HEMOSTASIS INNOVATION IS HERE.
At Instrumentation Laboratory, our commitment to worldwide total customer support is demonstrated in the Hemostasis field with a complete line of reagents, controls and calibrators, perfectly suited for our flexible range of automated analyzers. IL offers solutions to meet any customer or laboratory need through easy-to-use, cost-efficient, reliable and accurate instruments and reagents, coupled with the support of our people.

This comprehensive catalog illustrates our long-standing commitment to Hemostasis diagnostics.
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>aCL</td>
<td>Anti-Cardiolipin</td>
</tr>
<tr>
<td>ACL™ H/T</td>
<td>ACL Hundred/Thousand Series</td>
</tr>
<tr>
<td>AKV</td>
<td>Anti Vitamin K</td>
</tr>
<tr>
<td>APC</td>
<td>Activated Protein C</td>
</tr>
<tr>
<td>APC R V</td>
<td>Activated Protein C Resistance caused by Factor V Leiden mutation</td>
</tr>
<tr>
<td>APS</td>
<td>Antiphospholipid Syndrome</td>
</tr>
<tr>
<td>APTT</td>
<td>Activated Partial Thromboplastin Time</td>
</tr>
<tr>
<td>ASCVD</td>
<td>Atherosclerotic Cardiovascular Disease</td>
</tr>
<tr>
<td>ASTM</td>
<td>American Society for Testing and Materials</td>
</tr>
<tr>
<td>AT</td>
<td>Antithrombin</td>
</tr>
<tr>
<td>CLSI</td>
<td>Clinical and Laboratory Standards Institute</td>
</tr>
<tr>
<td>C4BP</td>
<td>C4b-binding Protein</td>
</tr>
<tr>
<td>DIC</td>
<td>Disseminated Intravascular Coagulation</td>
</tr>
<tr>
<td>DRVVT</td>
<td>Diluted Russel Viper Venom Time</td>
</tr>
<tr>
<td>DVT</td>
<td>Deep Vein Thrombosis</td>
</tr>
<tr>
<td>FDP</td>
<td>Fibrin/Fibrinogen Degradation Products</td>
</tr>
<tr>
<td>FIB</td>
<td>Fibrinogen</td>
</tr>
<tr>
<td>HIT</td>
<td>Heparin-Induced Thrombocytopenia</td>
</tr>
<tr>
<td>ICSH</td>
<td>International Committee for Standardisation in Haematology</td>
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<tr>
<td>ICTH</td>
<td>International Committee on Thrombosis and Haemostasis</td>
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<tr>
<td>INR</td>
<td>International Normalized Ratio</td>
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<tr>
<td>ISI</td>
<td>International Sensitivity Index</td>
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<tr>
<td>ISTH</td>
<td>International Society on Thrombosis and Haemostasis</td>
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<tr>
<td>KCT</td>
<td>Kaolin Clotting Time</td>
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<tr>
<td>LA/LAC</td>
<td>Lupus Anticoagulant</td>
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<tr>
<td>LMWH</td>
<td>Low Molecular Weight Heparin</td>
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<tr>
<td>MNPT</td>
<td>Mean Normal Prothrombin Time</td>
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<tr>
<td>NIBSC</td>
<td>National Institute for Biological Standards and Controls (UK)</td>
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<tr>
<td>OAT</td>
<td>Oral Anticoagulant Therapy</td>
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<tr>
<td>PC</td>
<td>Protein C</td>
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<tr>
<td>PE</td>
<td>Pulmonary Embolism</td>
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<tr>
<td>PI</td>
<td>Plasmin Inhibitor</td>
</tr>
<tr>
<td>PIICP%</td>
<td>Protac-induced Coagulation Inhibition Percent</td>
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<tr>
<td>PIVKA</td>
<td>Protein Induced by Vitamin K Antagonists/Absence</td>
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<tr>
<td>PLG</td>
<td>Plasminogen</td>
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<tr>
<td>PNA</td>
<td>Paranitroaniline</td>
</tr>
<tr>
<td>PS</td>
<td>Protein S</td>
</tr>
<tr>
<td>PT</td>
<td>Prothrombin Time</td>
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<td>Q.F.A.</td>
<td>Quantitative Fibrinogen Assay</td>
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<td>RTF</td>
<td>Recombinant Tissue Factor</td>
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<tr>
<td>SK</td>
<td>Streptokinase</td>
</tr>
<tr>
<td>SCT</td>
<td>Silica Clotting Time</td>
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<tr>
<td>TT</td>
<td>Thrombin Time</td>
</tr>
<tr>
<td>UFH</td>
<td>Unfractionated Heparin</td>
</tr>
<tr>
<td>VWD</td>
<td>von Willebrand Disease</td>
</tr>
<tr>
<td>VWF</td>
<td>von Willebrand Factor</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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INDEX

General Screening and Anticoagulant Monitoring
RecombiPlasTin 2G .............................................. 8
PT-Fibrinogen HS Plus ........................................ 8
PT-Fibrinogen .................................................. 8
ISI Calibrate ..................................................... 9
INR Validate .................................................... 9
ISweb .............................................................. 9
APTT-SP ........................................................ 10
Calcium Chloride 0.025 M ...................................... 10
Calcium Chloride 0.020 M ...................................... 10
SynthASil® ....................................................... 10
SynthAFax® ....................................................... 10
APTT Lyophilized Silica ........................................ 10
UF Heparin Controls .......................................... 16
Liquid Heparin Calibrators .................................... 15
Liquid Heparin .................................................. 15
Fibrinogen-C and Fibrinogen-C XL ......................... 13
O-FA-Thrombin ................................................. 13
Thrombin Time ................................................ 14
Pro-IL-Complex ................................................ 14
Hepatocomplex ................................................ 14
PCX/HPX Thromboplastin Diluent ............................ 14
Heparin .......................................................... 15
Liquid Heparin .................................................. 15
LiquiCyte Heparin Calibrators ............................... 15
UF Heparin Controls .......................................... 16
LMW Heparin Controls ........................................ 16

D-Dimer
D-Dimer .......................................................... 20
D-Dimer HS ...................................................... 20
D-Dimer Controls .............................................. 20
D-Dimer 500 ..................................................... 21
D-Dimer HS 500 ............................................... 21
D-Dimer HS 500 Controls .................................... 21
AcuStar D-Dimer .............................................. 22
AcuStar D-Dimer Controls ................................... 22
Dimentest Kit .................................................... 23

Heparin-Induced Thrombocytopenia
HIT-Ab(IgG/IgM) ................................................ 26
HIT Controls .................................................... 26

Thrombophilia
Liquid Antithrombin .......................................... 28

Antithrombin ................................................... 28
Protein C .......................................................... 28
ProClot ............................................................ 29
ProClot Diluent ................................................. 29
ProS ............................................................... 29
Free Protein S (antigenic immunoassay) .................... 29
Factor V Leiden (APC-RVI) ................................... 30
Homocysteine .................................................. 30
Homocysteine Controls ....................................... 30
ThromboPath ................................................... 31
Xpert® HemosIL® Fil & FV ..................................... 32
FIL & FV DNA Control ....................................... 32
GeneXpert® System .......................................... 32

Antiphospholipid Syndrome
LAC Screen and LAC Confirm ............................... 34
Silica Clotting Time .......................................... 34
ELECTRACHROME Factor VIII ............................ 38
von Willebrand Disease
von Willebrand Factor Antigen ............................. 40
von Willebrand Factor Activity ............................. 40

Coagulation Factors
Factor II, VII and X Deficient Plasmas ...................... 38
Factor VIII, IX, XI and XII Deficient Plasmas ............. 38
Factor XIII Antigen .......................................... 38
ELECTRACHROME Factor VIII ............................ 38

Fibrinolysis
Plasminogen .................................................... 42
Plasmin Inhibitor (α2-Antiplasmin) .......................... 42

Plasma Calibrators and Controls
Calibration Plasma ............................................. 44
Normal Control UNASSAYED .............................. 47
Low Abnormal Control 2 UNASSAYED .................... 47
High Abnormal Control 3 UNASSAYED ................... 47
Routine Control Level 1 ..................................... 48
Routine Control Level 2 ..................................... 48
Routine Control Level 3 ..................................... 48
OC Plasma Coagulation Control Level I .................... 48
OC Plasma Coagulation Control Level II ................... 48

Solutions
Sample diluent .................................................. 50
Factor diluent ................................................... 50
Reference Emulsion .......................................... 50
Wash-R Emulsion ............................................. 50
Cleaning solution (Clean A) .................................. 50
Cleaning agent (Clean B) ..................................... 50
Rinse Solution (for ACL Futura/Advance) .................. 50
Rinse Solution (for ACL TOP® Family) .................... 50
AcuStar Triggers ................................................ 50
AcuStar System Rinse ........................................ 50

Reagent Line Tables
Reagent Line Tables .......................................... 52

Instruments
ACL Systems .................................................. 62
ACL TOP® Family ............................................ 63
ACL TOP 700/ACL TOP 700 CTS/ACL TOP 700 LAS .... 64
ACL TOP 500 CTS ............................................ 65
ACL AcuStar™ .................................................. 66
ACL Advance ................................................... 67
ACL ELITE®/ELITE PRO .................................... 68
ACL 7000 ....................................................... 69

Consumables
Consumables ................................................... 72

Instrument Specs/Tests
Instrument Specifications .................................. 78
Test Availability ............................................... 79
GENERAL SCREENING AND ANTICOAGULANT MONITORING
**RecombiPlasTin 2G**

**Intended Use:** For the quantitative determination in human citrated plasma of Prothrombin Time and Fibrinogen on IL Hemostasis systems. The product is used for the evaluation of the extrinsic coagulation pathway and the monitoring of Oral Anticoagulant Therapy (OAT).

**Principle:** Contains recombinant human tissue factor repurposed in a synthetic phospholipid blend. RecombiPlasTin 2G Diluent is an aqueous solution containing calcium chloride and preservative.

**Sensitivity:** ISI approximately 1.0

**Standardization:** The ISI value is obtained using the WHO-recommended protocol on every lot of reagent and is instrument specific.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volumes**
- 5 x 8 mL RecombiPlasTin 2G (lyo)
- 5 x 8 mL RecombiPlasTin 2G Diluent (liq)
- 5 x 20 mL RecombiPlasTin 2G (lyo)
- 5 x 20 mL RecombiPlasTin 2G Diluent (liq)

**Part Number**
- 8 mL vials kit 0020002950
- 20 mL vials kit 0020003050

**Main Features**
- Designed for OAT monitoring
- Human tissue factor, recombinant technology
- ISI range approximately 1.00 on ACL systems
- Insensitive up to 1.0 U/mL Heparin
- Good Extrinsic Factor sensitivity
- Elevated reconstituted stability

---

**PT-Fibrinogen HS Plus**

**Intended Use:** For simultaneous determination of Prothrombin Time and Fibrinogen, for evaluation of the extrinsic coagulation pathway and monitoring Oral Anticoagulant Therapy (OAT) in human citrated plasma on the IL Hemostasis systems.

**Principle:** Contains very high sensitivity calcium thromboplastin, a lyophilized extract from rabbit brain tissue, with an optimum concentration of calcium ions.

**Sensitivity:** ISI approximately 1.2

**Standardization:** The ISI value is obtained using the WHO-recommended protocol on every lot of reagent and is instrument specific.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volumes**
- 5 x 8.5 mL Thromboplastin (lyo)
- 5 x 8.5 mL Buffer (liq)

**Part Number** 0008469810

**Main Features**
- Designed for OAT monitoring
- Rabbit brain thromboplastin extract
- ISI range approximately 1.2
- Insensitive up to 0.5 U/mL of Heparin
- Good Extrinsic Factor sensitivity

---

**PT-Fibrinogen**

**Intended Use:** For simultaneous determination of Prothrombin Time and Fibrinogen, for evaluation of the extrinsic coagulation pathway and monitoring Oral Anticoagulant Therapy in human plasma on IL Hemostasis systems.

**Principle:** Contains calcium thromboplastin, a lyophilized extract from rabbit brain tissue, with an optimum concentration of calcium ions.

**Sensitivity:** ISI approximately 2.0

**Standardization:** The ISI value is obtained using the WHO-recommended protocol on every lot of reagent and is instrument specific.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volumes**
- 10 x 8 mL Rabbit Thromboplastin (lyo)

**Part Number** 0009756710

**Main Features**
- Rabbit brain thromboplastin extract
- ISI range approximately 2.0
- Insensitive up to 1 U/mL of Heparin

---

**HemosIL®**
ISI Calibrate (NEW)

**Intended Use:** A set of four certified plasmas to establish a laboratory’s instrument/reagent-specific local International Sensitivity Index (ISI) and Mean Normal Prothrombin Time (MNPT) with designated HemosIL PT reagents on IL Hemostasis systems in conjunction with ISIweb software.

**Principle:** The calibrate plasmas from ISI Calibrate are run on IL instrument/reagent systems to establish a local ISI. The PT (sec) data is entered into the ISIweb, which generates a calibration curve from the PT and the International Normalized Ratio (INR) reference values by plotting an orthogonal regression of LogINR (X-axis) vs. LogPT (Y-axis). The ISI and MNPT are derived from the slope and y-intercept of the curve as:

\[
\text{ISI} = \frac{1}{\text{slope}} \\
\text{MNPT} = 10^{\text{y-intercept}}
\]

**Standardization:** ISI Calibrate follows the guidelines proposed by both the ISTH and CLSI on the procedures to prepare, certify and use reference plasmas for procedural validation of the INR and establishment of a local ISI.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volume**
- **Level A:** 1 x 1 mL vial of lyophilized human plasma with an INR range of 0.9 - 1.1
- **Level B:** 1 x 1 mL vial of lyophilized human AVK plasma with an INR range of 1.6 - 2.4
- **Level C:** 1 x 1 mL vial of lyophilized human AVK plasma with an INR range of 2.5 - 3.5
- **Level D:** 1 x 1 mL vial of lyophilized human AVK plasma with an INR range of 3.8 - 5.0

**Part Number** 0020010600

**Main Features**
- Reagent-specific INR levels
- Level A comprised of normal human donors
- Levels B - D comprised of plasma from human donors on long-term anticoagulant therapy. Therefore, levels of FII, FVII, FIX, FX, PC, PS and PIVKA are equivalent to concentrations normally expected in the plasma of patients undergoing AVK treatment.

INR Validate (NEW)

**Intended Use:** A tri-level quality control to monitor the accuracy of International Normalized Ratio (INR) reporting with designated HemosIL PT reagents on IL Hemostasis systems in conjunction with ISIweb software.

**Principle:** The control plasmas of INR Validate are run on a local instrument/reagent system using the manufacturer’s lot-specific International Sensitivity Index (ISI) value and the laboratory’s locally established lot-specific Mean Normal Prothrombin Time (MNPT). If the mean INRs of all the controls are within ±15% of their assigned INR reference values, as determined through the ISIweb, the PT/INR system is verified. If the mean INRs of the controls exceed +15% of their assigned INR reference values, as determined through the ISIweb, a new local ISI calibration is recommended using ISI Calibrate. Verification of the new local ISI and MNPT is then performed by running the INR Validate control plasmas a second time on the same instrument/reagent system with the local ISI and MNPT.

**Standardization:** ISI Validate follows the guidelines proposed by both the ISTH and the CLSI on the procedures to prepare, certify and use reference plasmas to validate INR and establish a local ISI.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volume**
- **Level 1:** 1 x 1 mL vial of lyophilized human AVK plasma with an INR range of 1.6 - 2.4
- **Level 2:** 1 x 1 mL vial of lyophilized human AVK plasma with an INR range of 2.5 - 3.5
- **Level 3:** 1 x 1 mL vial of lyophilized human AVK plasma with an INR range of 3.8 - 5.0

**Part Number** 0020010500

**Main Features**
- Allows customer to determine if a local ISI assignment is needed
- Determines the validity of the newly established local ISI
- Reagent-specific INR levels
- Levels 1 - 3 comprised of plasma from human donors on long-term anticoagulant therapy. Therefore, levels of FII, FVII, FIX, FX, PC, PS and PIVKA are equivalent to concentrations normally expected in the plasma of patients undergoing AVK treatment.

ISIweb Software (NEW)

**Intended Use:** ISIweb software is a web-based service to customers, used in conjunction with HemosIL INR Validate and HemosIL ISI Calibrate with designated HemosIL PT reagents on IL Hemostasis systems, whereby the PT seconds and INR results can be entered and calculated through a web-based interface (ISIweb software).

**CE Mark:** ✔

**510(k):** ✔

**Main Features**
- Accessible through IL corporate website: https://ilservices.ilww.com/isiweb
- Easy and intuitive system for reporting quality test results
- Increased efficiency in benchmarking standardized values
- Maximum performance of IL Hemostasis systems
- CLSI and ISTH compliant
- Electronically archives and reports all activities on local ISI assignment and validation
GENERAL SCREENING AND ANTICOAGULANT MONITORING

APTT-SP (Synthetic Phospholipids)

**Intended Use:** For the in vitro determination of Activated Partial Thromboplastin Time (APTT) in citrated plasma on IL Hemostasis systems, as a general screening procedure to evaluate the intrinsic coagulation pathway and to monitor patients receiving Heparin anticoagulant therapy.

**Principle:** Synthetic phospholipid preparation that includes micronized silica as activator for the determination of the APTT.

- **CE Mark:** ✔
- **510(k):** ✔

**Vials and Volumes**
- 5 x 9 mL APTT Reagent (liq)
- 5 x 8 mL Calcium Chloride (liq)

**Part Number** 0020006300

**Main Features**
- Synthetic phospholipid technology
- Liquid form: ready to use
- Micronized silica activator
- Excellent Intrinsic Factors sensitivity
- Excellent Heparin sensitivity
- Enhanced Lupus sensitivity

**Calcium Chloride 0.025 M**

To be used in combination with APTT-SP and Activated Partial Thromboplastin Time (APTT) Lyophilized Silica on the IL Hemostasis systems.

- **Vials and Volume** 10 x 8 mL Calcium Chloride (liq)
- **Part Number** 0019741910

**SynthASil**

**Intended Use:** For the in vitro determination of Activated Partial Thromboplastin Time (APTT) in human citrated plasma on IL Hemostasis systems, to evaluate the intrinsic coagulation pathway, APTT-substitution test and the monitoring of Heparin therapy.

**Principle:** Buffered reagent which contains phospholipids derived from a synthetic source for optimal platelet-like activity and a nonsettling particulate activator, colloidal silica, for optimal activation of the contact phase of coagulation.

- **CE Mark:** ✔
- **510(k):** ✔

**Vials and Volumes**
- 5 x 10 mL APTT Reagent (liq)
- 5 x 10 mL Calcium Chloride (liq)

**Part Number** 0020006800

**Main Features**
- Synthetic phospholipid technology
- Liquid form: ready to use
- Micronized silica activator
- Sensitive to the contact phase activation
- Excellent Heparin sensitivity
- Good Lupus sensitivity

**Calcium Chloride 0.020 M**

Used in combination with SynthASil and SynthAFax reagents during the Activated Partial Thromboplastin Time (APTT) test or Intrinsic Factor assays on IL Hemostasis systems.

- **Vials and Volume** 10 x 10 mL Calcium Chloride (liq)
- **Part Number** 0020006900

**SynthAFax**

**Intended Use:** For the in vitro determination of Activated Partial Thromboplastin Time (APTT) in human citrated plasma on IL Hemostasis systems, to evaluate the intrinsic coagulation pathway, APTT-substitution test and the monitoring of Heparin therapy.

**Principle:** Buffered reagent which contains phospholipids derived from a synthetic source for optimal platelet-like activity and a soluble plasma activator, ellagic acid.

- **CE Mark:** ✔
- **510(k):** ✔

**Vials and Volumes**
- 5 x 10 mL APTT Reagent (liq)
- 5 x 10 mL Calcium Chloride (liq)

**Part Number** 0020007400

**Main Features**
- Synthetic phospholipid technology
- Liquid form: ready to use
- Ellagic acid activator
- Sensitive to Factor VIII and IX
- Very good Heparin sensitivity
- Good Lupus sensitivity
**APTT Lyophilized Silica**

**Intended Use:** For the *in vitro* determination of Activated Partial Thromboplastin Time (APTT) in citrated plasma on IL Hemostasis systems, as a general screening procedure to evaluate the intrinsic coagulation pathway and to monitor patients receiving Heparin anticoagulant therapy.

**Principle:** Bovine-brain cephalin preparation that includes micronized silica as activator for the determination of the APTT.

**CE Mark:** ✔

510(k): Not FDA-cleared

**Vials and Volumes**
5 x 9 mL Bovine Cephalin (lyo)
5 x 8 mL Calcium Chloride (liq)

**Part Number** 0008468710

**Main Features**
- Micronized silica activator
- Good sensitivity to Intrinsic Factors deficiencies
- Very good Heparin sensitivity
- Good LA sensitivity

* Not available in all countries.
# GENERAL SCREENING AND ANTICOAGULANT MONITORING

## REAGENT CHARACTERISTICS

<table>
<thead>
<tr>
<th>Reagent</th>
<th>Approximate Factor VII Heparin Sensitivity</th>
<th>Heparin Sensitivity</th>
<th>Reconstituted Stability at 2-8°C</th>
</tr>
</thead>
<tbody>
<tr>
<td>RecombiPlasTin 2G</td>
<td>Excellent</td>
<td>Up to 1.0 U/mL</td>
<td>10 d</td>
</tr>
<tr>
<td>PT-Fibrinogen HS Plus</td>
<td>Very Good</td>
<td>Up to 0.5 U/mL</td>
<td>5 d</td>
</tr>
<tr>
<td>PT-Fibrinogen</td>
<td>Good</td>
<td>Up to 1.0 U/mL</td>
<td>5 d</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reagent</th>
<th>Heparin Sensitivity</th>
<th>Factor Sensitivity</th>
<th>Lupus Sensitivity</th>
<th>Liquid or Lyophilized</th>
<th>Open Vial or Reconstituted Stability at 2-8°C</th>
<th>Approximate Normal Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>APTT-SP</td>
<td>Excellent</td>
<td>Excellent</td>
<td>Excellent</td>
<td>Liquid</td>
<td>30 d</td>
<td>30 s</td>
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<tr>
<td>SynthASil</td>
<td>Excellent</td>
<td>Very Good</td>
<td>Very Good</td>
<td>Liquid</td>
<td>30 d</td>
<td>30 s</td>
</tr>
<tr>
<td>SynthAFax</td>
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<td>Good</td>
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<td>24 s</td>
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<tr>
<td>APTT Lyophilized Silica</td>
<td>Very Good</td>
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<td>Lyophilized</td>
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## REAGENT APPLICATIONS

<table>
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<tr>
<th>Reagent</th>
<th>ACL TOP Family</th>
<th>ACL Advance</th>
<th>ACL ELITE/ELITE PRO</th>
<th>ACL 200-7000</th>
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<tr>
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<td>APTT Lyophilized Silica</td>
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</tbody>
</table>

*d = day(s); s = second(s)*
**Fibrinogen-C and Fibrinogen-C XL**

**Intended Use:** For the quantitative determination of fibrinogen, based on the Clauss method, in human citrated plasma on IL Hemostasis systems.

**Principle:** An excess of thrombin to convert fibrinogen to fibrin in diluted plasma. At high thrombin and low fibrinogen concentration, the rate of reaction is a function of fibrinogen concentration.

**CE Mark:** ✔

**Vials and Volumes**
- Fib-C: 10 x 2 mL Bovine Thrombin (lyo)
- Fib-C XL: 10 x 5 mL Bovine Thrombin (lyo)

**Part Number**
- Fib-C 2 mL vials kit: 0020301100
- Fib-C XL 5 mL vials kit: 0020003900

**Main Features**
- Purified thrombin
- Insensitive to Heparin up to 1 U/mL
- Good linearity range

---

**Q.F.A. Thrombin**

**Intended Use:** For the quantitative determination of fibrinogen, based on the Clauss method, in human citrated plasma on IL Hemostasis systems.

**Principle:** Bovine thrombin (approximately 100 UNIH/mL). The concentration of fibrinogen can be determined in patient plasma samples diluted with Factor diluent and assayed with Q.F.A. Thrombin. Fibrinogen is determined by comparing results, in seconds, to a previously generated reference curve.

**CE Mark:** ✔

**Vials and Volume**
- 10 x 2 mL Bovine Thrombin (lyo)
- 10 x 5 mL Bovine Thrombin (lyo)

**Part Number**
- QFA 2 mL vials kit: 0020801800
- QFA 5 mL vials kit: 0020801700

**Main Features**
- Purified thrombin
- Bovine origin
- Good stability
- 100 UNIH/mL Thrombin
Thrombin Time

**Intended Use:** For the quantitative determination of Thrombin Time in human citrated plasma on IL Hemostasis systems.

**Principle:** Purified bovine thrombin. The assay is typically performed for the evaluation of Disseminated Intravascular Coagulation, Heparin anticoagulant therapy, fibrinolytic therapy and for the detection of Fibrin/Fibrinogen Degradation Products and hereditary or acquired fibrinogen abnormalities.

**CE Mark:** ✔
**510(k):** ✔

**Vials and Volumes**
- 4 x 2, 5, or 8 mL Bovine Thrombin (lyo)
- 1 x 9 mL Buffer (lyq)

**Part Number** 0009758515

**Main Features**
- Purified thrombin
- Different reconstitutions for the desired normal range:
  - 5 mL: approx. 11 - 18 seconds
  - 8 mL: approx. 16 - 27 seconds
  - 2 mL: approx. 5 - 8 seconds
- Specific reconstitution for Heparin therapy

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Pro-IL-Complex*

**Intended Use:** For the control of Oral Anticoagulant Therapy (OAT), both stabilized and in combination with Heparin, in human citrated plasma on IL Hemostasis systems. Due to its sensitivity to endogenous coagulation inhibitors, this assay, combined with the Hepatocomplex test, can help the user to identify the presence of inhibitors (i.e., PIVKA).

**Principle:** Optimized bovine brain thromboplastin containing specific levels of calcium ions and Heparin inhibitor (polybrene). A bovine-deficient plasma, containing all Factors except II, VII, X and IX, provides adequate levels of Fibrinogen and Factor V.

**CE Mark:** ✔
**510(k):** Not FDA-cleared

**Vials and Volumes**
- 5 x 7 mL Bovine Thromboplastin (lyo)
- 5 x 3 mL Bovine Plasma (lyo)

**Part Number** 0009758810

**Main Features**
- Specific for OAT monitoring
- PIVKA-sensitive
- Insensitive to Heparin up to 0.5 U/mL
- ISI approximately 1.2

---

Hepatocomplex*

**Intended Use:** For the detection of clinical situations associated with congenital or acquired deficiencies of Factor II-VII-X in human citrated plasma on IL Hemostasis systems. It can be used for the control of Oral Anticoagulant Therapy (OAT), both stabilized and in combination with Heparin. Due to its insensitivity to endogenous coagulation inhibitors, this assay, combined with the Pro-IL-Complex test, can help the user to identify the presence of inhibitors (i.e., PIVKA).

**Principle:** Optimized rabbit brain thromboplastin containing specific levels of calcium ions and Heparin inhibitor (polybrene). A bovine deficient plasma, containing all Factors except II, VII, X, IX, provides adequate levels of Fibrinogen and Factor V.

**CE Mark:** ✔
**510(k):** Not FDA-cleared

**Vials and Volumes**
- 5 x 7 mL Rabbit calcium thromboplastin (lyo)
- 5 x 3 mL Bovine plasma (lyo)

**Part Number** 0009758710

**Main Features**
- Specific for OAT monitoring
- PIVKA-insensitive
- Insensitive to Heparin up to 0.5 U/mL
- ISI approximately 1.3

---

PCX/HPX Thromboplastin Diluent*

**Intended Use:** For the reconstitution of the thromboplastin reagents for the Pro-IL-Complex and Hepatocomplex assays (calibration and analysis).

**CE Mark:** ✔
**510(k):** Not FDA-cleared

**Principle:** Dedicated saline solution.

**Bottle and Volume**
1 x 100 mL

**Part Number** 0008469600

* Not available in all countries.
Heparin

**Intended Use:** For the quantitative determination of Unfractionated Heparin (UFH) and Low Molecular Weight Heparin (LMWH) activity in human citrated plasma on IL Hemostasis systems.

**Principle:** Based on a synthetic chromogenic substrate and on Factor Xa inactivation.

**Measurement Principle**

Heparin + AT > [Heparin • AT]  
[Heparin • AT] + FXa (excess) > [Heparin • AT • FXa] + FXa (residual)  
S-2765 + FXa (residual) > Peptide + pNA

**CE Mark:** ✔  
**510(k):** ✔

**Vials and Volumes**  
1 x 5 mL Factor Xa reagent (lyo)  
1 x 4 mL Chromogenic substrate (S-2765) (lyo)  
1 x 3 mL Antithrombin (lyo)  
1 x 8 mL Buffer

**Part Number** 0020009400

**Main Features**  
- Linear response from 0 to 1 U/mL of UFH and/or LMWH  
- Enhanced reagent stability

**Liquid Heparin (NEW)**

**Intended Use:** For the quantitative determination of Unfractionated Heparin (UFH) and Low Molecular Weight Heparin (LMWH) activity in human citrated plasma on IL Hemostasis systems (ACL TOP Family, ACL ELITE/ELITE PRO/8/9/10000 and ACL Futura/ACL Advance Systems).

**Principle:** Based on a synthetic chromogenic substrate and on Factor Xa inactivation.

**Measurement Principle**

Heparin is analyzed as a complex with antithrombin present in the sample. The concentration of this complex is dependent on the availability of the patient’s endogenous antithrombin. When the Heparin – AT complex is formed, two competing reactions take place.

1. FXa is neutralized by Heparin-AT complex  
2. Residual FXa is quantified with a synthetic chromogenic substrate. The paranitroaniline released is monitored kinetically at 405 nm and is inversely proportional to the heparin level in the sample.

**CE Mark:** ✔  
**510(k):** ✔

**Vials and Volumes**

Calibrator 1 - 3: 3 x 1 mL vials (lyo)

**Part Number** 0020300600

**Main Features**  
- One set of calibrators for both UFH and LMWH  
- Calibrator set with predetermined heparin concentrations

**Liquid Heparin Calibrators (NEW)**

**Intended Use:** For the calibration of the HemosIL Liquid Heparin assay on IL Hemostasis systems (ACL TOP Family, ACL ELITE/ELITE PRO/8/9/10000 and ACL Futura/ACL Advance Systems).

**Principle:** Tri-level lyophilized calibrators prepared from human citrated plasma by means of a dedicated process at three different heparin concentrations: 0, 0.8 and 2.0 IU/mL, and are traceable to the World Health Organization (WHO) International Standards for Unfractionated Heparin (UFH) and Low Molecular Weight Heparin (LMWH).

**CE Mark:** ✔  
**510(k):** ✔

**Vials and Volumes**

Calibrator 1 - 3: 3 x 1 mL vials (lyo)

**Part Number** 0020300600

**Main Features**  
- One set of calibrators for both UFH and LMWH  
- Calibrator set with predetermined heparin concentrations
UF Heparin Controls (NEw)

**Intended Use:** For the quality control of the HemosIL Liquid Heparin assay when testing for Unfractionated Heparin (UFH) on IL Hemostasis systems (ACL TOP Family, ACL ELITE/ELITE PRO/8/9/10000 and ACL Futura/ACL Advance Systems).

**Principle:**
- **Low UF Heparin Control:** For the assessment of precision and accuracy of the assay at the low concentration of UFH.
- **High UF Heparin Control:** For the assessment of precision and accuracy of the assay at the high concentration of UFH.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volumes**
- Low UF Heparin: 5 x 1 mL vials (lyo)
- High UF Heparin Control: 5 x 1 mL (lyo)

**Part Number** 0020300300

**Main Features**
- Assayed controls
- Comprised of human plasma containing UFH only
- Bi-level Low and High controls

LMW Heparin Controls (NEw)

**Intended Use:** For the quality control of the HemosIL Liquid Heparin assay when testing for Low Molecular Weight Heparin (LMWH) on IL Hemostasis systems (ACL TOP Family, ACL ELITE/ELITE PRO/8/9/10000 and ACL Futura/ACL Advance Systems).

**Principle:**
- **Low LMWH Control:** For the assessment of precision and accuracy of the assay at the low concentration of LMWH.
- **High LMWH Control:** For the assessment of precision and accuracy of the assay at the high concentration of LMWH.

**CE Mark:** ✔

**Vials and Volumes**
- Low LMW Heparin: 5 x 1 mL vials (lyo)
- High LMW Heparin Control: 5 x 1 mL (lyo)

**Part Number** 0020300200

**Main Features**
- Assayed controls
- Comprised of human plasma containing LMWH only
- Bi-level Low and High controls
D-DIMER
### D-Dimer

**Intended Use:** Automated latex-enhanced immunoassay for the quantitative determination of D-Dimer in human citrated plasma on IL Hemostasis systems for use in conjunction with a clinical Pretest Probability (PTP) assessment model to exclude Venous Thromboembolism (VTE) in outpatients suspected of Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE).

**Principle:** Suspension of polystyrene latex particles of uniform size, coated with a monoclonal antibody, highly specific for the D-Dimer domain included in fibrin-soluble derivatives. When a plasma containing D-Dimer is mixed with the Latex Reagent and the Reaction Buffer, the coated latex particles agglutinate.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volumes**
- 4 x 2 mL Latex Reagent (lyo)
- 4 x 9 mL Reaction Buffer (liq)
- 2 x 1 mL D-Dimer Calibrator (lyo)

**Part Number** 0020008500

**Main Features**
- Fully automated immunoturbidimetric assay
- FDA-cleared for the exclusion of VTE, in conjunction with a PTP score
- Multi-center management study demonstrated 100% NPV with a cut-off of 230 ng/mL D-DU on IL Hemostasis systems
- Time to result less than seven minutes
- Test range up to 5,250 ng/mL with automatic rerun capability

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### D-Dimer HS

**Intended Use:** For the quantitative determination of D-Dimer in human citrated plasma on the ACL TOP Family of Hemostasis Testing Systems, in conjunction with a clinical Pretest Probability (PTP) assessment model, to exclude Venous Thromboembolism (VTE) in outpatients suspected of Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE).

**Principle:** Suspension of polystyrene latex particles of uniform size, coated with the F(ab')2 fragment of a monoclonal antibody, highly specific for the D-Dimer domain included in fibrin-soluble derivatives. The use of the F(ab')2 fragment allows a more specific D-Dimer detection, avoiding the interference of some endogenous factors, such as the Rheumatoid Factor. When a plasma containing D-Dimer is mixed with the Latex Reagent and the Reaction Buffer, the coated latex particles agglutinate.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volumes**
- 3 x 2 mL Latex Reagent (lyo)
- 3 x 8 mL Reaction Buffer (liq)
- 2 x 1 mL D-Dimer Calibrator (lyo)

**Part Number** 0020007700

**Main Features**
- Highly sensitive, fully automated immunoturbidimetric assay
- FDA-cleared for the exclusion of VTE, in conjunction with a PTP score
- Multi-center management study demonstrated 100% NPV with a cut-off of 230 ng/mL D-DU on the ACL TOP Family
- Time-to-result less than five minutes
- Test range up to 69,000 ng/mL with rerun on the ACL TOP Family

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### D-Dimer Controls

**Intended Use:** Low D-Dimer Control is for the assessment of precision and accuracy of the assay at D-Dimer borderline levels. High D-Dimer Control is for the assessment of precision and accuracy of the assay at D-Dimer abnormal levels. Use of both controls is recommended for a complete quality control program.

**Principle:** Prepared through a dedicated process and contains different concentrations of partially purified D-Dimer obtained by digestion of Factor XIIIa cross-linked human fibrin with human plasmin.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volumes**
- 5 x 1 mL High Control (lyo)
- 5 x 1 mL Low Control (lyo)

**Part Number** 0020008610

**Main Features**
- D-Dimer Low: control at the borderline level
- D-Dimer High: control at the pathological level
- For use with:
  - D-Dimer, part number 0020008500
  - D-Dimer HS, part number 0020007700
  - D-Dimer 500, part number 002030100
D-Dimer 500 (NEW)*

**Intended Use:** For the quantitative determination of D-Dimer in human citrated plasma on IL Hemostasis systems for use in conjunction with a clinical pretest probability (PTP) assessment model to exclude venous thromboembolism (VTE) in outpatients suspected of deep venous thrombosis (DVT) and pulmonary embolism (PE).

**Principle:** Suspension of polystyrene latex particles of uniform size coated with a monoclonal antibody highly specific for the D-Dimer domain included in fibrin soluble derivatives. When a plasma containing D-Dimer is mixed with the Latex Reagent and the Reaction Buffer, the coated latex particles agglutinate.

**CE Mark:** ✔

**510(k):** Pending FDA-clearance

**Vials and Volumes**
- 4 x 2 mL Latex Reagent (lyo)
- 4 x 9 mL Reaction Buffer (liq)
- 2 x 1 mL D-Dimer Calibrator (lyo)

**Part Number** 0020300100

**Main Features**
- Fully automated immunoturbidimetric assay
- Results expressed in Fibrinogen Equivalent Units ng/mL (FEU)
- Multi-center management study demonstrated 100% NPV with a cut-off of 500 ng/mL on IL Hemostasis systems
- Time to results < 7 mins

* Not available in all countries.

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D-Dimer HS 500 (NEW)

**Intended Use:** For the quantitative determination of D-Dimer in human citrated plasma on the ACL TOP Family of Hemostasis Testing Systems for use in conjunction with a clinical Pretest Probability (PTP) assessment model to exclude Venous Thromboembolism (VTE) in outpatients suspected of Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE).

**Principle:** Suspension of polystyrene latex particles of uniform size coated with the Fab’1 fragment of a monoclonal antibody highly specific for the D-Dimer domain included in fibrin degradation products or derivatives. The use of the Fab’1 fragment allows a more specific D-Dimer detection, avoiding the interference of some endogenous factors like the Rheumatoid Factor. When a plasma containing D-Dimer is mixed with the Latex Reagent and the Reaction Buffer, the coated latex particles agglutinate.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volumes**
- 5 x 4 mL Latex Reagent (liq)
- 5 x 6 mL Reaction Buffer (liq)
- 2 x 1 mL D-Dimer Calibrator (lyo)

**Part Number** 0020500100

**Main Features**
- Ready-to-use liquid latex formulation
- Results expressed in ng/mL (FEU)
- FDA-cleared for the exclusion of VTE, in conjunction with a PTP score
- Multi-center management study demonstrated 100% NPV with a cut-off of 500 ng/mL on ACL TOP Family
- Time to results < 5 mins

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D-Dimer HS 500 Controls (NEW)

**Intended Use:** For the quality control of D-Dimer HS 500 assay performed on the ACL TOP Family of Hemostasis Testing Systems.

**Principle:** Prepared through a dedicated process and contains different concentrations of partially purified D-Dimer obtained by digestion of Factor XIIIa cross-linked human fibrin with human plasmin.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volumes**
- 5 x 1 mL High Control (lyo)
- 5 x 1 mL Low Control (lyo)

**Part Number** 0020500200

**Main Features**
- Assigned for HemosIL D-Dimer HS 500
- Results expressed in ng/mL (FEU)
- Low Control: borderline level
- High Control: pathological level
**AcuStar D-Dimer (NEW)**

**Intended Use:** Fully automated chemiluminescent immunoassay for the quantitative determination of D-Dimer in human citrated plasma on the ACL AcuStar Hemostasis Testing System as an aid in the diagnosis of Venous Thromboembolism (VTE), Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE).

**Principle:** A two-step immunoassay with a chemiluminescent detection system. Magnetic particles are coated with a monoclonal antibody highly specific for D-Dimer. The particles capture D-Dimer, if present, in the sample. After incubation and washing, an isoluminol-labeled anti-XDP antibody is added and binds to the captured D-Dimer. Catalyst and H₂O₂ are added to the reaction, resulting in an emission of light, proportionate to the concentration of D-Dimer.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volumes**
- 1 D-Dimer cartridge for 100 tests (liq)
- 1 x 1 mL D-Dimer Calibrator 1 (lyo)
- 1 x 1 mL D-Dimer Calibrator 2 (lyo)
- 1 D-Dimer Calibrator 1 barcoded tube
- 1 D-Dimer Calibrator 2 barcoded tube

**Part Number** 0009802000

**Main Features**
- Cartridge-based, ready-to-use, precalibrated assays for unmatched simplicity
- Clinically validated 500 ng/mL Fibrinogen Equivalent Units (FEU) cut-off for management of patients with VTE
- Extended, eight-week onboard stability – optimal for analysis 24 hours/day, 7 days/week
- Highly sensitive, chemiluminescent immunoassay offers superior accuracy and precision
- Extremely wide linearity range and virtually no optical or Rheumatoid Factor interference

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**AcuStar D-Dimer Controls (NEW)**

**Intended Use:** For the quality control of AcuStar D-Dimer assay performed on the ACL AcuStar Hemostasis Testing System.

**Principle:** Prepared through a dedicated process and contains different concentrations of partially purified D-Dimer, obtained by digestion of Factor XIIIa cross-linked human fibrin with human plasmin.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volumes**
- 3 x 1 mL Low D-Dimer Control (lyo)
- 3 x 1 mL High D-Dimer Control (lyo)
- 3 x 1 mL Very High D-Dimer Control (lyo)
- 3 D-Dimer Low Control barcoded tubes
- 3 D-Dimer High Control barcoded tubes
- 3 D-Dimer Very High Control barcoded tubes

**Part Number** 0009802100

**Main Features**
- Assigned for AcuStar D-Dimer
- Results expressed in Fibrinogen Equivalent Units (FEU)
- Low Control: borderline level
- High Control: pathological level
- Very High Control: high pathological level

**Chemiluminescent technology assay. For use on ACL AcuStar Hemostasis Testing System.**
**Dimertest Kit**

**Intended Use:** A qualitative and semi-quantitative latex slide test for D-Dimer determination in human plasma.

**Principle:** Latex particles, coupled with a highly specific D-Dimer monoclonal antibody (3B6/22). The kit has an elevated stability and an optimal sensitivity (cut-off value at 200 ng/mL).

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volumes**
- 1 x 2 mL Latex Reagent (liq)
- 1 x 0.5 mL Positive Control (liq)
- 1 x 0.5 mL Negative Control (liq)
- 1 x 20 mL Buffer (liq)
- 8-well Reaction Test Cards
- Plastic Stir Rods

**Part Number** 49738960

**Main Features**
- Single-test use
- Liquid reagents: ready to use
- Enhanced stability
- Elevated sensitivity (cut-off value at 200 ng/mL)
- Elevated specificity
- Elevated negative predictive value

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**Dimertest Latex**

**Intended Use:** For the determination of D-Dimer

**Principle:** Latex, coupled with a highly specific D-Dimer monoclonal antibody (3B6/22).

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volume**
- 1 x 2 mL Latex Reagent (liq)

**Part Number** 49738920
HEPARIN-INDUCED THROMBOCYTOPENIA
HIT-Ab\textsubscript{PF4-H}* (NEW)

**Intended Use:** For the detection of total immunoglobulin in human citrated plasma against Platelet Factor 4-Heparin (PF4-H) complexes on the ACL TOP Family of Hemostasis Testing Systems. Heparin-associated antibodies are commonly found in patients with Heparin-Induced Thrombocytopenia (HIT).

**Principle:** Latex-enhanced immunoturbidimetric assay for the detection of PF4-H antibodies commonly associated with HIT. The HIT reagent is a suspension of polystyrene particles, coated with a monoclonal antibody against PF4-H. The competitive agglutination reaction occurs when a complex of PF4-PVS (polyvinyl sulfonate, a compound similar to heparin) is mixed with the latex and patient sample. PF4-H antibodies in a positive sample will bind to the complex, thereby inhibiting agglutination, while the absence of PF4-H antibodies will allow the complex to bind to the latex, thereby allowing agglutination to occur.

**CE Mark:** ✔

**510(k):** Pending FDA-clearance

**Vials and Volumes**
- 2 x 1.8 mL Latex Reagent (liq)
- 2 x 3.2 mL Stabilizer (liq)
- 2 x 0.8 mL Complex (liq)
- 2 x 1 mL Calibrator (liq)

**Part Number** 0020301200

**Main Features**
- Fully automated, liquid, ready-to-use
- Results available on-demand, 24/7
- Time to results < 12 mins

HIT Controls* (NEW)

**Intended Use:** Low HIT Control is for the control of the assay at low HIT Antibody levels. High HIT Control is for the assessment of precision and accuracy of the assay at abnormal HIT Antibody levels. Use of both controls is recommended for a complete quality control program.

**Principle:** Prepared from stock concentrate solutions, with a dedicated process, and contain different concentrations of a PF4-Heparin monoclonal antibody.

**CE Mark:** ✔

**510(k):** Pending FDA-clearance

**Vials and Volumes**
- 3 x 1 mL High Control (liq)
- 3 x 1 mL Low Control (liq)

**Part Number** 0020013200

**Main Features**
- HIT Low: control at low HIT Antibody levels
- HIT High: control at abnormal HIT Antibody levels
- For use with HemosIL HIT-Ab\textsubscript{PF4-H}*

*Not available in all countries.
THROMBOPHILIA
**Liquid Antithrombin**

**Intended Use:** For the quantitative determination of Antithrombin in human citrated plasma on the IL Hemostasis systems.

**Principle:** Based on a synthetic chromogenic substrate and on FXa inactivation.

**Measurement principle**

\[
\text{AT} + \text{Heparin} \rightarrow [\text{AT} \cdot \text{Heparin}] \\
[\text{AT} \cdot \text{Heparin}] + \text{FXa (excess)} \rightarrow [\text{AT} \cdot \text{Heparin} \cdot \text{FXa} \cdot \text{residual}] \\
\text{S-2765} + \text{FXa (residual)} \rightarrow \text{Peptide} + \text{pNA}
\]

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volumes**

- **ACL ELITE/ELITE PRO, ACL 8/9/10000**
  - 4 x 4 mL FXa Reagent (liq)
  - 2 x 2 mL Chromogenic Substrate S-2765 (liq)

- **ACL TOP Family, ACL Advance**
  - 4 x 4.5 mL FXa Reagent (liq)
  - 4 x 4.5 mL Chromogenic Substrate S-2765 (liq)

- **ACL TOP Family, ACL Advance, ACL 200-7000**
  - 2 x 2 mL FXa Reagent (liq)
  - 2 x 2 mL Chromogenic Substrate S-2765 (liq)

**Part Number**

- ACL ELITE/ELITE PRO, ACL 8/9/10000 kit 0020002500
- ACL TOP Family, ACL Advance kit 0020030100
- ACL TOP Family, ACL Advance, ACL 200-7000 kit 0020300400

**Main Features**

- Liquid form: ready to use
- Factor Xa-based assay
- Insensitive to Heparin Cofactor II
- Enhanced reagent stability

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**Antithrombin**

**Intended Use:** For the quantitative determination of Antithrombin in human citrated plasma on the IL Hemostasis systems.

**Principle:** Based on a synthetic chromogenic substrate and on FXa inactivation.

**Measurement principle**

\[
\text{AT} + \text{Heparin} \rightarrow [\text{AT} \cdot \text{Heparin}] \\
[\text{AT} \cdot \text{Heparin}] + \text{FXa (excess)} \rightarrow [\text{AT} \cdot \text{Heparin} \cdot \text{FXa} \cdot \text{residual}] \\
\text{S-2765} + \text{FXa (residual)} \rightarrow \text{Peptide} + \text{pNA}
\]

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volumes**

- 2 x 2.5 mL Factor Xa reagent (lyo)
- 2 x 2 mL Chromogenic Substrate S-2765 (liq)

**Part Number** 0020008900

**Main Features**

- Fully automated
- Factor Xa-based assay
- Insensitive to Heparin Cofactor II
- Enhanced reagent stability

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**Protein C**

**Intended Use:** For the quantitative determination of Protein C in human citrated plasma on IL Hemostasis systems.

**Principle:** Based on the activation of plasma Protein C with a Protein C Activator and on the measurement of the activated Protein C with a synthetic chromogenic substrate.

**Measurement principle**

\[
\text{Protein C} + \text{Protein C Activator} \rightarrow \text{Activated Protein C} \\
\text{Activated Protein C} + \text{S-2366} \rightarrow \text{Peptide} + \text{pNA}
\]

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volumes**

- 2 x 2.5 mL Protein C Activator (lyo)
- 2 x 2.5 mL Chromogenic Substrate S-2366 (lyo)
- 1 x 8 mL Diluent (liq)

**Part Number** 002000500

**Main Features**

- Improved reagent stability
- Improved linearity
- Improved formulation ensures better specificity
ProClot

**Intended Use:** For the quantitative determination of Protein C in human citrated plasma on IL Hemostasis systems.

**Principle:** Based on prolongation of an Activated Partial Thromboplastin Time (APTT) assay in presence of activated Protein C.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volumes**
- 4 x 1.5 mL Protein C activator (lyo)
- 4 x 1mL Protein C deficient plasma (lyo)
- 2 x 1mL Protein C control plasma (lyo)

**Part Number** 0008468310

**Main Features**
- Functional clotting assay for the Protein C determination
- Specific for thrombophilia investigation
- Can be used in combination with the IL APTT routine reagents

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ProClot Diluent

**Intended Use:** For the ProClot assay (calibration and analysis).

**Principle:** Dedicated saline solution.

**CE Mark:** ✔

**510(k):** ✔

**Bottle and Volume**
- 1 x 100 mL

**Part Number** 0008468600

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ProS

**Intended Use:** Functional assay for the quantitative determination of free Protein S (PS) in human citrated plasma on IL Hemostasis systems.

**Principle:** Determines the functional activity of free PS by measuring the degree of prolongation of a prothrombin time in the presence of the tissue factor, phospholipids, calcium ions and activated Protein C.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volumes**
- 3 x 3 mL Protein S reagent (lyo)
- 6 x 1 mL Protein S deficient plasma (lyo)
- 2 x 1 mL Protein S control plasma (lyo)

**Part Number** 0020002800

**Main Features**
- Fully automated functional PS assay for use with all IL Hemostasis systems
- Easy reagent preparation, resulting in a rapid turnaround time
- Recombinant rabbit tissue factor and synthetic phospholipids incorporated for better lot-to-lot consistency

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Free Protein S (antigenic immunoassay)

**Intended Use:** Immunoturbidimetric assay for the quantitative determination of free Protein S in human citrated plasma on IL Hemostasis systems.

**Principle:** Measures the increase of turbidity produced by the agglutination of two latex reagents. Purified C4BP adsorbed onto the first latex reagent reacts with a high affinity for free Protein S of patient plasma in the presence of calcium ions, the free Protein S adsorbed on the C4BP latex triggers the agglutination reaction with the second latex reagent which is sensitized with a monoclonal antibody directed against human Protein S. The degree of agglutination will be directly proportional to the free Protein S concentration in the test sample.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volumes**
- 3 x 4 mL C4BP Buffer (liq)
- 3 x 4 mL C4BP Latex (lyo)
- 3 x 2 mL Anti PS MAb Latex (lyo)

**Part Number** 0020002700

**Main Features**
- Quantitative assay specially designed for IL Hemostasis systems
- Latex turbidimetric ligand immunoassay with the affinity of a polyclonal antibody and the specificity of a monoclonal antibody
- Method based on binding to the natural free Protein S ligand (C4BP)
- High specificity (no interference with Factor V Leiden mutation)
- Excellent correlation with existing methods (both ELISA and latex-based assays)
- Extended calibration stability (three months)
THROMBOPHILIA

Factor V Leiden (APC R V)

**Intended Use:** For determination of resistance to activated Protein C, caused by the Factor V:Q506 (Factor V Leiden) mutation, in plasma from untreated individuals and from patients on Heparin or Oral Anticoagulant Therapy (OAT).

**Principle:** Sensitivity and specificity for the Factor V:Q506 mutation is significantly increased when the Activated Partial Thromboplastin Time (APTT)-based APC-resistance assay is performed in the presence of excess Factor V Reagent Plasma.

**CE Mark:** ✔

**Vials and Volumes**
- 2 x 4 mL APTT reagent (liq)
- 2 x 4 mL Factor V Reagent Plasma (lyo)
- 2 x 2 mL APC/CaCl₂ (lyo)
- 2 x 2 mL CaCl₂ (liq)
- 2 x 2 mL APC Control Plasma Level 1 (lyo)
- 2 x 1 mL APC Control Plasma Level 2 (lyo)

**Part Number**
- Factor V Leiden 0020008700
- Factor V Reagent Plasma 0020008800

**Main Features**
- High specificity Factor V Leiden detection
- 100% sensitivity for the FV:Q506 mutation
- Test results are not affected by OAT or Heparin present in the plasma samples (up to 1 U/mL)

Homocysteine

**Intended Use:** For the quantitative determination of total L-homocysteine in human citrated plasma on IL Hemostasis systems.

**Principle:** Homocysteine (Hcy) levels in patient plasma are measured automatically on IL Hemostasis systems in three stages:
1. Reduction of mixed disulfides and protein-bound forms of Hcy present in the plasma samples to free Hcy
2. Enzymatic conversion of free Hcy to S-adenosyl-L-Hcy (SAH) by the SAH hydrolase (SAHH) in the presence of an excess of adenosine
3. Competitive agglutination reaction between anti-SAH and SAH/conjugate

**CE Mark:** ✔

**510(k): ✔

**Vials and Volumes**
- 2 x 2 mL a-SAH Latex Reagent (lyo)
- 2 x 2 mL Reductant (liq)
- 2 x 2 mL Enzyme (liq)
- 2 x 2.5 mL Conjugate (liq)
- 2 x 9 mL Buffer (liq)
- 2 x 1 mL Calibrator (liq)

**Part Number** 0020007800

**Main Features**
- The first fully automated, immunoturbidimetric assay for the Hemostasis laboratory
- Proven technology
- Linearity up to 60 mmol/L

Homocysteine Controls

**Intended Use:** For the quality control of total L-homocysteine assays.

**Principle:** Prepared from a stock concentrate solution, with a dedicated process, and contains different concentrations of L-homocysteine.

**CE Mark:** ✔

**510(k): ✔

**Vials and Volumes**
- 3 x 1 mL Homocysteine Control Level 1 (lyo)
- 3 x 1 mL Homocysteine Control Level 2 (lyo)

**Part Number** 0020007900

**Main Features**
- Level 1: Borderline homocysteine levels
- Level 2: Abnormal homocysteine levels
**ThromboPath**

**Intended Use:** For the functional evaluation of the Protein C anticoagulant pathway in human citrated plasma on IL Hemostasis systems. Intended as an aid in the diagnosis of thrombophilic defects such as Protein S (PS), Protein C (PC) deficiencies, Factor V (FV) Leiden and Lupus Anticoagulants (LA).

**Principle:** Determines the dysfunction of the anticoagulant PC pathway by measuring Protac-induced Coagulation Inhibition Percent (PICi%). The plasma sample is diluted with ThP Diluent and tested as two separate aliquots. One aliquot is incubated with ThP Activator A (with Protac) and the other is incubated with ThP Activator B (without Protac). Thrombin generation in both aliquots is initiated by adding ThP Thromboplastin. Thrombin activity is quantified after addition of ThP Chromogenic Substrate by an increase in optical density at 405nm.

**CE Mark:** ✔

**510(k):** Not FDA-cleared

**Vials and Volumes**
- 2 x 10 mL Diluent (liq)
- 1 x 8 mL Substrate (lyo)
- 2 x 4 mL Thromboplastin (lyo)
- 1 x 5 mL Activator A
- 1 x 5 mL Activator B
- 2 x 1 mL Low Control plasma

**Part Number** 0020005500

**Main Features**
- Easy-to-use chromogenic assay
- Sensitive to PS and PC deficiencies, FV Leiden and LA
- Cut-off established to aid in the differentiation of pathologic and non-pathologic levels
- Insensitive to Heparin up to 0.75 U/mL

*Not available in all countries.*
Xpert® HemosIL FII & FV

**Intended Use**: Qualitative *in vitro* diagnostic genotyping test for the rapid detection of Factor II (G20210A) and Factor V Leiden (G1691A) single-point mutations, from sodium citrate or EDTA anticoagulated whole blood, on the GeneXpert System.

**Principle**: Detects Factor II/Factor V alleles from sodium citrate or EDTA anticoagulated whole blood. Integrates DNA extraction, amplification and detection in one cartridge. Each cartridge contains freeze-dried beads with all the necessary components for PCR: DNA polymerase, nucleotides, primers and scorpions. Scorpions include probes and primers specific for FII and FV normal and mutated DNA. Each scorpion sequence is labeled with a specific fluorophore. Through the PCR cycles, the specific binding of the scorpion sequence to the target mutation is detected by the system in real-time.

**CE Mark**: ✔

**Vials and Volumes**
- 10 FII & FV Assay Cartridges
- 10 x 2.8 mL Reagent 1
- 10 x 2.8 mL Reagent 2

**Part Number**: GXFIIFV-10

**Main Features**
- One cartridge = one sample
- Uses citrated or EDTA whole blood; fully integrated sample prep
- FII & FV combined testing in a single cartridge
- Time to result: 30 minutes
- Self-controlled

FII & FV DNA Control

**Intended Use**: For *in vitro* diagnostic use as a heterozygous quality control to monitor analytical performance of the extraction, amplification and detection steps of the Xpert HemosIL FII & FV genotyping assay on the GeneXpert Dx System used in the detection of both the Factor II 20210G>A and Factor V 1691G>A (Leiden) mutations.

**Principle**: Synthetic Factor II and Factor V DNA, suspended in a non-infectious blood-like matrix.

**CE Mark**: ✔

**Vials and Volume**
- 3 vials x 0.5 mL FII & FV (liq)

**Part Number**: 0020003500

**Main Features**
- Heterozygous control for both Factor II (G20210A) and Factor V Leiden (G1691A) mutations.

GeneXpert® System

GeneXpert System automates and integrates sample purification, nucleic acid amplification and detection of the target sequence in simple or complex samples using real-time PCR.

**CE Mark**: ✔

**510(k)**: ✔

**Main Features**
- Self-contained, fully integrated, real-time, automated PCR system
- From DNA extraction to results in a single cartridge
- Up to four random-access, independent modules per system

GeneXpert and Xpert HemosIL FII & FV are manufactured by Cepheid and distributed by Instrumentation Laboratory.
ANTIPHOSPHOLIPID SYNDROME
ANTIPHOSPHOLIPID SYNDROME

LAC Screen and LAC Confirm

**Intended Use:** For the detection of Lupus Anticoagulants (LA) in human citrated plasma on IL Hemostasis systems.

**Principle:** Improved Diluted Russell’s Viper Venom Test (DRVVT) reagents intended to simplify and standardize the detection of LA in clinical evaluations.

CE Mark: ✔

510(k): ✔

**Vials and Volumes**
- 10 x 2 mL LAC Screen (lyo)
- 10 x 2 mL LAC Confirm (lyo)

**Part Number**
- LAC Screen: 0020008000
- LAC Confirm: 0020008200

**Main Features**
- Based on the DRVVT, the most common screening and confirmatory test for LA in the laboratory
- Easy to use, fully automated
- Single-step reagents
- Insensitive to Heparin up to 1 IU/mL

Silica Clotting Time

**Intended Use:** For the detection of Lupus Anticoagulants (LA) in human citrated plasma on IL Hemostasis systems.

**Principle:** Silica Clotting Time (SCT) contains both SCT Screen and SCT Confirm reagents. SCT Screen has a low phospholipid level, making it sensitive to LA. The additional amount of phospholipid in SCT Confirm neutralizes LA to produce shorter clotting times.

CE Mark: ✔

510(k): ✔

**Vials and Volumes**
- 3 x 5 mL SCT Screen (liq)
- 3 x 5 mL SCT Confirm (liq)
- 3 x 10 mL SCT CaCl₂ (liq)

**Part Number**
- 0020004800

**Main Features**
- Screen (low phospholipid concentration) and Confirm (high phospholipid concentration) in one kit
- Liquid formulation, easy to use, fully automated
- Suitable for mixing studies
- Suitable for Oral Anticoagulant-treated patient samples
**AcuStar Anti-Cardiolipin (NEW)**

**Intended Use:** Fully automated chemiluminescent immunoassay for the semi-quantitative measurement of Anti-Cardiolipin (aCL) IgG or IgM antibodies in human citrated plasma or serum on the ACL AcuStar Hemostasis Testing System, as an aid in the diagnosis of thrombotic disorders related to primary and secondary Antiphospholipid Syndrome (APS) when used in conjunction with other laboratory and clinical findings.

**Principle:** Two-step immunoassays with a chemiluminescent detection system. Magnetic particles are coated with cardiolipin and human purified beta-glycoprotein I (β2GPI). The particles capture aCL antibodies, if present, in the sample. After incubation and washing, an isoluminol-labeled anti-human IgG or IgM antibody is added and binds to the captured aCL antibodies. Catalyst and H₂O₂ are added to the reaction, resulting in an emission of light, proportionate to the concentration of aCL antibodies.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volumes**
- 1 aCL IgG Cartridge for 50 tests (liq)
- 1 x 1 mL aCL IgG Calibrator 1 (liq)
- 1 x 1 mL aCL IgG Calibrator 2 (liq)
- 1 aCL IgM Cartridge for 50 tests (liq)
- 1 x 1 mL aCL IgM Calibrator 1 (liq)
- 1 x 1 mL aCL IgM Calibrator 2 (liq)

**Part Number**
- AcuStar Anti-Cardiolipin IgG 0009802004
- AcuStar Anti-Cardiolipin IgM 0009802008

**Main Features**
- Cartridge-based, ready-to-use, precalibrated assays for unmatched simplicity
- Extended, six-week onboard stability – optimal for analysis 24 hours/day, 7 days/week
- Highly sensitive, chemiluminescent immunoassays offer superior accuracy and precision
- Extremely wide linearity ranges, with and without rerun
- Clinically validated 20 U/mL cut-off for all assays
- Uses serum or citrated plasma samples

**AcuStar Anti-Cardiolipin Controls (NEW)**

**Intended Use:** For the quality control of AcuStar Anti-Cardiolipin IgG or IgM assays performed on the ACL AcuStar Hemostasis Testing System.

**Principle:** Prepared through a dedicated process and contains different concentrations of human Anti-Cardiolipin (aCL) antibodies.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volumes**
- 3 x 1 mL Low aCL IgG Control (liq)
- 3 x 1 mL High aCL IgG Control (liq)
- 3 x 1 mL Low aCL IgM Control (liq)
- 3 x 1 mL High aCL IgM Control (liq)

**Part Number**
- AcuStar Anti-Cardiolipin IgG Controls 0009802104
- AcuStar Anti-Cardiolipin IgM Controls 0009802108

**Main Features**
- Assigned for AcuStar Anti-Cardiolipin IgG or IgM
- Results expressed in U/mL
- Low aCL Control: borderline level
- High aCL Control: control at the pathological level

**Chemiluminescent technology assay. For use on ACL AcuStar Hemostasis Testing System.**
**AcuStar Anti-β<sub>2</sub> Glycoprotein-I (NEW)**

**Intended Use:** Fully automated chemiluminescent immunoassay for the semi-quantitative measurement of Anti-β<sub>2</sub> Glycoprotein-I (aβ<sub>2</sub>GPI) IgG or IgM antibodies in human citrated plasma or serum on the ACL AcuStar Hemostasis Testing System, as an aid in the diagnosis of thrombotic disorders related to primary and secondary Antiphospholipid Syndrome (APS) when used in conjunction with other laboratory and clinical findings.

**Principle:** Two-step immunoassays with a chemiluminescent detection system. Magnetic particles are coated with human purified β<sub>2</sub>GPI. The particles capture aβ<sub>2</sub>GPI antibodies, if present, in the sample. After incubation and washing, an isoluminol-labeled anti-human IgG or IgM antibody is added and binds to the captured aβ<sub>2</sub>GPI antibodies. Catalyst and H<sub>2</sub>O<sub>2</sub> are added to the reaction, resulting in an emission of light, proportionate to the concentration of aβ<sub>2</sub>GPI antibodies.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volumes**
- 1 aβ<sub>2</sub>GPI IgG Cartridge for 50 tests (liq)
- 1 x 1 mL aβ<sub>2</sub>GPI IgG Calibrator 1 (liq)
- 1 x 1 mL aβ<sub>2</sub>GPI IgG Calibrator 2 (liq)
- 1 aβ<sub>2</sub>GPI IgM cartridge for 50 tests (liq)
- 1 x 1 mL aβ<sub>2</sub>GPI IgM Calibrator 1 (liq)
- 1 x 1 mL aβ<sub>2</sub>GPI IgM Calibrator 2 (liq)

**Part Number**
- AcuStar Anti-β<sub>2</sub> Glycoprotein-I IgG 0009802012
- AcuStar Anti-β<sub>2</sub> Glycoprotein-I IgM 0009802016

**Main Features**
- Cartridge-based, ready-to-use, precalibrated assays for unmatched simplicity
- Extended, six-week onboard stability – optimal for analysis 24 hours/day, 7 days/week
- Highly sensitive, chemiluminescent immunoassays offer superior accuracy and precision
- Extremely wide linearity ranges, with and without rerun
- Clinically validated 20 U/mL cut-off for all assays
- Uses serum or citrated plasma samples

**Chemiluminescent technology assay. For use on ACL AcuStar Hemostasis Testing System.**

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**AcuStar Anti-β<sub>2</sub> Glycoprotein-I Controls (NEW)**

**Intended Use:** For the quality control of AcuStar Anti-β<sub>2</sub> Glycoprotein-I IgG or IgM assays performed on the ACL AcuStar Hemostasis Testing System.

**Principle:** Prepared through a dedicated process and contains different concentrations of human Anti-β<sub>2</sub> Glycoprotein-I (aβ<sub>2</sub>GPI) antibodies.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volumes**
- 3 x 1 mL Low aβ<sub>2</sub>GPI IgG Control (liq)
- 3 x 1 mL High aβ<sub>2</sub>GPI IgG Control (liq)
- 3 x 1 mL Low aβ<sub>2</sub>GPI IgM Control (liq)
- 3 x 1 mL High aβ<sub>2</sub>GPI IgM Control (liq)

**Part Number**
- AcuStar Anti-β<sub>2</sub> Glycoprotein-I IgG Controls 0009802112
- AcuStar Anti-β<sub>2</sub> Glycoprotein-I IgM Controls 0009802116

**Main Features**
- Assigned for AcuStar Anti-β<sub>2</sub> Glycoprotein-I IgG or IgM
- Results expressed in U/mL
- Low aβ<sub>2</sub>GPI Control: borderline level
- High aβ<sub>2</sub>GPI Control: pathological level

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**Antiphospholipid Syndrome (APS)**
COAGULATION FACTORS
Factor II, V, VII and X Deficient Plasmas

**Intended Use:** Deficient plasmas to be used in combination with the selected PT reagent for the determination of specific Factor activity in citrated plasma on IL Hemostasis systems.

**Principle:** Each deficient plasma is specifically deficient in the corresponding Factor at a minimum level: < 1%. All remaining Factors are at the optimal level to assure proper performance in the plasma being assayed. Deficient plasmas are obtained using immunodepletion technology. All deficient plasmas are tested and found nonreactive for hepatitis B, C and HIV.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volume**
10 x 1 mL Factor deficient plasma (lyo)

**Part Number**
- Factor II: 0020012200
- Factor V: 0020011500
- Factor VII: 0020011700
- Factor X: 0020010000

**Main Features**
- Specific for Factor assays
- Residual activity of specific Factor < 1%

Factor VIII, IX, XI and XII Deficient Plasmas

**Intended Use:** Deficient plasmas to be used in combination with the selected APTT reagent for the determination of specific Factor activity in citrated plasma on IL Hemostasis systems.

**Principle:** Each deficient plasma is specifically deficient in the corresponding Factor at a minimum level: < 1%. All remaining Factors are at the optimal level to assure proper performances in the plasma being assayed. Deficient plasmas are obtained using immunodepletion technology. All deficient plasmas are tested and found nonreactive for hepatitis B, C and HIV.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volume**
10 x 1 mL Factor deficient plasma (lyo)

**Part Number**
- Factor VIII: 0020011800
- Factor IX: 0020011900
- Factor XI: 0020011300
- Factor XII: 0020011200

**Main Features**
- Specific for Factor assays
- Residual activity of specific Factor < 1%

Factor XIII Antigen

**Intended Use:** For the quantitative determination of Factor XIII Antigen (FXIII Ag) in human citrated plasma on IL Hemostasis systems.

**Principle:** Contains a FXIII Ag Latex Reagent which is a suspension of uniform size polystyrene latex particles coated with rabbit polyclonal antibodies, highly specific for the A-subunit of FXIII. When a plasma containing the active A-subunit of FXIII is mixed with the Latex reagent and the Buffer included in the kit, the coated latex particles agglutinate. The degree of agglutination is directly proportional to the concentration of FXIII Ag in the sample and is determined by measuring the decrease of transmitted light caused by the aggregates.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volumes**
- 2 x 2.5 mL Latex Reagent (liq)
- 2 x 5 mL Buffer (liq)
- 2 x 6 mL Diluent (liq)

**Part Number**
0020201300

**Main Features**
- Liquid ready-to-use reagent
- Fully automated immunoturbidimetric assay
- Simplifies the screening of genetic and acquired deficiency of FXIII
- Correlates with the activity assay

ELECTRACHROME Factor VIII

**Intended Use**

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volumes**
- 1 x 6 or 7 mL Chromogenic substrate (lyo)
- 2 x 3 or 3.5 mL Factor reagent (lyo)
- 2 x 24 mL Buffer (liq)

**Part Number**
49730503

* FXIII assays are exempt from 510(k) clearance.
VON WILLEBRAND DISEASE
**von Willebrand Factor Antigen**

**Intended Use:** For the quantitative determination of von Willebrand Factor Antigen (VWF:Ag) in human citrated plasma on IL Hemostasis systems.

**Principle:** Latex particle-enhanced immunoturbidimetric assay. When a plasma containing VWF:Ag is mixed with the Latex Reagent and Reaction Buffer, the coated latex particles agglutinate. The degree of agglutination is directly proportional to the concentration of VWF:Ag in the sample and is determined by measuring the decrease of transmitted light caused by the aggregates.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volumes**
- 2 x 3 mL Latex Reagent (liq)
- 2 x 4 mL Reaction Buffer (liq)

**Part Number** 0020002300

**Main Features**
- Latex particle-based immunoassay
- Liquid reagents, ready to use
- Proven correlation with existing ELISA method
- No prozone effect up to 1600% VWF
- Linearity from 10 to 150% VWF
- Precision performance: below 3.5% CV
- Quick turnaround time, less than seven minutes

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**von Willebrand Factor Activity**

**Intended Use:** For the quantitative determination of von Willebrand Factor Activity (VWF Activity) in human citrated plasma on IL Hemostasis systems.

**Principle:** Latex particle-enhanced immunoturbidimetric assay. The activity of VWF is determined by measuring the increase of turbidity produced by the agglutination of the latex reagent. A specific anti-VWF monoclonal antibody adsorbed onto the latex reagent, directed against the platelet binding site of VWF (Glycoprotein Ib receptor), reacts with the VWF of patient plasma. The degree of agglutination is directly proportional to the activity of VWF in the sample and is determined by measuring the decrease of transmitted light caused by the aggregates.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volumes**
- 2 x 4.5 mL Latex Reagent (lyo)
- 2 x 4.5 mL Buffer (liq)

**Part Number** 0020004700

**Main Features**
- Easy to use, labor saving
- Fully automated on the IL Hemostasis systems
- Time to result: 12 minutes
- Good precision and correlation with Ristocetin Cofactor Activity assays
FIBRINOLYSIS

Plasminogen
Intended Use: For the quantitative determination of Plasminogen in human citrated plasma on IL Hemostasis systems.

Principle: Based on the measurement of Plasminogen-Streptokinase complex with a synthetic chromogenic substrate.

Measurement principle
PLG + SK / FIB > PLG • SK / FIB
PLG • SK/FIB + S-2403 > Peptide + pNA

CE Mark: ✔
510(k): ✔

Vials and Volumes
2 x 2.5 mL Streptokinase Reagent (lyo)
2 x 2 mL Chromogenic Substrate S-2403 (lyo)

Part Number 0020009000

Main Features
• Improved reagent stability
• Improved linearity
• Improved formulation ensures optimal specificity

Plasmin Inhibitor (α₂-Antiplasmin)
Intended Use: For the quantitative determination of Plasmin Inhibitor in human citrated plasma on IL Hemostasis systems.

Principle: Based on synthetic chromogenic substrate and on plasmin inactivation.

Measurement principle
PI + Plasmin (in excess) > PI • Plasmin + Plasmin (residual)
S-2403 + Plasmin (residual) > Peptide + pNA

CE Mark: ✔
510(k): ✔

Vials and Volumes
2 x 2.5 mL Plasmin Reagent (lyo)
1 x 4 mL Chromogenic Substrate S-2403 (lyo)
2 x 9 mL Buffer (liq)

Part Number 0020009200

Main Features
• True plasmin inhibitor assay capable of detecting homozygous plasmin-inhibitor-deficient individuals
• Minimized cross-reactivity with α₂-macroglobulin
PLASMA CALIBRATORS AND CONTROLS
## Calibration plasma

**Intended Use:** For the calibration of coagulation assays on IL Hemostasis systems.

**Principle:** Prepared using pooled citrated plasma from healthy donors.

**CE Mark:** ✔

**510(k):** ✔

**Standardization:** Values are traceable to the standards supplied by the National Institute for Biological Standards and Controls (NIBSC) according to the World Health Organization (WHO) recommendations.

**Vials and Volume**
10 x 1 mL Calibration plasma (lyo)

**Part Number** 0020003700

**Main Features**
- Single calibrator for IL Hemostasis systems
- Single calibrator for several parameters
- 24-hour stability for several assays
- Traceability versus the NIBSC standards

### Reagent Table

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<th>Reagent</th>
<th>ACL TOP Family</th>
<th>ACL Advance</th>
<th>ACL ELITE/ELITE PRO ACL 8/9/10000</th>
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* Not FDA-cleared. Not available in all countries.
** ACL 200 and greater.
Normal Control ASSAYED

**Intended Use:** For the quality control of coagulation assays in the normal range on IL Hemostasis systems.

**Principle:** An easy-to-use, reliable source of normal human plasma.

**CE Mark:** ✔
**510(k):** ✔

**Vials and Volume**
10 x 1 mL Normal Control (lyo)

**Part Number** 0020003110

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Low Abnormal Control ASSAYED

**Intended Use:** For the quality control of coagulation assays in the low abnormal range on IL Hemostasis systems.

**Principle:** Prepared from citrated pooled plasma from healthy donors (not on Heparin or Oral Anticoagulant Therapy) and modified to simulate an abnormal coagulation sample.

**CE Mark:** ✔
**510(k):** ✔

**Vials and Volume**
10 x 1 mL Low Abnormal Control (lyo)

**Part Number** 0020003210

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High Abnormal Control ASSAYED

**Intended Use:** For the quality control of coagulation assays in the high abnormal range on IL Hemostasis systems.

**Principle:** Prepared from citrated pooled plasma from healthy donors (not on Heparin or Oral Anticoagulant Therapy) and modified to simulate an abnormal coagulation sample.

**CE Mark:** ✔
**510(k):** ✔

**Vials and Volume**
10 x 1 mL High Abnormal Control (lyo)

**Part Number** 0020003310

**Main Features**
- Single control for several assays
- 24-hour reconstituted stability for routine assays

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<table>
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<tr>
<th>Assay</th>
<th>Normal Control ASSAYED</th>
<th>Low Abnormal Control ASSAYED</th>
<th>High Abnormal Control ASSAYED</th>
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<td>Factor II, V VII, X</td>
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<td>Factor VIII, IX XI, XII</td>
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<td>Factor XIII Antigen</td>
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</table>

* Not FDA-cleared. Not available in all countries.
PLASMA CALIBRATORS AND CONTROLS

Special Test Control Level 1

Intended Use: For quality control in the low abnormal range for the chromogenic tests Antithrombin, Plasminogen, Plasmin Inhibitor, Protein C and Factor VIII, quality control of free Protein S assay in the range of 50-60% and for quality control of von Willebrand Factor assays (Antigen and Activity) in the normal range on IL Hemostasis systems.

Principle: Prepared from human citrated plasma through a dedicated process to provide values in the abnormal range.

CE Mark: ✓
510(k): ✓

Vials and Volume
10 x 1 mL Special Test Level 1 (lyo)

Part Number 0020011000

Main Features
- Assigned for Antithrombin, Protein C, Plasminogen Plasmin Inhibitor and Protein S in the abnormal range
- Assigned for VWF (Activity and Antigen) in the normal range
- Traceability versus National Institute Biological Standards and Controls standards

Special Test Control Level 2

Intended Use: For quality control in the high abnormal range for the chromogenic tests Antithrombin, Plasminogen, Plasmin Inhibitor, Protein C and Factor VIII, quality control of free Protein S and Factor assays (clotting) in the range of 20-40% activity and quality control of von Willebrand Factor assays (Antigen and Activity) in the low abnormal range on IL Hemostasis systems.

Principle: Prepared from human citrated plasma through a dedicated process to provide values in the abnormal range.

CE Mark: ✓
510(k): ✓

Vials and Volume
10 x 1 mL Special Test Level 2 (lyo)

Part Number 0020012000

Main Features
- Assigned for Antithrombin, Protein C, Plasminogen Plasmin Inhibitor and Protein S in the abnormal range
- Assigned for VWF (Activity and Antigen) and Factor assays (II, V, VII, VIII, IX, XI, XII) in the abnormal range
- Traceability versus National Institute Biological Standards and Controls standards
Low Fibrinogen Control

**Intended Use:** Provides a reliable marker in the abnormal range. Recommended for a complete quality control program on IL Hemostasis systems.

**Principle:** Contains human plasma with a reduced level of fibrinogen (approximately 100 mg/dL or 1 g/L). Fibrinogen, a plasma protein, is converted to fibrin by the action of thrombin. The use of a quantitative fibrinogen control is essential in monitoring the accuracy and precision of the fibrinogen assay system.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volume**
10 x 1 mL Low Fibrinogen Control (lyo)

**Part Number** 0020004200

**Main Features**
- Abnormal control assigned using the PT-based method
- Abnormal control assigned using the Clauss method
- Traceability versus the National Institute Biological Standards and Controls standards (according to World Health Organization recommendations)

Normal Control 1 UNASSAYED

**Intended Use:** For the quality control coagulation assays in the normal range on IL Hemostasis systems.

**Principle:** Human plasma.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volume**
10 x 1 mL Normal Control (lyo)

**Part Number** 0020003120

High Abnormal Control 3 UNASSAYED

**Intended Use:** For the quality control of coagulation assays in the high abnormal range on IL Hemostasis systems.

**Principle:** Prepared from citrated, pooled human plasma from healthy donors (not on Heparin or Oral Anticoagulant Therapy) and modified to simulate an abnormal coagulation sample.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volume**
10 x 1 mL High Abnormal Control (lyo)

**Part Number** 0020003320

Low Abnormal Control 2 UNASSAYED

**Intended Use:** For the quality control of coagulation assays in the low abnormal range on IL Hemostasis systems.

**Principle:** Prepared from citrated, pooled human plasma from healthy donors (not on Heparin or Oral Anticoagulant Therapy) and modified to simulate an abnormal coagulation sample.

**CE Mark:** ✔

**510(k):** ✔

**Vials and Volume**
10 x 1 mL Low Abnormal Control (lyo)

**Part Number** 0020003220
PLASMA CALIBRATORS AND CONTROLS

Routine Control Level 1*
**Intended Use:** For the quality control of coagulation assays in the normal range. The product is intended in the assessment of precision and accuracy for PT, APTT and Fibrinogen tests performed on coagulation systems.

**Principle:** Prepared from human citrated plasma from healthy donors.

CE Mark: N/A
510(k): ✔

Vials and Volume
10 x 1 mL Routine Control Level 1 (lyo)

Part Number 0020005600

QC Plasma Coagulation Control Level I*
**Intended Use:** A reliable and convenient source of normal human plasma used as a normal control in routine coagulation assays such as the PT, APTT, Fibrinogen, Antithrombin and Protein C to detect significant changes in certain variables, inherent in coagulation testing.

**Principle:** Lyophilized normal human plasma from a pool of freshly drawn citrated plasma.

CE Mark: ✔
510(k): Not FDA-cleared

Vials and Volume
10 x 1 mL QC Plasma Level 1 (lyo)

Part Number 0020010700

Routine Control Level 2*
**Intended Use:** For the quality control of coagulation assays in the low abnormal range. The product is intended in the assessment of precision and accuracy for PT and APTT tests performed on coagulation systems.

**Principle:** Prepared from human citrated plasma from healthy donors and modified, by means of a dedicated process, to simulate an abnormal coagulation sample.

CE Mark: N/A
510(k): ✔

Vials and Volume
10 x 1 mL Routine Control Level 2 (lyo)

Part Number 0020005700

QC Plasma Coagulation Control Level II*
**Intended Use:** A reliable and convenient source of abnormal human plasma used as a mid-range abnormal control in routine coagulation assays such as the one-stage PT, APTT, Fibrinogen, Antithrombin and Protein C to detect significant changes in certain variables, inherent in coagulation testing.

**Principle:** Lyophilized adsorbed human plasma from a pool of citrated normal plasma.

CE Mark: ✔
510(k): Not FDA-cleared

Vials and Volume
10 x 1 mL QC Plasma Level II (lyo)

Part Number 0020010800

Routine Control Level 3*
**Intended Use:** For the quality control of coagulation assays in the high abnormal range. The product is intended in the assessment of precision and accuracy for PT and APTT tests performed on coagulation systems.

**Principle:** Prepared from human citrated plasma from healthy donors and modified, by means of a dedicated process, to simulate an abnormal coagulation sample.

CE Mark: N/A
510(k): ✔

Vials and Volume
10 x 1 mL Routine Control Level 3 (lyo)

Part Number 0020005800

* Not available in all countries.
SOLUTIONS
SOLUIONS

Sample Diluent
Intended Use: For the calibration of both PT and Fibrinogen tests on the ACL H/T and ACL 7000.
Principle: Dedicated saline solution.
Bottle and Volume
1 x 100 mL
Part Number 0009756800

Wash-R Emulsion
Intended Use: Optical reference for nephelometric analysis and as a washing solution on ACL ELITE/ELITE PRO and ACL 8/9/10000.
Principle: Emulsion.
Bottle and Volume
1 x 100 mL
Part Number 0020002400

Factor Diluent
Intended Use: For the calibration of both PT and Fibrinogen tests on the ACL Advance, ACL ELITE/ELITE PRO, ACL 8/9/10000, ACL TOP Family, and for Factor Assays. It is also used to dilute calibrators, controls and patient samples in the Antithrombin and Plasminogen chromogenic kits on all IL Hemostasis Systems.
Principle: Dedicated saline solution.
Bottle and Volume
1 x 100 mL
Part Number 0009757600

Cleaning Solution (Clean A)
Intended Use: To properly wash analyzers. This recommended product minimizes carryover effects between assays.
Principle: Based on Hydrochloric Acid.
Bottle and Volume
1 x 500 mL
Part Number 0009831700

Reference Emulsion
Intended Use: For nephelometric analysis and as a washing solution on the ACL H/T and ACL 7000.
Principle: Emulsion.
Bottle and Volume
4 x 500 mL
Part Number 0009756904

Cleaning Agent (Clean B)
Intended Use: To decontaminate analyzers when suspected infected samples have been analyzed.
Principle: Based on Sodium Hypochlorite.
Bottle and Volume
1 x 80 mL
Part Number 0009832700

Rinse Solution (for ACL Advance)
Intended Use: Rinsing solution on the ACL Advance.
Bottle and Volume
1 x 2000 mL
Part Number 0020009320

Rinse Solution (for ACL TOP Family)
Intended Use: Rinsing solution on ACL TOP Family systems.
Bottle and Volume
1 x 4000 mL
Part Number 0020009700

AcuStar Triggers
Intended Use: Catalyst and oxidizer solutions necessary for the chemiluminescent reaction on the ACL AcuStar Hemostasis Testing System.
Bottle and Volume
2 x 290 mL
Part Number 0009802201

AcuStar System Rinse
Intended Use: Rinsing solution on the ACL AcuStar Hemostasis Testing System.
Bottle and Volume
1 x 5 L
Part Number 0009802200
REAGENT LINE TABLES
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<tr>
<th>Test</th>
<th>Part Number</th>
<th>Component</th>
<th>Vials per kit</th>
<th>Volume (mL)</th>
<th>Stability at 2-8 °C (after reconstitution or opening)</th>
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<tbody>
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<td>Recombinant Thromboplastin</td>
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<td>8</td>
<td>10 d</td>
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<td></td>
<td>Diluent</td>
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* Not FDA-cleared. Not available in all countries. \(h = \text{hour(s)}, \ d = \text{day(s)}\)
### General Screening and Anticoagulant Monitoring

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<th>Test</th>
<th>Part Number</th>
<th>Component</th>
<th>Vials per kit</th>
<th>Volume (mL)</th>
<th>Stability at 2-8 °C after reconstitution or opening</th>
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*Not FDA-cleared. Not available in all countries. h = hour(s); d = day(s); m = month(s)*
## D-DIMER

| Test                  | Part Number     | Component                  | Vials per kit | Volume (mL) | Stability at 2-8 °C
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* Pending FDA-clearance. Not available in all countries. d = days  w = weeks  m = months. ✨ Chemiluminescent technology assay. For use on ACL AcuStar Hemostasis Testing System.
## Heparin-Induced Thrombocytopenia

<table>
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<th>Volume (mL)</th>
<th>Stability at 2-8 °C</th>
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* Pending FDA clearance. Not available in all countries.  
  d = day(s)  w = week(s)  m = month(s)
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<td>30 d</td>
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* Not FDA-cleared. Not available in all countries. min = minute(s); h = hour(s); d = day(s); w = week(s); m = month(s)
## ANTIPHOSPHOLIPID SYNDROME

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<th>Stability at 2-8 °C</th>
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* h = hour(s), d = day(s), w = week(s)  
* Chemiluminescent technology assay.  For use on ACL AcuStar Hemostasis Testing System.
## Coagulation Factors

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<th>Component</th>
<th>Vials per kit</th>
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<th>Stability at 2-8 °C</th>
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## Von Willebrand Disease

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\( h = \text{hour(s)} \)
\( m = \text{month(s)} \)
## Plasma

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<td>24 h**</td>
</tr>
<tr>
<td>Special Test Control Level 1</td>
<td>0020011000</td>
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<td>24 h**</td>
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<tr>
<td>Low Fibrinogen Control</td>
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<td>Normal Control 1 UNASSAYED*</td>
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<td>Plasma</td>
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<td>Routine Control Level 1*</td>
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* Not available in all countries.  ** For Routine assays, eight hours for Faster assays

\[ k = \text{hour(s)} \quad d = \text{day(s)} \quad m = \text{month(s)} \]
## REAGENT LINE TABLES

### SOLUTIONS

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<tr>
<td>PCX/HPX Thromboplasmin diluent*</td>
<td>0008469600</td>
<td>1 x 100 mL bottle</td>
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<tr>
<td>Sample diluent</td>
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<td>1 x 100 mL bottle</td>
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<tr>
<td>Factor diluent</td>
<td>0009757600</td>
<td>1 x 100 mL bottle</td>
</tr>
<tr>
<td>Reference Emulsion</td>
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<td>4 x 500 mL bottle</td>
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<tr>
<td>Wash-R Emulsion</td>
<td>0020002400</td>
<td>1 x 1000 mL bottle</td>
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<td>Cleaning solution (Clean A)</td>
<td>0009831700</td>
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<td>Cleaning agent (Clean B)</td>
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<td>1 x 80 mL bottle</td>
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<td>Rinse Solution (for ACL Advance)</td>
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<td>1 x 2000 mL bottle</td>
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<td>Rinse Solution (for ACL TOP Family)</td>
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<td>1 x 4000 mL bottle</td>
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<td>System Rinse AcuStar</td>
<td>0009802200</td>
<td>1 x 5 L bottle</td>
</tr>
<tr>
<td>Triggers AcuStar</td>
<td>0009802201</td>
<td>2 x 250 mL bottle</td>
</tr>
</tbody>
</table>

* Not available in all countries.
INSTRUMENTS
## ACL SYSTEMS

### Easy, Comprehensive Solutions

Instrumentation Laboratory was the first to automate clot-timing tests, and we are now the world’s leading developer of hemostasis systems. Our ACL testing systems use advanced optical technology and set a new standard for precision and operational simplicity, while our HemosIL reagents are first in flexibility, reliability and accuracy. Using the same system, you can perform routine clotting tests or handle specialty assays with ease. Working with your lab’s volumes and demands, IL can build a complete testing solution that meets your needs and helps you deliver quality care.

### HemosIL Assays

**General Screening and Anticoagulant Monitoring**

- PT
- APTT
- Fibrinogen Clauss
- Thrombin Time
- Hepatocomplex*
- Pro-IL-Complex*
- Heparin (FXa)

**D-Dimer**

- D-Dimer
- D-Dimer 500**
- D-Dimer HS
- D-Dimer HS 500

**Heparin-Induced Thrombocytopenia**

- HIT-Ab(PF4-H)**

**Thrombophilia**

- Antithrombin
- Protein C (chromogenic)
- Protein C (clotting)
- Free Protein S (antigenic)
- Pro S
- FV Leiden (APC-R V)
- Homocysteine
- ThromboPath*

**Antiphospholipid Syndrome**

- Silica Clotting Time
- LAC Screen/Confirm

**Bleeding Disorders**

- Intrinsic Factors
- Extrinsic Factors
- FXIII Antigen
- VWF Antigen
- VWF Activity

**Fibrinolysis**

- Plasminogen
- Plasmin Inhibitor

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* Not FDA-cleared. Not available in all countries.
** Pending FDA-clearance. Not available in all countries.
ACL TOP FAMILY

ACL TOP 700 • ACL TOP 700 CTS • ACL TOP 700 LAS • ACL TOP 500 CTS

• Same accurate results
• Same reagents and consumables
• Same broad test menu features and usability
• Same powerful and intuitive software

Speed, Simplicity and Intelligence
The ACL TOP Family of Hemostasis Testing Systems, combines speed, simplicity and intelligence to meet the varied needs of hospitals and specialty labs. All ACL TOP Systems run routine and specialty assays and operate quickly, easily and continuously, with real-time STAT capability, to deliver automated reagent management, quality control and maintenance.

Take advantage of Testing Process Automation, reducing workload while expanding productivity, and enabling true standardization throughout the lab and hospital. Available with CTS, to process capped tubes with a cap-piercing system.

ACL TOP 700 (NEW)
For routine, high-volume labs
Run more tests in less time — the user-friendly, high-throughput ACL TOP 700 is appropriate for routine analysis in laboratories with the heaviest workloads.

For specialty labs
Specialty assays are highly automated for easier setup, faster turnaround and fewer demands on laboratory staff. The ACL TOP 700 accelerates and standardizes complex testing processes, allowing more reliable results.

ACL TOP 700 CTS (NEW)
For routine and specialty high-volume labs
Same features as the ACL TOP 700, with the increased safety of Closed-Tube Sampling (CTS).

ACL TOP 700 LAS
• For connectivity to Laboratory Automated System
• High throughput, versatile front-load capability without interruption of track sampling
• Unlimited STAT positions

ACL TOP 500 CTS
For routine, medium-to-high-volume labs
Run more tests in less time — the user-friendly, high-throughput ACL TOP 500 CTS is appropriate for routine analysis in laboratories with moderate-to-heavy workloads.

For specialty labs
Specialty assays are highly automated for easier setup, faster turnaround and fewer demands on laboratory staff. The ACL TOP 500 CTS accelerates and standardizes complex testing processes, allowing more reliable results.

As a companion to the ACL TOP 700 in large labs
As a mid-size companion or backup for the high-volume ACL TOP 700, ACL TOP 700 CTS and the ACL TOP 700 LAS, the ACL TOP 500 CTS provides the same great IL quality and familiar operation as the larger system.
ACL TOP 700/ACL TOP 700 CTS/ACL TOP 700 LAS (NEW)

Maximum Speed
- Up to 360 PT results/hour (Base model);
- 270 PT results/hour (CTS model)
- State-of-the-art software with Windows® XP interface and touchscreen
- Comprehensive, intuitive operation
- Minimal maintenance
- Laboratory Automation track option

Consolidated and Complete
- Broad test menu
- High throughput routine assays
- Specialty assays as simple as routine
- Clotting, chromogenic and immunoassays

Real-Time STAT Capability
- STAT samples loaded on any rack, in any position, at any time
- System ready to run 24 hours/day
- PT result in less than three minutes when processing one sample from idle system status

Optimal Sample Management
- Closed-Tube Sampling (CTS model)
- Direct from automation track sampling (LAS model)
- Parallel loading of racks – no sample queuing
- Continuous loading up to 120 samples onboard
- Barcode identification
- Sample presence detection, for non-barcoded samples
- Automatic sample predilution
- Factor parallelism testing with automatic multiple dilutions

Automatic Checks and Validation
- Sample liquid-level sensing
- Automatic rerun testing with possibility of extra sample predilution for enhanced test linearity
- Automatic reflex testing with configurable results validation

Optimal Reagent Management
- Parallel loading of racks for reagents, calibrators, controls, deficient plasma and any required material
- Continuous loading up to 60 materials onboard
- Barcoded vials for random loading and automatic identification, including vial size, expiration date and lot
- Vial presence detection for non-barcoded materials
- Handling of multiple vials of the same material

Automatic Sensing and Tracking
- Reagent liquid-level sensing with volume tracking
- Onboard stability and expiration date tracking
- Calibration stability tracking with Westgard Multi-rules

Remote Diagnostics
- Web-based access (optional)
- Maintenance and technical support
- Troubleshooting and training features
- Patient data security
**Peak Performance**
Introducing the ACL TOP 500 CTS - a mid-to-high-volume testing system with the flexibility, speed and intelligence of the largest automated hemostasis analyzers. The system addresses the challenges of fast-paced hemostasis testing environments, maximizing operator productivity while providing unprecedented testing capabilities in a system of its size.

The ACL TOP 500 CTS features the same advanced technology as the ACL TOP, the industry standard for analytical performance and operational simplicity. With end-to-end automation, highest-quality assays and proven results, the ACL TOP 500 CTS is a system that defines excellence in hemostasis testing, and is adaptable to the workload of your lab.

- Complete solution for medium-to-high volume and specialty labs
- Broad menu for routine and specialty assays
- Continuous operation and superior walkaway time
- Real-time STAT capability
- Closed-Tube Sampling (CTS) through a cap-piercing system
- Automated reagent management, QC and maintenance

**Fast and Easy**
- Advanced automation features
- Up to 360 PT results/hour (Base model)
- State-of-the-art software with Windows interface and touch-screen
- Comprehensive, intuitive operation
- Minimal maintenance
- High capacity: 800 cuvettes, 80 samples, 40 reagents
- Continuous loading and unloading of samples, reagents and cuvettes
- Onboard barcode reader automatically identifies reagents and samples

**Consolidated and Complete**
- Broad test menu
- Specialty assays as simple as routine
- Clotting, chromogenic and immunoassays

**Real-Time STAT Capability**
- STAT samples loaded on any rack, in any position, at any time
- System ready to run 24 hours/day
- PT result in less than three minutes when processing one sample from idle system status

**Optimal Sample Management**
- Parallel loading of racks - no sample queuing
- Continuous loading
- Simultaneous loading of different sample containers
- Sample presence detection, for non-barcoded samples
- Automatic sample predilution
- Factor parallelism testing with automatic multiple dilutions

**Automatic Checks and Validation**
- Sample liquid-level sensing
- Automatic rerun testing with possibility of extra sample predilution for enhanced test linearity
- Automatic reflex testing
- Automatic results validation

**Optimal Reagent Management**
- Parallel loading of racks for reagents, calibrators, controls, deficient plasma and any required material
- Continuous loading
- Barcoded vials for random loading and automatic identification, including vial size, expiration date and lot
- Vial presence detection for non-barcoded materials
- Handling of multiple vials of the same material

**Automatic Sensing and Tracking**
- Reagent liquid-level sensing
- Volume tracking
- Onboard stability tracking
- Expiration date tracking
- Calibration stability tracking
The first specialty-test analyzer that offers full automation of highly sensitive immunoassays for the hemostasis lab. Labor-intensive specialty tests that previously required specialized training and up to two hours to perform, can now be performed in as little as 25 minutes, with no special training required.

The first hemostasis analyzer to incorporate chemiluminescent technology, broadly considered the most accurate and sensitive method for routine immunoassay testing. Advanced assay technology, complemented with end-to-end automation, provides a quantum leap in simplicity and throughput, while ensuring uncompromised results. A true breakthrough in specialty testing. It’s about time. And accuracy.

**Test panel**
- D-Dimer
- aCL IgG
- aCL IgM
- aβ2GPI IgG
- aβ2GPI IgM
- HIT IgG*
- HIT IgG/M/A*
- VWF:Ag*
- VWF:RCo*
* In development

**Fast and efficient**
- Unprecedented efficiency for key specialty assays
- Up to 20 reagent cartridges onboard
- Up to 20 different assays onboard and available 24 hours/day, 7 days/week
- Up to 60 tests/hour
- Time to first results: ~ 30 minutes
- STAT or batch sample processing

**Highly accurate**
- Automated chemiluminescent technology boosts accuracy and sensitivity
- Each assay is factory precalibrated to assure accuracy and standardization
- High sensitivity and broad working range with one-stage or two-stage immunoassays
- No optical interference
- Differentiation among Ig isotypes

**Simple to use**
- No reagent handling: self-contained, ready-to-use, precalibrated reagent cartridges
- Integrated barcode reader for cartridges and samples
- Cartridges refrigerated at 4°C and stable up to six weeks onboard
- Easy rack-loading system accommodates up to 30 samples
- Windows interface and touchscreen, flat LCD monitor with intuitive prompts

*Chemiluminescent technology*
Versatile
- PC-based, random-access analyzer for routine and specialty tests
- Turbidimetric (for clotting assays) and absorbance (for chromogenic and immunological assays) channels

Continuous loading
- System holds 120 samples (10 samples/12 racks) for primary tubes and/or cups
- Adaptable to varying workloads
- STAT samples can be programmed at any time and in any position
- On-board capacity of 264 cuvettes with continuous loading
- Walk-away capability

Reliability and Robustness
- Reagent area has 34 refrigerated positions for original reagent vials
- Random access capability allows system to perform turbidimetric and absorbance assays simultaneously
- Eight channels (680 nm) for clotting tests and eight channels (405 nm) for absorbance reactions (chromogenic and latex immunological assays)

Additional Operator Safety
- Transparent safety cover allows complete visibility of instrument operations
- Cover design allows sample and cuvette loading during analysis without opening

Powerful Database
- Bi-directional interface allows automatic download and upload to the local LIS
- Automatic rerun testing available
- Up to 200 applications saved in the test definition
- Pre-programmed IL applications and user-configurable applications settings
- Integrated QC module with database capabilities and Levey-Jennings charts
Proven Technology
• Fully automated family of systems for clotting, chromogenic and immunological assays
• True random access, walk-away and STAT capabilities
• Continuous sample and consumables loading
• Extensive test menu

Walk-away
• Greater independence and time savings for the user
• 40-position sample tray accommodates cups and tubes
• Internal barcode reader provides positive sample identification
• External reagent barcode reader identifies reagent placement and verifies lot number and expiration date (standard on ACL ELITE PRO)
• Reagents monitored for volume and on-board stability
• 18 positions for original reagent vials on ACL ELITE
• 22 positions for original reagent vials on ACL ELITE PRO

Flexibility
• Rotor-cuvettes transported by “robotic arm”*
• Up to 240 cuvettes available with continuous loading*
• One touch initiates the run with results available upon return
• Results can be printed and transmitted automatically to the LIS
• Reflex and rerun tests

Touchscreen
• Windows®-like user interface is easy to use
• Icons, message boxes and buttons provide an intuitive guide
• Selections and decisions made immediately
• Powerful integrated PC offers unrivaled capabilities
• Standard keyboard and mouse supplement system use

* ELITE PRO only
Flexibility
- Extensive test menu with clotting, chromogenic and immunoassay capabilities
- Primary tube handling
- Positive sample ID using integrated barcode reader

Precision
- Routine and specialty assays
- Maintenance-free dilutors
- Optical system provides high range of assay capability
- Nephelometric (660 nm) and absorbance (405 nm) reading

Complete Automation
- 18-position sample tray
- Three main reagent positions (two refrigerated and stirred)
- Additional calibrator, diluent and deficient plasma positions available on sample tray
- Centrifugal analysis principle using 20-reaction cuvette-rotor

Enhanced Features
- Onboard patient database (up to 2400 results)
- Onboard QC database (up to 100 files)
- Random access (in profiles) and single tests
- Autodilution for samples and calibrations
- Stored calibrations
- Bidirectional interface to LIS
- Automatic requests download
- Automatic results upload
- Configurable print options
- Easy-to-use, step-by-step screen guidance
CONSUMABLES
<table>
<thead>
<tr>
<th>Description</th>
<th>Part Number</th>
<th>ACL TOP Family</th>
<th>ACL Advance</th>
<th>ACL ELITE/ELITE PRO ACL 8/9/10000</th>
<th>ACL 100-7000</th>
<th>ACL AcuStar</th>
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<td>Sample Cups 2 mL (1000 pcs)</td>
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</tr>
</tbody>
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* Not FDA-cleared. Not available in all countries.
<table>
<thead>
<tr>
<th>Description</th>
<th>Part Number</th>
<th>ACL TOP 700</th>
<th>ACL TOP 700 CTS</th>
<th>ACL TOP 700 LAS</th>
<th>ACL TOP 500 CTS</th>
<th>ACL Advance</th>
<th>ACL ELITE/ELITE PRO 8/9/10000</th>
<th>ACL 100-7000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic stirrers</td>
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<td>★</td>
<td>★</td>
<td>★</td>
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* Open tubes or cap. Rack sets compatible with all ACL TOP Family systems. Rack numbering and rack counts vary by set.

Sarstedt CTS Racks and sample adapters may be used on any ACL TOP system with CTS (Software version 4.0 or higher). Rack numbering and rack counts vary by set.
## CONSUMABLES

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<th>ACL TOP 700 CTS</th>
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* Open tubes or cups. Rack sets compatible with all ACL TOP Family systems. Rack numbering and rack counts vary by set.
INSTRUMENT
SPECs/TESTS
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* Optional  ** In development  †† Chemiluminescent technology  †††ACL AcuStar throughput is 60 tests/hour PT/APTT are not applicable. For supported assays, refer to page 64.
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* Not FDA-cleared. Not available in all countries. ** Pending FDA-clearance. Not available in all countries.
(1) Only on ACL 200 (2) Using TT cycle (3) Using APTT cycle (4) Using D-Dimer cycle