Siemens Healthcare Diagnostics, a global leader in clinical diagnostics, provides healthcare professionals in hospital, reference, and physician office laboratories and point-of-care settings with the vital information required to accurately diagnose, treat, and monitor patients. Our innovative portfolio of performance-driven solutions and personalized customer care combine to streamline workflow, enhance operational efficiency, and support improved patient outcomes.

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Hemostasis Reagents Portfolio

For more than 30 years, we have held the distinction of being recognized as the global leader in hemostasis testing.

Our comprehensive portfolio of instruments and reagent offerings enables custom-fit solutions to laboratories of all sizes. Our assays offer a broad selection of various 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 found in our INNOVANCE® VWF Ac Assay. No matter how routine or specialized your testing may be, we have the solutions to ensure quality testing, standardize results, and offer solutions to meet the needs of your laboratory.

<table>
<thead>
<tr>
<th>Reagent Name</th>
<th>Reagent Description</th>
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</thead>
<tbody>
<tr>
<td>Thromborel® S Reagent</td>
<td>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 V, VII, IX, and 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 VIII, IX, and X. The reagent differentiates abnormal plasmas, even in the mildly pathological range.</td>
</tr>
<tr>
<td>Dade Innovin® Reagent</td>
<td>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 intrinsic 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.</td>
</tr>
<tr>
<td>Dade Actin® Activated Cephaloplastin Reagent</td>
<td>Dade Actin Activated Cephaloplastin Reagent has moderate sensitivity to factor deficiencies (VIII, IX, XI, and X) in the intrinsic system. It is the ideal choice for laboratories requiring a moderate screening APTT reagent for routine testing. Dade Actin has low heparin sensitivity, allowing the monitoring of heparin therapy even with high heparin dosages. Dade Actin® Reagent has moderate sensitivity to lupus anticoagulants.</td>
</tr>
<tr>
<td>Dade Actin FS Activated PTT Reagent</td>
<td>Dade Actin FS Activated PTT Reagent is a highly sensitive reagent for the detection of factor deficiencies (VIII, IX, XI, XII) of the intrinsic system. With moderate sensitivity to lupus anticoagulants and high sensitivity to heparin, it fulfills all requirements of routine coagulation testing.</td>
</tr>
<tr>
<td>Pathromtin® SL Reagent</td>
<td>Pathromtin® SL Reagent exhibits high sensitivity to lupus anticoagulants, factor deficiencies, and heparin.</td>
</tr>
<tr>
<td>Multifibren® U Reagent</td>
<td>Multifibren® U Reagent is a bovine thrombin reagent used in the modified Clapp 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.</td>
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<tr>
<td>Dade Thrombin Reagent</td>
<td>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. The reagent offers long stability after reconstitution.</td>
</tr>
<tr>
<td>Dade Fibrinogen Determination Reagent</td>
<td>The Dade Fibrinogen Determination Reagent consists of Dade Thrombin Reagent, Fibrinogen Standard, and Dade Owens’ 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 is insensitive to therapeutic levels of heparin, which, in combination with high sensitivity to these coagulation factors, makes Dade Innovin Reagent ideal for monitoring oral anticoagulant therapy and differentiating abnormal plasmas, even in the mildly pathological range.</td>
</tr>
<tr>
<td>BC Thrombin Reagent</td>
<td>BC Thrombin Reagent is utilized for the determination of the thrombin time. The BC Thrombin 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 Baccitracin Reagent.</td>
</tr>
<tr>
<td>Thrombostatin® Reagent</td>
<td>Thrombostatin® Reagent is intended for the determination of thrombin time in 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 Baccitracin Reagent.</td>
</tr>
<tr>
<td>Reagent Name</td>
<td>Reagent Description</td>
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<tr>
<td>Test Thrombin Reagent</td>
<td>Test Thrombin Reagent is intended for the determination of thrombin time in citrated human plasma. The reagent is suitable for monitoring fibrinolysis, screening for disorders of fibrin formation, and 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.</td>
</tr>
<tr>
<td>Batroxobin Reagent</td>
<td>Batroxobin Reagent is a snake venom-based reagent intended for the determination of the batroxobin time. It is ideal for monitoring fibrinolysis by determination of fibrinogen/fibrin degradation products, diagnosis of alpha-thromboglobulin and dyshomologemia, and evaluation of prolonged thrombin times in suspected presence of heparin.</td>
</tr>
<tr>
<td>Coagulation Factor II</td>
<td>Coagulation Factor II Deficient Plasma is a human plasma-based reagent for the detection of hereditary or acquired deficiencies of factor X (prothrombin). It is manufactured by immunosorption and contains a residual factor concentration of &lt;1% prothrombin 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 Thrombin® 5 Reagents.</td>
</tr>
<tr>
<td>Coagulation Factor V</td>
<td>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 immunosorption and contains a residual factor concentration of &lt;1% factor V 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 Thrombin® 5 Reagents.</td>
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<tr>
<td>Coagulation Factor VII</td>
<td>Coagulation Factor VII Deficient Plasma is a human plasma-based reagent for the detection of hereditary or acquired deficiencies of factor VIII. It is manufactured by immunosorption and contains a residual factor concentration of &lt;1% factor VIII 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 Thrombin® 5 Reagents.</td>
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<tr>
<td>Coagulation Factor VIII</td>
<td>Coagulation Factor VIII Deficient Plasma is a lyophilized reagent immunosorbed from human plasma. It contains ≤1% residual factor VIII and normal levels of fibrinogen and other intrinsic clotting coagulation factors. It is used for the determination of factor VIII activity in the diagnosis of congenital and acquired deficiencies of factor VIII.</td>
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<tr>
<td>Coagulation Factor IX</td>
<td>Coagulation Factor IX Deficient Plasma is a human plasma-based reagent for the detection of hereditary or acquired deficiencies of factor IX (factor Christmas). With a residual factor concentration of &lt;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.</td>
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<tr>
<td>Coagulation Factor X</td>
<td>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 immunosorption and contains a residual factor concentration of &lt;1% factor X 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 Thrombin® 5 Reagents.</td>
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<tr>
<td>Coagulation Factor XI</td>
<td>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 &lt;1% factor XI and was designed to be used in combination with Dade Actin, Dade Actin FS, Dade Actin FSL, or Pathromtin SL Reagents.</td>
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<tr>
<td>Coagulation Factor XII</td>
<td>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 &lt;1% factor XII and was designed to be used in combination with Dade Actin, Dade Actin FS, Dade Actin FSL, or Pathromtin SL Reagents.</td>
</tr>
<tr>
<td>Benrichrom Factor XIII Kit</td>
<td>The Benrichrom Factor XIII Kit is a chromogenic, quantitative assay for the detection of hereditary or acquired factor XII deficiencies. The chromogenic activity reagent is also utilized for the monitoring of patients undergoing factor XII substitution therapy.</td>
</tr>
<tr>
<td>Factor VII Chromogenic Assay</td>
<td>The Factor VII Chromogenic Assay is recommended for factor FVII determination in therapeutic factor FVII preparations and the detection of hereditary or acquired factor VII deficiencies. The chromogenic method is insensitive to heparin at levels of &lt;10 IU/mL.</td>
</tr>
</tbody>
</table>

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**von Willebrand Factors**

**INNOVANCE® VWF Ag Kit**

The INNOVANCE VWF Kit is a sensitive, reliable, and convenient test system for direct determination of VWF activity. It employs an advanced new technology, allowing the assay to mimic the way in which VWF binds to glycoprotein Ib (GPIb) on the surface of platelets. This technology uses recombinant 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 Reagent**

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 of 250 seconds, is sensitive to types 1, 2, and 3 of von Willebrand disease (except VWD 2N) and is the recommended screening method for von Willebrand disease.

**vWF Ag® Kit**

The vWF Ag Kit contains a quantitative, automated immunoassay used to determine the differentiation of quantitative versus qualitative von Willebrand factor deficiencies. It is sensitive to types 1 and 3 vWF deficiencies and offers a wide measuring range of 2–200%.

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**Systems and Analyzers**

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<tr>
<th>Catalog No.</th>
<th>Package Size</th>
<th>BCS</th>
<th>BCS XP</th>
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<th>BFT II</th>
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<th>CA-1500</th>
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</table>

**Instrument Availability**

- **BCT**
- **BFT II**
- **CA-7000**
- **CA-1500**
- **CA-560**
- **CS-2000**
- **CS-2100**

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**Comments**

- **OPHLD3 Kit**
- **OUBJ07 5 x 4 mL**
- **OUBD23 5 x 2 mL**
- **OPAB03 Kit**
- **manual method**
**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 heparin-insensitive reagent is useful in screening individuals affected by thrombophilia. ProC Global Kit is sensitive to deficiencies of factor V Leiden and proteins C and S, certain lupus anticoagulants, and high factor VIII levels.

**ProC Ac Kit** 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.

**Protein S Ac Reagent**, a coagulometric activity reagent, is utilized for the detection of hereditary or acquired protein S deficiencies.

**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.

**LA 1 Screening Reagent** is a simplified dilute Russell’s viper venom test used in the simplified DRVVT as an indicator of a thrombophilic state and hypofibrinolysis. The reagent 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.

**Berichrom® Protein C Kit** is a chromogenic activity assay, utilized 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.

**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., pre-eclampsia and HELLP syndrome).

**Dade Dimension Latex Assay** is a rapid agglutination test system using latex particles coated with a specific D-dimer monoclonal antibody. Dimension is intended for the qualitative or semi-quantitative evaluation of cross-linked fibrin degradation products containing D-dimers.

**D-Dimer Latex Beads** are latex particles coated with a specific D-dimer monoclonal antibody used in the qualitative or semi-quantitative evaluation of cross-linked fibrin degradation products containing D-dimers.
The Complement Reagent Kit is a functional-activity assay for the determination of total complement. It is useful in the diagnosis of hereditary and acquired defects of the complement system and for monitoring response to treatment.

Berichrom C1-Inhibitor Kit

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-result of <10 minutes and detects hereditary or acquired deficiencies of the C1 inhibitor (e.g., in angioedema). This chromogenic activity reagent is used for the diagnosis of angioedema and for monitoring substitution or steroid therapy in angioedema.

INNOVANCE ETP Kit

The INNOVANCE ETP Kit is a global hemostasis-function test system to assess endogenous thrombin potential (ETP). Several parameters are commonly used to describe ETP, from which the area under the curve (AUC) and peak height (Cmax) have been shown to be of diagnostic relevance:

- Increased AUC has been demonstrated to correlate with an increased risk for recurrent venous thromboembolism after discontinuance of anticoagulation.
- Increased AUC and Cmax have been observed due to prothrombin mutation G20210A.
- AUC and Cmax are known to be decreased under anticoagulant treatment with vitamin K antagonists.
- Reduction of AUC and Cmax have been demonstrated during treatment with argatroban (direct thrombin inhibitor).

Calcium Chloride Solution

Calcium Chloride Solution is used as a supplementary reagent for various coagulation tests.

Dade Heparzyme® Reagent

Dade Heparzyme Reagent is used as a heparin neutralizer in plasma to rule out heparin contamination in coagulation testing.

Concrete Reagent

Concrete Reagent is used in the determination of total protein and for the measurement of lipid and fatty acid levels in plasma.

Calcium Chloride Solution

Calcium Chloride Solution is used as a supplementary reagent for various coagulation tests.

Dade Heparzyme® Reagent

Dade Heparzyme Reagent is used as a heparin neutralizer in plasma to rule out heparin contamination in coagulation testing.

Owren’s Veronal Buffer

Owren’s Veronal Buffer is a dilution buffer for coagulation testing.

INNOVANCE PFA® F2b Reagent

INNOVANCE PFA® F2b Reagent is an easy and reliable test for the detection of P2Y12 receptor blockade by patients undergoing therapy with a P2Y12 receptor blocker (e.g., clopidogrel).

Dade PFA Collagen/EPi Test Cartridges

The Dade Collagen/EPi Test Cartridges is used for the detection of platelet dysfunction; screening for intrinsic platelet defects; von Willebrand disease; and exposure to platelet inhibitory agents; prescreening for bleeding risk, and monitoring of aspirin effect and DDAPB. 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 IIb/IIIa antagonists.

Dade PFA Collagen/ADP Test Cartridges

The Dade PFA Collagen/ADP Test Cartridges are utilized for the differentiation of aspirin effect on platelets versus other platelet dysfunctions. It is insensitive to aspirin, yet sensitive to VMD, low platelet counts, and other platelet dysfunctions.

Dade PFA Trigger Solution

Dade PFA Trigger Solution is an isotonic buffer solution used for triggering the membrane for cartridges for the PFA Systems.

Dade Cluster Platelet Aggregation Reagents

Dade Cluster Platelet Aggregation Reagents—consisting of collagen, ADP, and epi-spinone—are utilized in platelet aggregation studies for screening of inherited and acquired platelet dysfunction.

Standard Human Plasma

Standard Human Plasma is citrated normal human pooled plasma intended for the calibration of various coagulation and fibrinolytic 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 Kit

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 Healthcare Diagnostics’ Multifibren U Reagent. (Fibrinogen levels 1-4 have a range of approximately 0.6-9 g/L.)

Berichrom Heparin UF Calibrator

The Berichrom Heparin UF Calibrator is for use in the preparation of an unfractionated heparin calibration curve with the Berichrom Heparin Kit. It is calibrated against the fifth WHO standard for unfractionated heparin (human pooled plasma containing UFH ≤1.5 U/mL).

Berichrom Heparin LMWH Calibrator

The Berichrom Heparin-LMWH Calibrator is for use in preparation of a LMWH heparin calibration curve with the Berichrom Heparin Kit. It is calibrated against the second WHO standard for LMWH (human pooled plasma containing LMWH ≤1.5 U/mL).
Global Control consists of citrated normal human pooled plasma from selected healthy blood donors. The control is utilized for precision control of coagulation tests in the normal range.

Control Plasma P
Control Plasma P is citrated human plasma from selected healthy blood donors. 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.

Dade C-Trol Coagulation Control Level 1, 2, and 3
Dade C-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 global assays. The controls provide assigned values for the respective available analytes.

LA Control Low Control
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 Control
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 inhibitory control to estimate precision and analytical deviation of the ProC time of tests in the pathological range.

Ci-Trol Heparin Control Low
Ci-Trol Heparin Control Low is a low-level control using the activated partial thromboplastin time (APTT).

Ci-Trol Heparin Control High
Ci-Trol Heparin Control High is a high-level control using the activated partial thromboplastin time (APTT).

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.

Berichrom Heparin UF Control 1
Berichrom Heparin UF Control 1 is a precision and accuracy control used to monitor the performance of the Berichrom Heparin Assay in the therapeutical low-molecular weight heparin range.

Berichrom Heparin UF Control 2
Berichrom Heparin UF Control 2 is a precision and accuracy control used to monitor the performance of the Berichrom Heparin Assay in the subtherapeutical low-molecular weight heparin range.

Berichrom Heparin LMW Control 1
Berichrom Heparin LMW Control 1 is a precision and accuracy control used to monitor the performance of the Berichrom Heparin Assay in the pathological low-molecular weight heparin range.