatran Controls are used as assayed controls for the INNOVANCE DTI Assay for the quantification of Dabigatran in human citrated plasma. Concentration of Dabigatran: Control L ~65 ng/mL and Control H ~250 ng/mL.	10873470 OPOK03	2 x 5 x for 1 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 using the Atellica® COAG 360 System.	10446655 OWSY13	3 x 1 mL
	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.		10 x for 1 mL
	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.	10445969 OPAT03	6 x for 1 mL
	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 Siemens Healthineers Multifibren U reagent. (Fibrinogen levels 1–6 have a range of approximately 0.6–9.0 g/L.)	10446148 OQVK11	6 x for 1 mL
Standards and Calibrators	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.	10873453 OPOB03	5 x 1 x for 1 mL
	INNOVANCE Rivaroxaban Standards	INNOVANCE Rivaroxaban Standards are used for calibration of the 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.	10873677 OPPT03	2 x 2 x for 1 mL
	INNOVANCE Apixaban Standards	INNOVANCE Apixaban Standards are used for calibration of the 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.	10873673 OPPW03	2 x 2 x for 1mL
	Dabigatran Standards	Dabigatran Standards are used for the calibration of the 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 concentration of dabigatran >500 ng/mL.	10873471 OPOL03	2 x 3 x for 1 mL
	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	10446449 OUI13	3 x 1 mL

		Instrument availability					
		Systems and analyzers			Sysmex systems		
	Reagent name	Atellica COAG 360	BCS XP	BFT II	CA-660*	CS-2500 CS-5100	CN-3000 CN-6000
	INNOVANCE Heparin UF Control 1	•	•		•	•	•
	INNOVANCE Heparin UF Control 2	•	•		•	•	•
	INNOVANCE Heparin LMW Control 1	•	•		•	•	•
rols	INNOVANCE Heparin LMW Control 2	•	•		•	•	•
Controls	INNOVANCE Rivaroxaban Controls	•	•			•	•
	INNOVANCE Apixaban Controls	•	•			•	•
	Dabigatran Controls	•	•			•	•
	N/T Protein Control PY	•					
	Standard Human Plasma	•	•	•	•	•	•
	PT-Multi Calibrator	•	•	•	•	•	•
	Fibrinogen Calibrator	•	•	•	•		
Calibrators	INNOVANCE Heparin Calibrator	•	•		•	•	•
Standards and Calibrators	INNOVANCE Rivaroxaban Standards	•	•			•	•
22	INNOVANCE Apixaban Standards	•	•			•	•
	Dabigatran Standards	•	•			•	•
	N Protein Standard PY	•					

 $<sup>{\</sup>rm *Application\ on\ the\ Sysmex\ CA-620\ System\ may\ vary}.$ 

	Reagent name	Reagent description and ready-to-use assay features		SMN Catalog no.	Package size
Supplementary	Calcium Chloride Solution	Calcium Chloride Solution is used as a supplementary reagent for various coagulation tests.	<b>\( \lambda \)</b>	10446232 ORHO37	10 x 15 mL
	Dade Hepzyme®	Dade Hepzyme reagent is used as a heparin neutralizer in plasma to rule out heparin contamination in coagulation testing.		10445730 B4240-10	10 x for 1 mL
	Dade Owren's Veronal Buffer	Owren's Veronal Buffer is a dilution buffer for coagulation testing.	<b>\( \lambda \)</b>	10445724 B4234-25	10 x 15 mL
	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.	<b>\( \lambda \)</b>	10487039 OPBR03	10 x 5 mL
	Imidazole Buffer Solution	Imidazole Buffer Solution is used as a supplementary reagent for various coagulation assays that run on the BFT II System.	<b>\( \lambda \)</b>	10446032 OQAA33	6 x 15 mL
	Kaolin Suspension	Kaolin Suspension is used as a supplementary reagent for various assays for the BFT II System.	<b>\( \lambda \)</b>	10446033 OQAB42	1 x 50 mL
	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).	on.	10446632 OWMG15	Kit
	Enzygnost F 1+2 (monoclonal)	Enzygnost F 1+2 (monoclonal) is an ELISA assay for prothrombin fragment 1 and 2 determine The reagent is used for the diagnosis of hyper- and hypocoagulable states.	nation.	10445978 OPBD03	Kit
Other	Berichrom C1-Inhibitor	The Berichrom C1-Inhibitor Kit, a human C1 esterase-based assay, determines the presence of C1 inhibitors in patient samples. The reagent offers a fast-turnaround time to result of <10 minutes and detects hereditary or acquired deficiencies of the C1 inhibitor (e.g., in angioneurotic edema). This chromogenic activity reagent is used for the diagnosis of diminished C1-inhibitor synthesis, increased consumption and for monitoring substitution therapy and androgen therapy.	<b>~</b>	10446446 OUIA15	Kit
	N Antiserum to Human C1-Inhibitor	Immunoassay (antigen) for the quantitative determination of C1-Inhibitor (C1-inactivator, C1-esterase inhibitor) in human plasma. Measurement of C1-Inhibitor aids in the diagnosis of hereditary angioneurotic edema and a rare form of angioedema associated with lymphoma. Acquired C1-Inhibitor deficiency occurs in diseases of the B-cell system, e.g. chronic lymphatic leukemia, multiple myeloma and other malignant lymphomas. In combination with the activity assay, the antigen assay can provide valuable additional information in the case of e.g. substitution or oral anticoagulant therapy.	<b>\( </b>	10873657 OQEY13	1 x 2 mL

 $\bigwedge$  Liquid formulation, no reconstitution required.  $\checkmark$  No standing time required.





		Instrument availability							
		Systems and analyzers			Sysmex systems				
	Reagent name	Atellica COAG 360	BCS XP	BFT II	CA-660*	CS-2500 CS-5100	CN-3000 CN-6000		
	Calcium Chloride Solution	•	•	•	•	•	•		
	Dade Hepzyme	•	•	•	•	•	•		
Supplementary	Dade Owren's Veronal Buffer	•	•		•	•	•		
Suppler	INNOVANCE D-Dimer Diluent	•	•		•	•	•		
	Imidazole Buffer Solution			•					
	Kaolin Suspension			•					
	Enzygnost TAT micro	ELISA							
	Enzygnost F 1+2 (monoclonal)	ELISA							
Other	Berichrom C1-Inhibitor	•	•			•	•		
	N Antiserum to Human C1-Inhibitor	•							

<sup>\*</sup>Application on the Sysmex CA-620 System may vary.



	Reagent name	Reagent description and ready-to-use assay features	SMN Catalog no.	Package size
	INNOVANCE PFA P2Y Cartridges	The INNOVANCE PFA P2Y Cartridge is used for the detection of P2Y12 receptor blockade in patients undergoing therapy with a P2Y12 receptor blockade antagonist.	10445700 B4170-22	1 x 20 Cartridges
	Dade PFA Collagen/EPI Test Cartridges	The 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; and monitoring of aspirin effect and DDAVP. It is sensitive to all types of von Willebrand disease (except 2N), hereditary platelet defects, low platelet count (<150,000/µL), and to aspirin and anti-GP Ilb/Illa antagonists.	10445696 B4170-20	1 x 20 Cartridges
	Dade PFA Collagen/ADP Test Cartridges	The 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.	10445698 B4170-21	1 x 20 Cartridges
	Dade PFA Trigger Solution	Dade PFA Trigger Solution is an isotonic buffer solution used for triggering the membrane for cartridges for the PFA Systems.	10445701 B4170-50	3 x 11 mL
Platelets	ADP	The 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.	10873606 AG001K	3 x 0.5 mL
ď	Epinephrine	The Epinephrine reagent is used for screening of systemic or acquired thrombocytopathy as well as biological monitoring of anti-platelet therapy. 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.	10873608 AG002K	3 x 0.5 mL
	Arachidonic Acid	Arachidonic Acid reagent is used for the measurement of platelet aggregation. Besides the diagnosis of systemic or aquired platelet dysfunction, it can be used for the biological monitoring of patients undergoing an anti-platelet therapy.	10873610 AG003K	3 x 0.5 mL
	Ristocetin	The 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. Ristocetin reagent can also be used with lyophilized platelets (AG006A) for the Ristocetin Co-factor Activity Assay (vWF:RCo) to assist in the diagnosis of von Willebrand disease.	10873612 AG004K	3 x 0.5 mL
	Collagen	Collagen reagent is used for the detection of constitutional or acquired thrombo-cytopathy. Further, it can be used for biological monitoring of anti-platelet therapy.	10873614 AG005K	3 x 0.5 mL
	INNOVANCE LOCI F 1+2 reagent Cartridge	The INNOVANCE LOCI F 1+2 reagent Cartridge is a quantitative diagnostic test based on LOCI technology for the automated determination of prothrombin F1+2 on the Atellica COAG 360 System. Measurements of F1+2 are used as an aid in the diagnosis, monitoring, and evaluation of acquired or hereditary blood coagulation disorders. The assay is indicated as an aid in assessing risk of thrombosis and in monitoring efficacy of anticoagulant therapy.	10714510 OPOM03	1 Cartridge containing 50 tests
	INNOVANCE LOCI hs D-Dimer reagent Cartridge**	INNOVANCE LOCI hs D-Dimer reagent Cartridge is an automated immunoassaay for the quantification of D-dimer based on LOCI technology on the Atellica COAG 360 System. The assay is intended for research use only (RUO).	10873445 OPOR03	1 Cartridge containing 50 tests
loci	INNOVANCE LOCI Control 1	INNOVANCE LOCI Control 1 is used for quality control of INNOVANCE LOCI assays.  The INNOVANCE LOCI Control 1 is an assayed, low-level, intralaboratory quality control for the assessment of precision and analytical bias in the quantitative determination of F1+2 on the Atellica COAG 360 System.	10873435 OPOP03	10 x for 1 mL
	INNOVANCE LOCI Control 2	INNOVANCE LOCI Control 2 is used for quality control of INNOVANCE LOCI assays. The INNOVANCE LOCI Control 2 is an assayed, high-level, intralaboratory quality control for the assessment of precision and analytical bias in the quantitative determination of F1+2on the Atellica COAG 360 System.	10873434 OPOQ03	10 x for 1 mL
	INNOVANCE LOCI Calibrator	INNOVANCE LOCI Calibrator is used for calibration of INNOVANCE LOCI assays on the Atellica COAG 360 System.	10873433 OPO03	3 x for 3 mL
	INNOVANCE LOCI Diluent	INNOVANCE LOCI Diluent is used as LOCI Diluent for INNOVANCE LOCI assays on the Atellica COAG 360 System.	10873432 OPON03	3 x 4.5 mL

 $<sup>\</sup>bigwedge$  Liquid formulation, no reconstitution required.  $\checkmark$  No standing time required.

		Instrument availability							
		Systems and analyzers			Sysmex systems				
	Reagent name	Atellica COAG 360	PFA-100®	INNOVANCE PFA-200®	CS-2500 CS-5100	CN-3000 CN-6000			
	INNOVANCE PFA P2Y Cartridges		•	•					
	Dade PFA Collagen/EPI Test Cartridges		•	•					
	Dade PFA Collagen/ADP Test Cartridges		•	•					
	Dade PFA Trigger Solution		•	•					
Platelets	ADP	•			•	•			
<u>a.</u>	Epinephrine	•			• §	•			
	Arachidonic Acid	•			•	• §			
	Ristocetin	•			• 5	•			
	Collagen	•			•§	•			
	INNOVANCE LOCI F 1+2 reagent Cartridge	•							
	INNOVANCE LOCI hs D-Dimer reagent Cartridge**	•							
IDOI	INNOVANCE LOCI Control 1	•							
	INNOVANCE LOCI Control 2	•							
	INNOVANCE LOCI Calibrator	•							
	INNOVANCE LOCI Diluent	•							

§HYPHEN BioMed application.
\*\*For research use only.

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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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