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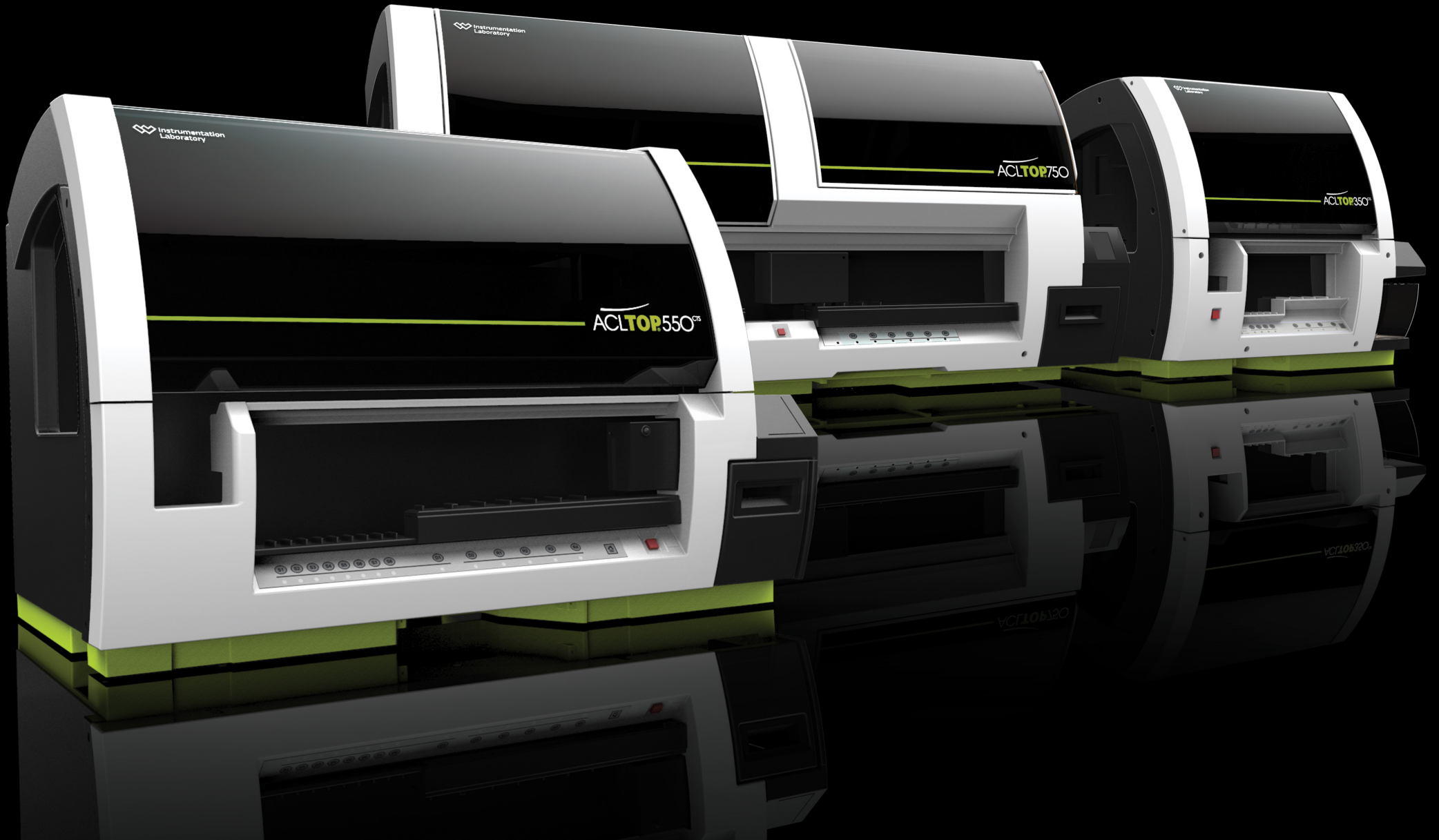
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Abbreviations

$a\beta_2GPI$	Anti-β_2 Glycoprotein-I
aCL	Anti-Cardiolipin
ACL™ H/T	ACL Hundred/Thousand Series
APC	Activated Protein C
APC-R V	Activated Protein C Resistance caused by Factor V Leiden Mutation
aPL	Antiphospholipid
APS	Antiphospholipid Syndrome
APTT	Activated Partial Thromboplastin Time
AT	Antithrombin
C4BP	C4b-Binding Protein
CLSI	Clinical and Laboratory Standards Institute
DDU	D-Dimer Units
DIC	Disseminated Intravascular Coagulation
dRVVT	Diluted Russell's Viper Venom Test
DVT	Deep Vein Thrombosis
FII, FV, FVII, FVIII, FIX, FX, FXI, FXII, FXIII	Factors II, V, VII—XIII
FDP	Fibrin/Fibrinogen Degradation Products
FEU	Fibrinogen Equivalent Units
FIB	Fibrinogen
HIT	Heparin-Induced Thrombocytopenia
IgA	Immunoglobulin A
IgG	Immunoglobulin G
IgM	Immunoglobulin M
INR	International Normalized Ratio
ISI	International Sensitivity Index
ISTH	International Society on Thrombosis and Hemostasis
LA	Lupus Anticoagulant
liq	Liquid
LIS	Laboratory Information System
LMWH	Low Molecular Weight Heparin
lyo	Lyophilized
NIBSC	National Institute for Biological Standards and Controls (UK)
PC	Protein C
PE	Pulmonary Embolism
PF4	Platelet Factor 4
PF4-H	Platelet Factor 4-Heparin
PI	Plasmin Inhibitor
PIVKA	Protein Induced by Vitamin K Antagonists/Absence
PLG	Plasminogen
PS	Protein S
PT	Prothrombin Time
PTP	Pretest Probability
Q.F.A.	Quantitative Fibrinogen Assay
RCo	Ristocetin Cofactor
SCT	Silica Clotting Time
SK	Streptokinase
TT	Thrombin Time
UFH	Unfractionated Heparin
VKA	Vitamin K Antagonist
VTE	Venous Thromboembolism
VWD	von Willebrand Disease
VWF:Act	von Willebrand Factor Activity
VWF:Ag	von Willebrand Factor Antigen
VWF:RCo	von Willebrand Factor Ristocetin Cofactor Activity
VWF:CB	von Willebrand Factor Collagen Binding
WHO	World Health Organization

HemosIL®
SynthASil
10 mL APT
IVD
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303193R3
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IL SpA-V.le Monza 338-Milano
HemosIL®
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R
For In Vitro Diagnostic Use.
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Instrumentation Laborat
IL Company, Bedford, MA
IL SpA-V.le Monza 338-

General Screening and Anticoagulant Monitoring/Measurement for Testing

HemosIL®

Prothrombin Time (PT)

Product	Description	Key Features	Kit Configuration
ReadiPlasTin *(p/n 0020301300 - 10 mL)* *(p/n 0020301400 - 20 mL)*	For the quantitative determination in human citrated plasma of PT and Fibrinogen on ACL TOP Family and ACL TOP Family 50 Series systems to evaluate the extrinsic coagulation pathway and the monitoring of VKA therapy.	• Liquid, ready-to-use PT reagent • Human tissue factor, recombinant technology • ISI range ~1.00 on ACL systems • Insensitive ≤ 1.0 U/mL of Heparin • 10-day onboard stability • Standardized using WHO-recommended protocol	5 x 0.5 mL ReadiPlasTin Reagent (liq) 5 x 9.5 mL ReadiPlasTin Diluent (liq) 5 x 1 mL ReadiPlasTin Reagent (liq) 5 x 19 mL ReadiPlasTin Diluent (liq)
RecombiPlasTin 2G *(p/n 0020002950 - 8 mL)* *(p/n 0020003050 - 20 mL)*	For the quantitative determination in human citrated plasma of PT and Fibrinogen on IL Hemostasis systems to evaluate the extrinsic coagulation pathway and the monitoring of VKA therapy.	• Human tissue factor, recombinant technology • ISI range ~1.00 on ACL systems • Insensitive ≤ 1.0 U/mL of Heparin • Up to 10-day onboard stability • Elevated reconstituted stability • Standardized using WHO-recommended protocol	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)
PT-Fibrinogen HS Plus *(p/n 0008469810)*	For simultaneous determination of PT and Fibrinogen, to evaluate the extrinsic coagulation pathway and monitor VKA therapy in human citrated plasma on IL Hemostasis systems.	• Rabbit brain thromboplastin extract • ISI range ~1.2 • Insensitive ≤ 0.5 U/mL of Heparin • Standardized using WHO-recommended protocol	5 x 8.5 mL Rabbit Thromboplastin (lyo) 5 x 8.5 mL Buffer (liq)
PT-Fibrinogen *(p/n 0009756710)*	For simultaneous determination of PT and Fibrinogen, to evaluate the extrinsic coagulation pathway and monitor VKA therapy in human plasma on IL Hemostasis systems.	• Rabbit brain thromboplastin extract • ISI range ~2.0 • Insensitive ≤ 1 U/mL of Heparin	10 x 8 mL Rabbit Thromboplastin (lyo)

PT

Product	Description	Key Features	Kit Configuration
INR Validate *(p/n 0020010500)*	A tri-level quality control for monitoring the accuracy of INR reporting with designated HemosIL PT reagents on IL Hemostasis systems, in conjunction with ISIweb software.	• Determines if local ISI assignment is needed • Validates newly established local ISI • Reagent-specific INR levels • Levels 1–3 comprised of donors on long-term anticoagulant therapy • Levels of FII, FVII, FIX, FX, PC, PS and PIVKA are equivalent to concentrations expected in VKA-treated patients • Follows ISTH and CLSI guidelines for validation of INR and ISI plasmas	Level 1: 1 x 1 mL (lyo) of human VKA plasma with an INR range of 1.6–2.4 Level 2: 1 x 1 mL (lyo) of human VKA plasma with an INR range of 2.5–3.5 Level 3: 1 x 1 mL (lyo) of human VKA plasma with an INR range of 3.8–5.0
ISI Calibrate *(p/n 0020010600)*	A set of four certified plasmas to establish instrument-/reagent-specific local ISI and Mean Normal PT with designated HemosIL PT reagents on IL Hemostasis systems in conjunction with ISIweb software.	• Reagent-specific INR levels • Level A comprised of normal human donors • Levels B–D comprised of donors on VKA therapy. Levels of FII, FVII, FIX, FX, PC, PS and PIVKA are equivalent to concentrations expected in VKA-treated patients • Follows ISTH and CLSI guidelines for validation of INR and ISI plasmas	Level A: 1 x 1 mL (lyo) of human plasma with an INR range of 0.9–1.1 Level B: 1 x 1 mL (lyo) of human VKA plasma with an INR range of 1.6–2.4 Level C: 1 x 1 mL (lyo) of human VKA plasma with an INR range of 2.5–3.5 Level D: 1 x 1 mL (lyo) of human VKA plasma with an INR range of 3.8–5.0
ISIweb Software	A web-based ISIweb software tool for calculating PT seconds and INR results using HemosIL INR Validate, HemosIL ISI Calibrate and designated HemosIL PT reagents on IL Hemostasis systems.	• Accessible through mywerfen.com • Easy and intuitive interface • Increases efficiency in benchmarking standardized values • Maximizes performance of IL Hemostasis systems • ISTH- and CLSI-compliant • Electronically archives and reports all activities on local ISI assignment and validation	

APTT

Product	Description	Key Features	Kit Configuration
SynthASil *(p/n 0020006800)*	For the determination of APTT in human citrated plasma on IL Hemostasis systems, to evaluate the intrinsic coagulation pathway, and to monitor Heparin therapy.	• Synthetic phospholipid technology • Liquid, ready-to-use • Micronized silica activator • Sensitive to the contact phase activation • 30-day open vial stability	5 x 10 mL APTT Reagent (liq) 5 x 10 mL Calcium Chloride (liq)
SynthAFax *(p/n 0020007400)*	For the determination of APTT in human citrated plasma on IL Hemostasis systems, to evaluate the intrinsic coagulation pathway, and to monitor Heparin therapy.	• Synthetic phospholipid technology • Liquid, ready-to-use • Ellagic acid activator • Sensitive to Factors VIII and IX • 30-day open vial stability	5 x 10 mL APTT Reagent (liq) 5 x 10 mL Calcium Chloride (liq)
APTT-SP (Synthetic Phospholipids) *(p/n 0020006300)*	For the determination of APTT in citrated plasma on IL Hemostasis systems, as a general screening procedure to evaluate the intrinsic coagulation pathway and monitor patients on Heparin.	• Synthetic phospholipid technology • Liquid, ready-to-use • Micronized silica activator • Sensitive to the contact phase activation • 30-day open vial stability	5 x 9 mL APTT Reagent (liq) 5 x 8 mL Calcium Chloride (liq)
Calcium Chloride 0.025 M *(p/n 0019741910)*	Used in combination with APTT-SP on IL Hemostasis systems.		10 x 8 mL Calcium Chloride (liq)

Fibrinogen Clauss

Product	Description	Key Features	Kit Configuration
Fibrinogen-C *(p/n 0020301100)* *(p/n 0020003900 - XL)*	For the quantitative determination of Fibrinogen in human citrated plasma, based on the Clauss method, on IL Hemostasis systems.	• Purified Thrombin • Insensitive to Heparin < 1.0 U/mL • Good linear range	10 x 2 mL Bovine Thrombin (lyo) 10 x 5 mL Bovine Thrombin (lyo)
Q.F.A. Thrombin *(p/n 0020301800 - 2 mL)* *(p/n 0020301700 - 5 mL)*	For the quantitative determination of Fibrinogen in human citrated plasma, based on the Clauss method, on IL Hemostasis systems.	• Purified Thrombin • Bovine origin • Good stability • 100 UNIH/mL Thrombin • Insensitive to Heparin < 2.0 U/mL	10 x 2 mL Bovine Thrombin (lyo) 10 x 5 mL Bovine Thrombin (lyo)

UF/LMW Heparin

Product	Description	Key Features	Kit Configuration
Liquid Anti-Xa *(p/n 0020302600)*	For the quantitative determination of UFH and LMWH activity in human citrated plasma on IL Hemostasis systems.	• One-stage assay • Uses endogenous Antithrombin from patient sample • One universal calibration curve for UFH and LMWH • Linear range of 0–2 IU/mL for UFH and LMWH • Liquid, ready-to-use format	5 x 2.5 mL Factor Xa Reagent (liq) 5 x 3 mL Chromogenic Substrate (liq)
Heparin *(p/n 0030009400)*	For the quantitative determination of UFH and LMWH activity in human citrated plasma on IL Hemostasis systems.	• Linear response 0–1 U/mL for Heparin • Enhanced reagent stability	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
UF Heparin Controls *(p/n 0020300300)*	For quality control of HemosIL Liquid heparin assay when testing for UFH on IL Hemostasis systems.	• Assayed Controls • Comprised of human plasma containing UFH only • Bi-level Low and High Controls	5 x 1 mL Low UF Heparin (lyo) 5 x 1 mL High UF Heparin Control (lyo)
LMW Heparin Controls *(p/n 0020300200)*	For quality control of HemosIL Liquid heparin assay when testing for LMWH on IL Hemostasis systems.	• Assayed Controls • Comprised of human plasma containing LMWH only • Bi-level Low and High Controls	5 x 1 mL Low LMW Heparin (lyo) 5 x 1 mL High LMW Heparin Control (lyo)
Heparin Calibrators *(p/n 0020300600)*	For calibration of the HemosIL Liquid Heparin assay on IL Hemostasis systems.	• One set of calibrators for both UFH and LMWH • Calibrator set with predetermined Heparin concentrations	3 x 1 mL Calibrator 1-3 (lyo)

DOACs

Product	Description	Key Features	Kit Configuration
Direct Thrombin Inhibitor Assay* *(p/n 0020302800)*	For the quantitative determination of the Direct Thrombin Inhibitor Dabigatran in citrated human plasma on the ACL TOP Family of analyzers. Intended to be used for the measurement of active Dabigatran levels in situations where measurement is warranted.	• Dilute thrombin-based method • Excellent linear range (20–2000 ng/mL) • Low limit of detection (2 ng/mL) • Unaffected by Heparin up to 2.2 IU/mL	3 x 2 mL DTI Thrombin Reagent (lyo) 3 x 2.2 mL DTI Thrombin Diluent (liq) 3 x 2 mL DTI Plasma Diluent (lyo)
Dabigatran Calibrators* *(p/n 0020013400)*	For the calibration of the HemosIL Direct Thrombin Inhibitor assay on the ACL TOP Family of analyzers.	• Bi-level calibrators • Dabigatran Calibrator 1 (0 ng/mL) • Dabigatran Calibrator 2 (~500 ng/mL)	5 x 2 mL Dabigatran Calibrator 1 (lyo) 5 x 1 mL Dabigatran Calibrator 2 (lyo)
Dabigatran Controls* *(p/n 0020013500)*	For the quality control of the HemosIL Direct Thrombin Inhibitor assay on the ACL TOP Family of analyzers.	• Bi-level controls • Dabigatran Low Control (~50 ng/mL) • Dabigatran High Control (~200 ng/mL)	5 x 1 mL Dabigatran Low Control (lyo) 5 x 1 mL Dabigatran High Control
Liquid Anti-Xa* *(p/n 0020302601)*	For the quantitative determination of unfractionated heparin (UFH) and low molecular weight heparin (LMWH) activity in human citrated plasma on IL Coagulation System when used in conjunction with HemosIL Heparin Calibrators. Also intended for the measurement of direct FXa inhibitor concentrations (*e.g.,* Rivaroxaban, Apixaban) in human citrated plasma on ACL TOP Family Systems when used with HemosIL Rivaroxaban and/or Apixaban calibrators.	• One-stage assay • Uses endogenous Antithrombin from patient sample • One universal calibration curve for UFH and LMWH • Linear range of 0.04–2 IU/mL for UFH and LMWH • Linear range of 20–1000 ng/mL for Rivaroxaban • Linear range of 15–1000 ng/mL for Apixaban • Liquid, ready-to-use format	5 x 2.5 mL Factor Xa Reagent (liq) 5 x 3 mL Chromogenic Substrate (liq)
Rivaroxaban Calibrators* *(p/n 0020013600)*	For the calibration of the HemosIL Liquid Anti-Xa assay when testing for Rivaroxaban on ACL TOP Systems.	• Bi-level calibrators • Rivaroxaban Calibrator 1 (0 ng/mL) • Rivaroxaban Calibrator 2 (~500 ng/mL)	5 x 1 mL Rivaroxaban Calibrator 1 (lyo) 5 x 1 mL Rivaroxaban Calibrator 2 (lyo)
Rivaroxaban Controls* *(p/n 0020013700)*	For the quality control of the HemosIL Liquid Anti-Xa assay when testing for Rivaroxaban on ACL TOP Systems.	• Bi-level controls • Rivaroxaban Low Control (~80 ng/mL) • Rivaroxaban High Control (~300 ng/mL)	5 x 1 mL Rivaroxaban Low Control (lyo) 5 x 1 mL Rivaroxaban High Control (lyo)
Apixaban Calibrators* *(p/n 0020014200)*	For the calibration of the HemosIL Liquid Anti-Xa assay when testing for Apixaban on ACL TOP Systems.	• Bi-level calibrators • Apixaban Calibrator 1 (0 ng/mL) • Apixaban Calibrator 2 (~500 ng/mL)	5 x 1 mL Apixaban Calibrator 1 (lyo) 5 x 1 mL Apixaban Calibrator 2 (lyo)
Apixaban Controls* *(p/n 0020014300)*	For the quality control of the HemosIL Liquid Anti-Xa assay when testing for Apixaban on ACL TOP Systems.	• Bi-level controls • Apixaban Low Control (~80 ng/mL) • Apixaban High Control (~300 ng/mL)	5 x 1 mL Apixaban Low Control (lyo) 5 x 1 mL Apixaban High Control (lyo)

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Other

Product	Description	Key Features	Kit Configuration
Thrombin Time *(p/n 0009758515)*	For the quantitative determination of Thrombin Time in human citrated plasma on IL Hemostasis systems.	• Purified Thrombin • Different reconstitutions for desired normal range: 5 mL: ~11–18 seconds 8 mL: ~16–27 seconds 2 mL: ~5–8 seconds • Specific reconstitution for Heparin therapy	4 x 2, 5 or 8 mL Bovine Thrombin (lyo) 1 x 9 mL Buffer (liq)
Hepatocomplex* *(p/n 0009758710)*	For the detection of clinical situations associated with congenital or acquired deficiencies of Factors II-VII-X in human citrated plasma on IL Hemostasis systems. Used for the control of VKA therapy, both stabilized and in combination with Heparin. Due to its endogenous coagulation inhibitor insensitivity, this assay, combined with HemosIL Pro-IL-Complex, can identify the presence of inhibitors.	• Specific for VKA monitoring • PIVKA-insensitive • Insensitive to Heparin < 0.5 U/mL • ISI ~1.3	5 x 7 mL Rabbit Calcium Thromboplastin (lyo) 5 x 3 mL Bovine Plasma (lyo)
Pro-IL-Complex* *(p/n 0009758810)*	For the control of VKA therapy, 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 HemosIL Hepatocomplex, can identify the presence of inhibitors (*e.g.*, PIVKA).	• Specific for VKA monitoring • PIVKA-sensitive • Insensitive to Heparin < 0.5 U/mL • ISI ~1.2	5 x 7 mL Bovine Thromboplastin (lyo) 5 x 3 mL Bovine Plasma (lyo)
PCX/HPX Thromboplastin Diluent* *(p/n 0008469600)*	For the reconstitution of Thromboplastin reagents, Pro-IL-Complex and Hepatocomplex assays (calibration and analysis).	• Dedicated saline solution for PCX/HPX	1 x 100 mL

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Fibrin Formation and Degradation

D-Dimer

HemosIL®

Product	Description	Key Features	Kit Configuration
D-Dimer HS 500 *(p/n 0020500100)*	For the quantitative determination of D-Dimer in human citrated plasma on ACL TOP systems. For use in conjunction with a clinical PTP assessment model to exclude VTE in outpatients suspected of DVT and PE.	• Automated, latex-enhanced immunoassay • Liquid, ready-to-use • Validated cut-off of 500 ng/mL FEU on ACL TOP Family • Results in < 5 mins	3 x 4 mL Latex Reagent (liq) 3 x 6 mL Reaction Buffer (liq) 2 x 1 mL D-Dimer Calibrator (lyo)
D-Dimer HS 500 Controls (Liquid) *(p/n 0022550030)** *(p/n 0020013100)***	For the quality control of D-Dimer HS 500 assay performed on ACL TOP systems.	• Liquid, ready-to-use • Eliminates variability from reconstitution • Level 1 control recovers at cut-off value • Reduces start-up time required for quality control	5 x 1 mL Level 1 D-Dimer HS 500 Control (liq) 5 x 1 mL Level 2 D-Dimer HS 500 Control (liq)
D-Dimer HS 500 Controls *(p/n 0020500200)*	For the quality control of D-Dimer HS 500 assay performed on ACL TOP systems.	• Low Control: borderline level • High Control: pathological level • For use with D-Dimer HS 500 *(p/n 0020500100)*	5 x 1 mL High Control (lyo) 5 x 1 mL Low Control (lyo)
D-Dimer HS *(p/n 0020007700)*	For the quantitative determination of D-Dimer in human citrated plasma on ACL TOP systems. For use in conjunction with a clinical PTP assessment model to exclude VTE in outpatients suspected of DVT and PE.	• Automated, latex-enhanced immunoassay • Validated cut-off of 230 ng/mL DDU on ACL TOP systems • Results in < 5 mins	3 x 2 mL Latex Reagent (lyo) 3 x 8 mL Reaction Buffer (liq) 2 x 1 mL D-Dimer Calibrator (lyo)
D-Dimer 500** *(p/n 0020301000)*	For the quantitative determination of D-Dimer in human citrated plasma on IL Hemostasis systems. For use in conjunction with a clinical PTP assessment model to exclude VTE in outpatients suspected of DVT and PE.	• Automated, latex-enhanced immunoassay • Validated cut-off of 500 ng/mL FEU on IL Hemostasis systems • Results in < 7 mins	4 x 3 mL Latex Reagent (lyo) 4 x 9 mL Reaction Buffer (liq) 2 x 1 mL D-Dimer Calibrator (lyo)
D-Dimer *(p/n 0020008500)*	For the quantitative determination of D-Dimer in human citrated plasma on IL Hemostasis systems. For use in conjunction with a clinical PTP assessment model to exclude VTE in outpatients suspected of DVT and PE.	• Automated, latex-enhanced immunoassay • Validated cut-off of 230 ng/mL DDU on IL Hemostasis systems • Results in < 7 mins	4 x 3 mL Latex Reagent (lyo) 4 x 9 mL Reaction Buffer (liq) 2 x 1 mL D-Dimer Calibrator (lyo)

**For US and Canada.*

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D-Dimer

Product	Description	Key Features	Kit Configuration
D-Dimer Controls (Liquid)* *(p/n 0020013000)*	For the quality control of D-Dimer, D-Dimer 500 and D-Dimer HS assays on IL Hemostasis systems.	• Liquid, ready-to-use • Eliminates variability from reconstitution • Minimizes human error • Reduces start-up time required for quality control	5 x 1 mL Level 1 D-Dimer Control (liq) 5 x 1 mL Level 2 D-Dimer Control (liq)
D-Dimer Controls *(p/n 0020008610)*	For the quality control of D-Dimer, D-Dimer 500 and D-Dimer HS assays on IL Hemostasis systems.	• Low and High combined, offers a complete quality control program • For use with D-Dimer, D-Dimer HS and D-Dimer 500 • Low D-Dimer Control: borderline level • High D-Dimer Control: abnormal level	5 x 1 mL High Control (lyo) 5 x 1 mL Low Control (lyo)
D-Dimer HS 2000** *(p/n 0020014400)*	For the quantitative determination of D-Dimer in human citrated plasma on ACL TOP Family Systems.	• Automated, latex-enhanced immunoassay • Liquid, ready-to-use • Extended linearity 0.5–32 µg/mL, up to 300 µg/mL with automatic rerun • Results in < 5 mins	3 x 4 mL Latex Reagent (liq) 3 x 6 mL Reaction Buffer (liq) 2 x 1 mL D-Dimer Calibrator (lyo)
D-Dimer HS 2000 Controls** *(p/n 0020014500)*	For the quality control of D-Dimer HS 2000 assay on ACL TOP Family Systems.	• Low and High Controls combined offer a complete quality control program • For use with D-Dimer HS 2000 • Low Control: low D-Dimer levels • High Control: high D-Dimer levels	5 x 1 mL High Control (lyo) 5 x 1 mL Low Control (lyo)
AcuStar D-Dimer ✳ *(p/n 0009802000)*	Fully automated chemiluminescent immunoassay for the quantitative determination of D-Dimer in human citrated plasma on the ACL AcuStar system as an aid in the diagnosis of VTE (DVT and PE).	• Clinically validated 500 ng/mL FEU cut-off value • Extended 8-week onboard stability • Extended linearity 54.3–74,000 ng/mL, up to 1,110,000 ng/mL with automatic rerun	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
AcuStar D-Dimer Controls ✳ *(p/n 0009802100)*	For the quality control of D-Dimer assays performed on the ACL AcuStar system.	• Low Control: borderline level • High Control: pathological level • Very High Control: high pathological level	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

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***Not currently 510(k)-cleared. For exclusive use in Japan.*

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

Fibrinolysis

Product	Description	Key Features	Kit Configuration
FDP* *(p/n 0020009900)*	For the quantitative determination of Fibrinogen degradation products (FDP) in human citrated plasma on ACL TOP Family systems.	• Automated, latex-enhanced immunoassay • Innovative technology mitigates Fibrinogen interference • Excellent agreement with commercially available FDP test methods • Enhanced analytical performance with extended measurement range of 2.5–120 µg/mL	3 x 4 mL FDP Latex Reagent (liq) 3 x 4 mL FDP Reaction Buffer
FDP Calibrator* *(p/n 0020009910)*	For the calibration of FDP on ACL TOP Family systems.	• 5-vial calibrator set with predetermined FDP concentrations	1 x 1 mL FDP Calibrator 1 (lyo) 1 x 1 mL FDP Calibrator 2 (lyo) 1 x 1 mL FDP Calibrator 3 (lyo) 1 x 1 mL FDP Calibrator 4 (lyo) 1 x 1 mL FDP Calibrator 5 (lyo) 1 x 1 mL FDP Calibrator 0 Barcode Label
FDP Controls* *(p/n 0020009920)*	For the quality control of FDP on ACL TOP Family systems.	• Low FDP Control targets low abnormal FDP levels • High FDP Control targets abnormal FDP levels	3 x 1 mL Low FDP Control (lyo) 3 x 1 mL High FDP Control (lyo)
Plasminogen *(p/n 0020009000)*	For the quantitative determination of Plasminogen in human citrated plasma on IL Hemostasis systems.	• Improved reagent stability • Improved linearity • Optimized specificity	2 x 2.5 mL Streptokinase Reagent (lyo) 2 x 2 mL Chromogenic Substrate S-2403 (lyo)
Plasmin Inhibitor (α_2-Antiplasmin) *(p/n 0020009200)*	For the quantitative determination of Plasmin Inhibitor in human citrated plasma on IL Hemostasis systems.	• Detects quantitative plasmin-inhibitor-deficiency • Minimized cross-reactivity with α_2-macroglobulin	2 x 2.5 mL Plasmin Reagent (lyo) 1 x 4 mL Chromogenic Substrate S-2403 (lyo) 2 x 9 mL Buffer (liq)

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Bleeding Disorders
Coagulation Factors

HemosIL®

Product	Description	Key Features	Kit Configuration
Factor Deficient Plasma **FII** *(p/n 0020012200)* **FV** *(p/n 0020011500)* **FVII** *(p/n 0020011700)* **FX** *(p/n 0020010000)*	For use in combination with PT reagents to determine specific Factor activity in citrated plasma on IL Hemostasis systems.	• Immunodepleted deficient plasmas • Residual activity of specific Factor ≤ 1%	10 x 1 mL Factor Deficient Plasma (lyo)
Factor Deficient Plasma **FVIII** *(p/n 0020011800)* **FIX** *(p/n 0020011900)* **FXI** *(p/n 0020011300)* **FXII** *(p/n 0020011200)*	For use in combination with APTT reagents to determine specific Factor activity in citrated plasma on IL Hemostasis systems.	• Immunodepleted deficient plasmas • Residual activity of specific Factor ≤ 1%	10 x 1 mL Factor Deficient Plasma (lyo)
FVIII Deficient Plasma *(p/n 0020012800)*	For use in combination with APTT reagents to determine specific Factor activity in citrated plasma on IL Hemostasis systems.	• Artificially depleted deficient plasma with normal levels of von Willebrand Factor (VWF) activity • < 1% Residual FVIII activity	10 x 1 mL Factor Deficient Plasma (lyo)
ELECTRACHROME Factor VIII *(p/n 49730503)*	For the quantitative determination of FVIII on ACL Elite/Elite Pro.	• Chromogenic FVIII assay	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)
Factor XIII Antigen* *(p/n 0020201300)*	For the quantitative determination of FXIII Antigen in human citrated plasma on IL Hemostasis systems.	• Fully automated immunoturbidimetric assay • Liquid, ready-to-use reagent • Correlates with activity assay**	2 x 2.5 mL Latex Reagent (liq) 2 x 5 mL Buffer (liq) 2 x 6 mL Diluent (liq)

**FXIII antigen assays are exempt from 510(k)-clearance.*
***IL, data on file.*

HemosIL®
VWF Activity
4.5 mL
IVD
R
For In Vitro Diagnostic Use.
Instrumentation Laboratory
IL Company, Bedford, MA 01730
IL SpA-V.le Monza 338-Milano
3800-3104 R1
HemosIL®
VWF:RCo
IVD
R
2°C
For In Vitro Diagnostic Use.
Instrumentation Laboratory
IL Company, Bedford, MA 01730
IL SpA-V.le Monza 338-Milano
3800-4108 R02
HemosIL®
VWF:Ag
3 mL
IVD
R
For In Vitro Diagnostic Use.
Instrumentation Laboratory
IL Company, Lexington, MA 02421
IL SpA-V.le Monza 338-Milano
302628 R2
HemosIL®
Factor VIII deficient plasma
IVD
V
For In Vitro Diagnostic Use.
Instrumentation Laboratory
IL Company, Bedford, MA 01730
IL SpA-V.le Monza 338-Milano
303650R1

von Willebrand Disease

Product	Description	Key Features	Kit Configuration
von Willebrand Factor Antigen *(p/n 0020002300)*	For the quantitative determination of VWF Antigen in human citrated plasma on IL Hemostasis systems.	• Latex, particle-based immunoassay • Liquid, ready-to-use • Results in < 7 minutes	2 x 3 mL Latex Reagent (liq) 2 x 4 mL Reaction Buffer (liq)
von Willebrand Factor Activity *(p/n 0020004700)*	For the quantitative determination of VWF Activity in human citrated plasma on IL Hemostasis systems.	• Automated, latex-enhanced immunoassay • Easy-to-use, labor-saving • Results in 12 minutes • Good precision and correlation with VWF:RCo Activity assays	2 x 4.5 mL Latex Reagent (lyo) 2 x 4.5 mL Buffer (liq)
von Willebrand Factor Ristocetin Cofactor Activity* *(p/n 0020300900)*	For the quantitative determination of VWF:RCo Activity in human citrated plasma on ACL TOP systems.	• Automated, latex-enhanced immunoassay • Liquid, ready-to-use • Recombinant technology replaces platelets • Excellent agreement with platelet aggregation assays	2 x 2 mL Latex Reagent (liq) 2 x 1.6 mL Ristocetin (liq) 2 x 4 mL Reaction Buffer (liq) 2 x 3.6 mL Diluent (liq)

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von Willebrand Disease

Product	Description	Key Features	Kit Configuration
AcuStar von Willebrand Factor Antigen* *(p/n 0009802020)*	For the quantitative determination of von Willebrand Factor Antigen in human citrated plasma on ACL AcuStar systems.	• Fully automated chemiluminescent immunoassay • Extended linearity range to quantify VWF levels below 1% • Broad working range enhances accuracy at all medical decision levels for VWD investigation • 8-week onboard stability	1 VWF:Ag cartridge for 25 tests (liq) 1 x 1 mL VWF:Ag Calibrator 1 (liq) 1 x 1 mL VWF:Ag Calibrator 2 (lyo) 1 VWF:Ag Calibrator 2 Barcoded Tube
AcuStar von Willebrand Factor Ristocetin Cofactor Activity* *(p/n 0009802024)*	For the quantitative determination of von Willebrand Factor Ristocetin Cofactor Activity in human citrated plasma on ACL AcuStar systems.	• Fully automated chemiluminescent, platelet-free immunoassay • Recombinant technology replaces platelets and enhances accuracy • 8-week onboard stability	1 VWF:RCo cartridge for 25 tests (liq) 1 x 1 mL VWF:RCo Calibrator 1 (liq) 1 x 1 mL VWF:RCo Calibrator 2 (lyo) 1 VWF:RCo Calibrator 2 Barcoded Tube
AcuStar von Willebrand Factor Collagen Binding Activity* *(p/n 0009802044)*	For the quantitative determination of von Willebrand Factor Collagen Binding Activity in human citrated plasma on ACL AcuStar systems.	• Chemiluminescent immunoassay • First and only fully automated VWF:CB assay • Cartridge-based, ready-to-use, for unmatched simplicity • Enhanced sensitivity for High Molecular Weight Multimer (HMWM) and intact VWF collagen-binding site • 5-week onboard stability	1 VWF:CB Cartridge for 25 tests (liq) 1 x 1 mL VWF:CB Calibrator 1 (liq) 1 x 1 mL VWF:CB Calibrator 2 (lyo) 1 VWF:CB Calibrator 2 Barcoded Tube
AcuStar von Willebrand Factor Controls* *(p/n 0009802119)*	For the quality control of AcuStar VWF assays performed on ACL AcuStar systems.	• For use with AcuStar VWF:Ag, AcuStar VWF:RCo and AcuStar VWF:CB • Results expressed in % • Low VWF Control reports in the low-abnormal range • Normal VWF Control reports in the normal range	3 x 1 mL Low VWF Control (lyo) 3 x 1 mL Normal VWF Control (lyo) 3 Low VWF Control Barcoded Tubes 3 Normal VWF Control Barcoded Tubes

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

**Not 510(k)-cleared and not Canadian licensed. Not for sale in the US and Canada.*

Heparin-Induced Thrombocytopenia (HIT)

HemosIL®

Product	Description	Key Features	Kit Configuration
HIT-Ab$_{(PF4-H)}$* *(p/n 0020302700)*	For the semi-quantitative detection of total immunoglobulin (Ig) in human citrated plasma against PF4-H complexes on ACL TOP systems. Heparin-associated antibodies are commonly found in patients with HIT.	• Automated, latex-enhanced immunoassay • Liquid, ready-to-use • On-demand results in minutes • Validated 1.0 U/mL cut-off value	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 (lyo)
HIT-Ab$_{(PF4-H)}$ Controls* *(p/n 0020013300)*	For the quality control of HIT-Ab$_{(PF4-H)}$ assay (*p/n 0020302700*).	• Low Control: borderline HIT antibody level • High Control: abnormal HIT antibody level	3 x 1 mL High Control (liq) 3 x 1 mL Low Control (liq)
HIT-Ab$_{(PF4-H)}$ *(p/n 0020014600)*	For the qualitative detection of anti-platelet-factor-4/heparin (PF4-H) antibodies. Anti-PF4/Heparin antibodies are commonly found in patients with HIT.	• Automated, latex-enhanced immunoassay • Liquid, ready-to-use • On-demand results in minutes • Validated 1.0 U/mL cut-off value	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 (lyo)
HIT-Ab$_{(PF4-H)}$ Controls *(p/n 0020014700)*	For the quality control of HIT-Ab$_{(PF4-H)}$ assay (*p/n 0020014600*).	• Low Control: borderline HIT antibody level • High Control: abnormal HIT antibody level	3 x 1 mL High Control (liq) 3 x 1 mL Low Control (liq)

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HIT

Product	Description	Key Features	Kit Configuration
AcuStar HIT-IgG$_{(PF4-H)}$* ✳ *(p/n 0009802028)*	For the detection of IgG antibodies in human citrated plasma and serum that react with PF4-H complexes on ACL AcuStar systems. Heparin-associated antibodies are commonly found in patients with HIT.	• Fully automated, chemiluminescent immunoassay • Cartridge-based, ready-to-use, precalibrated assays • Results in ~30 minutes • Extended 12-week onboard stability • Results available ondemand, 24/7 • Validated 1.00 U/mL cut-off • Uses serum or citrated plasma	1 HIT-IgG$_{(PF4-H)}$ Cartridge for 25 Tests (liq) 1 x 1 mL HIT-IgG$_{(PF4-H)}$ Calibrator 1 (liq) 1 x 1 mL HIT-IgG$_{(PF4-H)}$ Calibrator 2 (liq)
AcuStar HIT Controls* ✳ *(p/n 0009802122)*	For use with AcuStar HIT-IgG$_{(PF4-H)}$ (*p/n 0009802028*) and AcuStar HIT-Ab$_{(PF4-H)}$ (*p/n 0009802032*) performed on ACL AcuStar systems.	• Results expressed in U/mL • Low HIT Control: below cut-off value • High HIT Control: above cut-off value	3 x 1 mL Low HIT Control (liq) 3 x 1 mL High HIT Control (liq)
AcuStar Multi-Ab* Controls ✳ *(p/n 00009800003)*	For the quality control of the HemosIL AcuStar Anti-Cardiolipin IgG/IgM, Anti-ß$_2$ Glycoprotein-I IgG/IgM, HIT-Ab$_{(PF4-H)}$ *(p/n 0009802032)* and HIT-IgG$_{(PF4-H)}$ *(p/n 0009802028)* as performed on ACL AcuStar systems.	• Liquid, ready-to-use multi-assay control material for monitoring chemiluminescent aPL and HIT assays • Low Control assesses precision and accuracy at normal or cut-off antibody levels • High Control assesses precision and accuracy at abnormal antibody levels	3 x 2 mL Low Multi-Ab Control (liq) 3 x 2 mL High Multi-Ab Control (liq)
AcuStar HIT-IgG$_{(PF4-H)}$** ✳ *(p/n 0009800127)*	For the qualitative detection of IgG antibodies in human serum or plasma that react with Platelet Factor 4 (PF4) when complexed to heparin on ACL AcuStar systems. Anti-PF4-H antibodies are commonly found in patients with HIT.	• Fully automated chemiluminescent immunoassay • Cartridge-based, ready-to-use, precalibrated assays • Results in ~30 minutes • Extended 12-week onboard stability • Results available ondemand, 24/7 • Validated 1.00 U/mL cut-off • Uses serum or citrated plasma	1 HIT-IgG$_{(PF4-H)}$ Cartridge for 25 Tests (liq) 1 x 1 mL HIT-IgG$_{(PF4-H)}$ Calibrator 1 (liq) 1 x 1 mL HIT-IgG$_{(PF4-H)}$ Calibrator 2 (liq)
AcuStar HIT Controls** ✳ *(p/n 0009800131)*	For the quality control of AcuStar HIT assays performed on ACL AcuStar Systems. For use with AcuStar HIT-IgG$_{(PF4-H)}$ (*p/n 0009800127*).	• Results expressed in U/mL • Low HIT Control: below cut-off value • High HIT Control: above cut-off value	3 x 1 mL Low HIT Control (liq) 3 x 1 mL High HIT Control (liq)

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***For US and Canada.*

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

Thrombophilia

HemosIL®

Product	Description	Key Features	Kit Configuration
Liquid Antithrombin *(p/n 0020002500)* *(p/n 0020030100)* *(p/n 0020300400)*	For the quantitative determination of AT in human citrated plasma on IL Hemostasis systems.	• Liquid, ready-to-use • Factor Xa-based assay • Insensitive to Heparin Cofactor II • Enhanced reagent stability • Improved onboard stability	*ACL Elite/Elite Pro* 4 x 4 mL FXa Reagent (liq) 2 x 2 mL Chromogenic Substrate S-2765 (liq) *ACL TOP Family, ACL TOP Family 50 Series* 4 x 4.5 mL FXa Reagent (liq) 4 x 4.5 mL Chromogenic Substrate S-2765 (liq) *ACL TOP Family, ACL TOP Family 50 Series ACL 200–7000* 2 x 2 mL FXa Reagent (liq) 2 x 2 mL Chromogenic Substrate S-2765 (liq)
Antithrombin *(p/n 0020008900)*	For the quantitative determination of AT in human citrated plasma on IL Hemostasis systems.	• Fully automated • Factor Xa-based assay • Enhanced reagent stability	2 x 2.5 mL Factor Xa Reagent (lyo) 2 x 2 mL Chromogenic Substrate S-2765 (lyo)
Protein C *(p/n 0020300500)*	For the quantitative determination of PC in human citrated plasma on IL Hemostasis systems.	• Improved reagent stability and linearity	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)
ProClot *(p/n 0008468310)*	For the quantitative determination of PC in human citrated plasma on IL Hemostasis systems.	• Functional clotting assay • Can be used in combination with HemosIL APTT-SP	4 x 1.5 mL Protein C Activator (lyo) 4 x 1 mL Protein C Deficient Plasma (lyo) 2 x 1 mL Protein C Control Plasma (lyo)
ProClot Diluent *(p/n 0008468600)*	For the calibration and analysis of ProClot.		1 x 100 mL

Thrombophilia

Product	Description	Key Features	Kit Configuration
Free Protein S *(p/n 0020002700)*	For the quantitative determination of free PS in human citrated plasma on IL Hemostasis systems.	• Immunoturbidimetric assay • Binds to natural free PS ligand (C4BP) • High specificity (no interference with FV Leiden mutation) • Excellent correlation with ELISA and latex-based assays	3 x 4 mL C4BP Buffer (liq) 3 x 4 mL C4BP Latex (lyo) 3 x 2 mL Anti PS mAb Latex (lyo)
Protein S Activity *(p/n 0020302000)*	For the quantitative determination of free PS in human citrated plasma on IL Hemostasis systems.	• Fully automated, functional assay • 6-hour onboard stability at 15°C on ACL TOP systems	3 x 2 mL Protein S Reagent (lyo) 2 x 6 mL Calcium Reagent (liq) 3 x 2 mL Protein S Deficient Plasma (lyo)
Factor V Leiden *(p/n 0020008700)*	For determination of resistance to activated PC, caused by the FV mutation, in plasma from untreated individuals and from patients on Heparin or VKA therapy.	• High-specificity FV Leiden detection • 100% sensitivity for FV:Q506 mutation • Factor V Reagent Plasma (*p/n 0020008800*) included in kit or sold separately	2 x 4 mL APTT Reagent (liq) 2 x 4 mL Factor-V Reagent Plasma (lyo) 2 x 2 mL APC/$CaCl_2$ (lyo) 2 x 2 mL $CaCl_2$ (liq) 2 x 1 mL APC Control Plasma Level 1 (lyo) 2 x 1 mL APC Control Plasma Level 2 (lyo)
Homocysteine *(p/n 0020007800)*	For the quantitative determination of total L-homocysteine in human citrated plasma on IL Hemostasis systems.	• The first fully automated, immunoturbidimetric Homocysteine assay for the Hemostasis laboratory • Linearity ≤ 4.5–60 µmol/L	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)
Homocysteine Controls *(p/n 0020007900)*	For the quality control of total L-homocysteine assays.	• Level 1: borderline homocysteine levels • Level 2: abnormal homocysteine levels	3 x 1 mL Homocysteine Control Level 1 (lyo) 3 x 1 mL Homocysteine Control Level 2 (lyo)

Thrombophilia

Product	Description	Key Features	Kit Configuration
Xpert HemosIL FII & FV Combined Test *(p/n 460GXHEMOSIL-10)*	For the rapid detection of FII and FV single-point mutations, from sodium citrate or EDTA anticoagulated whole blood, on the GeneXpert system.	• Qualitative diagnostic genotyping test • One cartridge = one sample • Uses citrated or EDTA whole blood; fully integrated sample prep • FII & FV testing in a single cartridge • Results in 30 minutes • Self-controlled	10 FII & FV Assay Cartridges
FII & FV DNA Control *(p/n 0020003500)*	For heterozygous quality control to monitor analytical performance of the extraction, amplification and detection steps of the Xpert HemosIL FII & FV assay on the GeneXpert Dx system. Used in the detection of the FII and FV mutations.	• Heterozygous control for both FII (G20210A) and FV Leiden (G1691A) mutations	3 x 0.5 mL FII & FV (liq)
GeneXpert System	For automation and integration of sample purification, nucleic acid amplification and detection of the target sequence in simple or complex samples, using real-time PCR.	• Self-contained, fully integrated, real-time, automated PCR system • Single cartridge for DNA extraction to results • ≤ 4 random-access, independent modules per system	

Molecular technology.

ACL AcuStar
Instrumentation Laboratory
Hemosil® AcuStar
D-Dimer Controls
3 x 1 mL Low D-Dimer Control
3 x 1 mL High D-Dimer Control
3 x 1 mL Very High D-Dimer Control
9 D-Dimer Control Barcoded Tubes
0009802100
For the Quality Control of D-Dimer assays.
Composition: human D-Dimer.
For In Vitro Diagnostic Use.
Instrumentation Laboratory
A Werfen Company
Hemosil® AcuStar
D-Dimer
100 Tests
1 D-Dimer Reagent Cartridge
1 x 1 mL D-Dimer Calibrator 1
1 x 1 mL D-Dimer Calibrator 2
2 D-Dimer Calibrator Barcoded Tubes
0009802000
Automated chemiluminescense immunoassay for the determination of D-Dimer.
Composition: Magnetic particles, sample diluent, tracer, assay buffer, human D-Dimer and less than 0.1% of sodium azide.
For In Vitro Diagnostic Use.
Instrumentation Laboratory
A Werfen Company

Antiphospholipid Syndrome (APS)

HemosIL®

Product	Description	Key Features	Kit Configuration
Silica Clotting Time *(p/n 0020004800)*	For the detection of Lupus Anticoagulant (LA) in human citrated plasma on IL Hemostasis systems.	• Screen (low phospholipid concentration) and Confirm (high phospholipid concentration) in one kit • Liquid formulation, easy-to-use, fully automated • Suitable for mixing studies and patients receiving VKA therapy	3 x 5 mL SCT Screen (liq) 3 x 5 mL SCT Confirm (liq) 3 x 10 mL SCT $CaCl_2$ (liq)
dRVVT Screen *(p/n 0020301500)* **dRVVT Confirm** *(p/n 0020301600)*	For the detection of LA in human citrated plasma on IL Hemostasis systems.	• Easy-to-use, fully automated • No Heparin interference < 1.0 U/mL • Improved stability: 15 days at 2–8°C and 3 days at 15°C onboard ACL TOP systems	10 x 2 mL dRVVT Screen (lyo) 10 x 2 mL dRVVT Confirm (lyo)
LA Positive Control *(p/n 0020012500)*	For use as an LA Positive Quality Control of LA assays on IL Hemostasis systems.	• Developed from Platelet-poor plasma from LA-positive patients • Stability: 24 hours at 2–8°C and 24 hours at 15°C onboard ACL TOP systems	10 x 1 mL LA Positive Control (lyo)
LA Negative Control *(p/n 0020012600)*	For use as an LA Negative Quality Control of LA assays on IL Hemostasis systems.	• Optimized for LA mixing tests • Negative Control developed from human citrated platelet-poor plasma from > 100-donor pool • Stability: 24 hours at 2–8°C and 24 hours at 15°C onboard ACL TOP systems	10 x 1 mL LA Negative Control (lyo)
AcuStar Anti-Cardiolipin (aCL) ✳ **IgG** *(p/n 0009802004)* **IgM** *(p/n 0009802008)*	For the semi-quantitative measurement of aCL IgG or IgM antibodies in human citrated plasma, or serum, on ACL AcuStar systems, as an aid in the diagnosis of thrombotic disorders related to primary and secondary APS when used in conjunction with other laboratory and clinical findings.	• Fully automated, chemiluminescent immunoassay • Cartridge-based, ready-to-use, precalibrated assays • Extended 6-week onboard stability • Extremely wide linearity ranges, with and without rerun • Clinically validated 20 U/mL cut-off for all assays • Uses serum or citrated plasma	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)

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

APS

Product	Description	Key Features	Kit Configuration
AcuStar Anti-Cardiolipin Controls ✳ **IgG** *(p/n 0009802104)* **IgM** *(p/n 0009802108)*	For the quality control of AcuStar aCL IgG or IgM assays performed on ACL AcuStar systems.	• Assigned for AcuStar aCL IgG or IgM • Results expressed in U/mL • Low aCL Control: borderline level • High aCL Control: pathological level	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)
AcuStar Anti-ß$_2$ Glycoprotein-I ✳ **IgG** *(p/n 0009802012)* **IgM** *(p/n 0009802016)*	For the semi-quantitative measurement of aß$_2$GPI IgG or IgM antibodies in human citrated plasma or serum on ACL AcuStar systems, as an aid in the diagnosis of thrombotic disorders related to APS when used in conjunction with other laboratory and clinical findings.	• Fully automated, chemiluminescent immunoassay • Cartridge-based, ready-to-use, precalibrated assays • Extended 6-week onboard stability • Extremely wide linearity ranges, with and without rerun • Clinically validated 20 U/mL cut-off for all assays • Uses serum or citrated plasma	1 aß$_2$GPI IgG Cartridge for 50 Tests (liq) 1 x 1 mL aß$_2$GPI IgG Calibrator 1 (liq) 1 x 1 mL aß$_2$GPI IgG Calibrator 2 (liq) 1 aß$_2$GPI IgM Cartridge for 50 Tests (liq) 1 x 1 mL aß$_2$GPI IgM Calibrator 1 (liq) 1 x 1 mL aß$_2$GPI IgM Calibrator 2 (liq)
AcuStar Anti-ß$_2$ Glycoprotein-I Controls ✳ **IgG** *(p/n 0009802112)* **IgM** *(p/n 0009802116)*	For the quality control of AcuStar aß$_2$GPI IgG or IgM assays performed on ACL AcuStar systems.	• Assigned for AcuStar aß$_2$GPI IgG or IgM • Results expressed in U/mL • Low aß$_2$GPI Control: borderline level • High aß$_2$GPI Control: pathological level	3 x 1 mL Low aß$_2$GPI IgG Control (liq) 3 x 1 mL High aß$_2$GPI IgG Control (liq) 3 x 1 mL Low aß$_2$GPI IgM Control (liq) 3 x 1 mL High aß$_2$GPI IgM Control (liq)
AcuStar Anti-ß$_2$GPI Domain 1 ✳ *(p/n 00009800015)*	For the semi-quantitative determination of IgG auto-antibodies to ß$_2$GPI Domain 1 in human serum or citrated plasma on ACL AcuStar systems used in conjunction with clinical and other laboratory findings as an aid in the diagnosis of APS.	• Fully automated, chemiluminescent immunoassay • Cartridge-based precalibrated assay • Extended 60-day onboard stability • Extremely wide linear ranges, with and without rerun • 99.6% specificity for APS • Uses serum or citrated plasma	1 Anti-ß$_2$GPI Domain 1 Cartridge for 50 tests (lyo) 1 Resuspension Buffer (liq) 1 x 1 mL Anti-ß$_2$GPI Domain 1 Calibrator 1 (liq) 1 x 1 mL Anti-ß$_2$GPI Domain 1 Calibrator 2 (lit)
AcuStar Anti-ß$_2$GPI Domain 1 Controls ✳ *(p/n 00009800022)*	For the quality control of AcuStar Anti-ß$_2$GPI Domain 1 assay performed on ACL AcuStar systems.	• Assigned for AcuStar Anti-ß$_2$GPI Domain 1 • Results expressed in U/mL • Low Control assesses precision and accuracy at normal or cut-off antibody levels • High Control assesses precision and accuracy at abnormal antibody levels	3 x 1 mL Anti-ß$_2$GPI Domain 1 Low Control (liq) 3 x 1 mL Anti-ß$_2$GPI Domain 1 High Control (liq)
AcuStar Multi-Ab* Controls ✳ *(p/n 00009800003)*	For the quality control of the HemosIL AcuStar Anti-Cardiolipin IgG/IgM, Anti-ß$_2$ Glycoprotein-I IgG/IgM, and HIT-IgG$_{(PF4-H)}$ assays as performed on the ACL AcuStar system.	• Liquid, ready-to-use multi-assay control material for monitoring chemiluminescent aPL and HIT assays • Low Control: assesses precision and accuracy at normal or cut-off antibody levels • High Control: assesses precision and accuracy at abnormal antibody levels	3 x 2 mL Low Multi-Ab Control (liq) 3 x 2 mL High Multi-Ab Control (liq)

**Not available in all countries.*

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

Plasma Calibrators and Controls

HemosIL®

Product	Description	Key Features	Kit Configuration
Calibration Plasma *(p/n 0020003700)*	For the calibration of assays on IL Hemostasis systems.	• Single calibrator for IL Hemostasis systems, including several parameters • 24-hour stability for several assays • Traceability vs. NIBSC standards	10 x 1 mL Calibration Plasma (lyo)
Normal Control Assayed *(p/n 0020003110)*	For the quality control of assays in the normal range on IL Hemostasis systems.	• Easy-to-use, reliable source of normal human plasma • 24-hour reconstituted stability for routine assays	10 x 1 mL Normal Control (lyo)
Low Abnormal Control Assayed *(p/n 0020003210)*	For the quality control of assays in the low abnormal range on IL Hemostasis systems.	• Citrated pooled plasma from healthy donors (not on Heparin or VKA) • Modified to simulate an abnormal coagulation sample • 24-hour reconstituted stability for routine assays	10 x 1 mL Low Abnormal Control (lyo)
High Abnormal Control Assayed *(p/n 0020003310)*	For the quality control of assays in the high abnormal range on IL Hemostasis systems.	• Single control for several assays • 24-hour reconstituted stability for routine assays • Modified to simulate an abnormal coagulation sample	10 x 1 mL High Abnormal Control (lyo)
Special Test Control Level 1 *(p/n 0020011000)*	For quality control in the low abnormal range for the chromogenic tests: AT, PLG, PI, PC and FVIII; quality control of free PS assay in the range of 50–60% activity; and quality control of VWF assays (Antigen, Activity and RCo) in the normal range on IL Hemostasis systems.	• Traceability vs. NIBSC standards	10 x 1 mL Special Test Level 1 (lyo)
Special Test Control Level 2 *(p/n 0020012000)*	For quality control in the high abnormal range for the chromogenic tests: AT, PLG, PI, PC and FVIII; quality control of free PS and Factor (clotting) assays (II, V, VII, VIII, IX, XI, XII) in the range of 20–40% activity; and quality control of VWF assays (Antigen and RCo) in the low abnormal range on IL Hemostasis systems.	• Traceability vs. NIBSC standards	10 x 1 mL Special Test Level 2 (lyo)

Plasma Calibrators and Controls

Product	Description	Key Features	Kit Configuration
Low Fibrinogen Control *(p/n 0020004200)*	For a complete quality control program in the abnormal range on IL Hemostasis systems.	• Abnormal control assigned using the PT-based and Clauss methods • Traceability vs. NIBSC standards and WHO recommendations	10 x 1 mL Low Fibrinogen Control (lyo)
Routine Control Level 1* *(p/n 0020005600)*	For quality control of Hemostasis assays in the normal range, to assess precision and accuracy of PT, APTT and FIB tests on Hemostasis systems.	• Normal range assay quality control • Assesses precision and accuracy of PT, APTT and Fibrinogen tests	10 x 1 mL Routine Control Level 1 (lyo)
Routine Control Level 2* *(p/n 0020005700)*	For quality control of Hemostasis assays in the low abnormal range, to assess precision and accuracy of PT and APTT tests on Hemostasis systems.	• Low abnormal range assay quality control • Assesses precision and accuracy of PT and APTT tests	10 x 1 mL Routine Control Level 2 (lyo)
Routine Control Level 3* *(p/n 0020005800)*	For quality control of Hemostasis assays in the high abnormal range, to assess the precision and accuracy of PT and APTT tests on Hemostasis systems.	• High abnormal range assay quality control • Assesses precision and accuracy of PT and APTT tests	10 x 1 mL Routine Control Level 3 (lyo)
QC Plasma Coagulation Control Level I* *(p/n 0020010700)*	Normal human plasma used as a normal control in routine Hemostasis assays such as PT, APTT, FIB, AT and PC to detect significant changes in certain variables inherent in Hemostasis testing.	• Normal control	10 x 1 mL QC Plasma Level I (lyo)
QC Plasma Coagulation Control Level II* *(p/n 0020010800)*	Abnormal human plasma used as a mid-range abnormal control in routine Hemostasis assays such as the one-stage PT, APTT, FIB, AT and PC, to detect significant changes in certain variables inherent in Hemostasis testing.	• Mid-range abnormal control	10 x 1 mL QC Plasma Level II (lyo)
HemosIL Normal Control 1* *(p/n 0020013900)*	For the quality control of assays in the normal range IL Hemostasis systems.	• Assigned for routine assays • 24-hour reconstituted stability	10 x 1 mL Normal Control 1 (lyo)
HemosIL Abnormal Control 2* *(p/n 0020014000)*	For the quality control of assays in the low abnormal range on IL Hemostasis systems.	• Assigned for routine assays • 24-hour reconstituted stability • Modified to simulate an abnormal coagulation sample	10 x 1 mL Abnormal Control 2 (lyo)
HemosIL Abnormal Control 3* *(p/n 0020014100)*	For the quality control of assays in the high abnormal range on IL Hemostasis systems.	• Assigned for routine assays • 24-hour reconstituted stability • Modified to simulate an abnormal coagulation sample	10 x 1 mL Abnormal Control 3 (lyo)

**Not available in all countries.*

Controls								
Reagent	**Normal Control Assayed**	**Low Abnormal Control Assayed**	**High Abnormal Control Assayed**	**Special Test Control Level 1**	**Special Test Control Level 2**	**Normal Control 1***	**Abnormal Control 2***	**Abnormal Control 3***
PT	•	•	•			•	•	•
APTT	•	•	•			•	•	•
Fibrinogen	•	•				•	•	
Thrombin Time	•	•				•	•	
Pro-IL-Complex*	•	•	•					
Hepatocomplex*	•	•	•					
Antithrombin	•	•		•	•	•	•	
Protein C	•	•		•	•			
Protein S	•	•		•	•			
VWF Antigen	•			•	•			
VWF Activity	•			•				
VWF:RCo**	•			•	•			
FII, V, VII, X	•				•			
FVIII, IX, XI, XII	•				•			
FXIII Antigen***	•				•			
Plasminogen	•			•	•			
Plasmin Inhibitor	•			•	•			

**Not 510(k)-cleared and not Canadian licensed. Not saleable in the US and Canada. Not available in all countries.*

***Not 510(k)-cleared. Not saleable in the US. Not available in all countries.*

****FXIII antigen assays are exempt from 510(k)-clearance. Not available in all countries.*

Plasma Calibrators and Controls

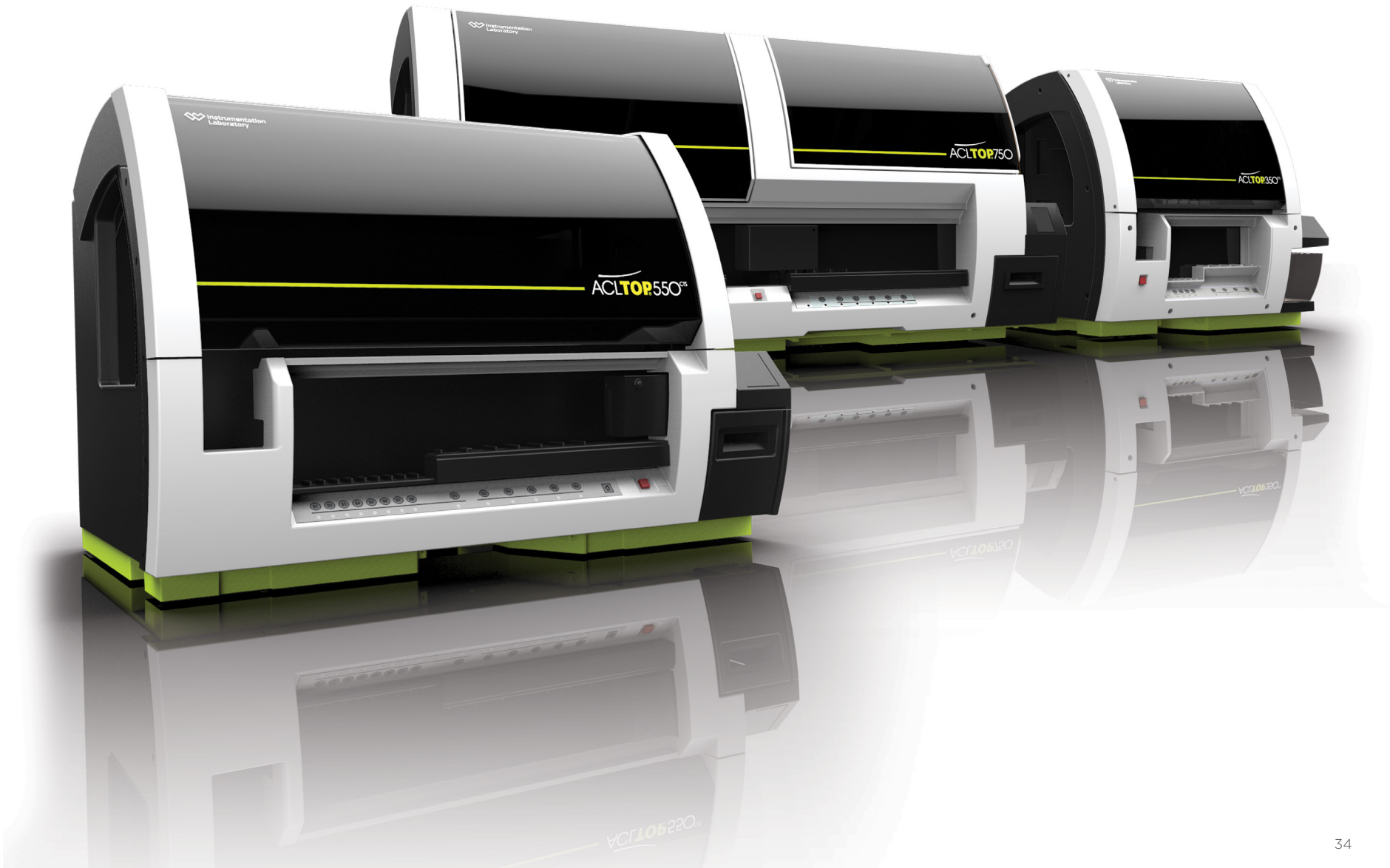
Calibration Plasma			
Reagent	**ACL TOP Family/ ACL TOP Family 50 Series**	**ACL Elite/Elite Pro**	**ACL 7000**
PT	•	•	•
APTT	•	•	•
Fibrinogen	•	•	•
TT (2 mL)	•	•	•
TT (5 mL)	•	•	•
TT (8 mL)	•	•	•
Pro-IL-Complex*	•	•	•
Hepatocomplex*	•	•	•
Antithrombin	•	•	•
ProClot	•	•	•
Protein C	•	•	•
Protein S Activity	•	•	•
Free Protein S Antigen	•	•	
VWF Antigen	•	•	
VWF Activity	•	•	
VWF:RCo*	•		
FII, V, VII, X	•	•	•
FVIII, IX, XI, XII	•	•	•
FXIII Antigen**	•		
Plasminogen	•	•	•
Plasmin Inhibitor	•	•	•

**Not 510(k)-cleared. Not saleable in the US. Not available in all countries.*
***FXIII assays are exempt from 510(k)-clearance.*

Solutions

HemosIL®

Product	Description	Kit Configuration
Sample Diluent *(p/n 0009756800)*	For calibration of PT and FIB tests on ACL 7000 systems.	1 x 100 mL
Factor Diluent *(p/n 0009757600)*	For calibration of PT and FIB tests for Factor assays. Also to dilute calibrators, controls and patient samples in AT and PLG chromogenic kits.	1 x 100 mL
Reference Emulsion *(p/n 0009756900)*	Optical reference for nephelometric analysis and washing solution for ACL 7000 systems.	1 x 500 mL
Wash-R Emulsion *(p/n 0020002400)*	Optical reference for nephelometric analysis and washing solution on ACL Elite/Elite Pro systems.	1 x 1000 mL
Cleaning Solution (Clean A) *(p/n 0009831700)*	Cleaning solution for ACL systems.	1 x 500 mL
Cleaning Agent (Clean B) *(p/n 0009832700)*	Cleaning solution and decontaminant for ACL systems.	1 x 80 mL
Rinse Solution (for ACL TOP Family) *(p/n 0020302400)*	Rinsing solution for ACL TOP systems.	1 x 4000 mL
AcuStar Triggers *(p/n 0009802201)*	Catalyst and oxidizer solutions for triggering chemiluminescent reaction on the ACL AcuStar systems.	2 x 250 mL
AcuStar System Rinse *(p/n 0009802200)*	For magnetic wash cycles and as a rinsing solution on the ACL AcuStar systems.	1 x 5000 mL
AcuStar Cleaning Solution *(p/n 0009802204)*	Cleaning solution for the ACL AcuStar systems.	6 x 4 mL


Instrumentation Laboratory
ACLTOP550
Instrumentation Laboratory
ACLTOP750
ACLTOP350

Instruments

ACL Systems

Easy, comprehensive solutions

Instrumentation Laboratory was the first to automate clotting assays, 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, routine clotting tests or specialty assays are performed with ease. Working with the specific volume and demand in your lab, IL can build a complete testing solution that meets your needs and helps deliver quality care.

NEW

ACL TOP® Family 50 series

A breakthrough in Hemostasis testing

New ACL TOP Family 50 Series

Offering the most advanced automation and quality management, from routine to specialty assays. Standardized across all ACL TOP systems—for superior performance across your entire testing process.

- **Same** quality results
- **Same** comprehensive reagent portfolio
- **Same** powerful and intuitive software
- **Same** features and usability

And now:

- **Same** pre-analytical sample checks with assay-specific thresholds
- **Same** advanced lab accreditation support
- **Same** advanced quality management

For high-volume labs

ACL TOP 750/CTS/LAS

Run more tests in less time—user-friendly and high throughput for routine analysis in laboratories with the heaviest workloads.

For medium- to high-volume labs

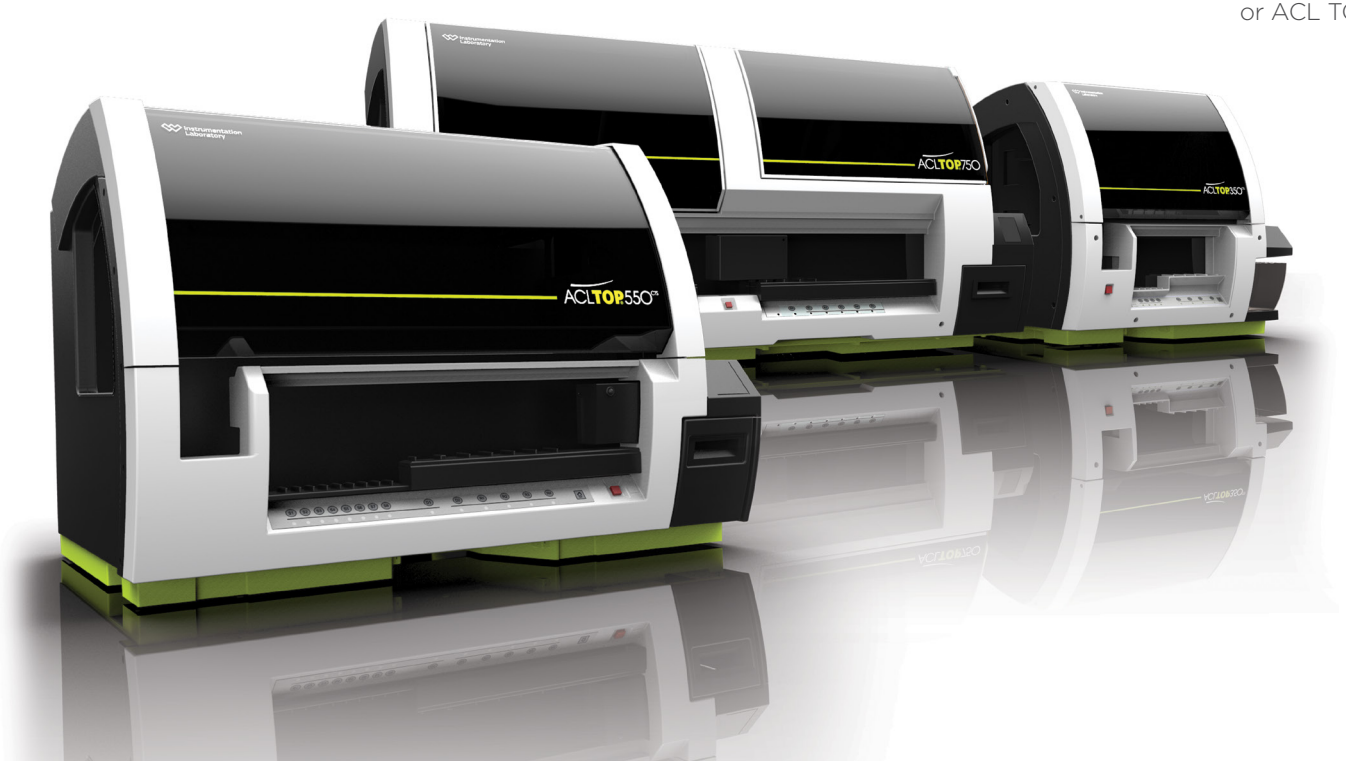
ACL TOP 550 CTS

Highly automated testing processes in routine, medium- to high-volume and specialty labs.

For medium-volume labs

ACL TOP 350 CTS

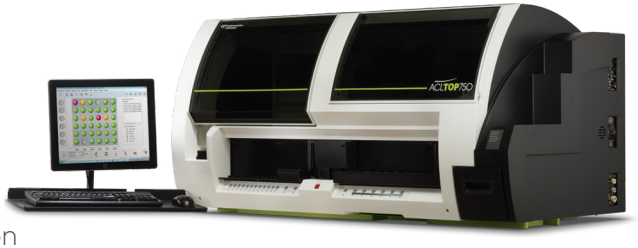
Smallest ACL TOP system for routine or specialty assays in medium-volume labs. Perfect companion to ACL TOP 750 CTS or ACL TOP 550 CTS system.



NEW

ACL TOP 750 / 750 CTS / 750 LAS

Advanced testing automation and quality management for high-volume labs



Maximum speed, intelligence and simplicity

Delivers the highest level of performance for the best possible results—in any lab environment. Every ACL TOP 750 system maximizes simplicity, speed and productivity, elevating testing automation and quality to the highest level. Provides true standardization across all applications—whether used in routine, high-volume, specialty labs or as part of a fully integrated Laboratory Automation System.

Various configurations offer greater flexibility

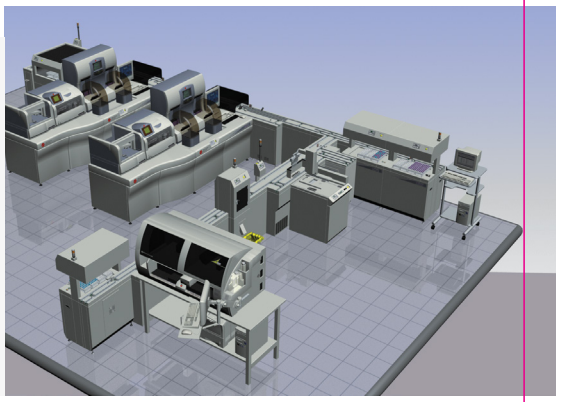
- **ACL TOP 750** (Open-Tube Sampling)
- **ACL TOP 750 CTS** (Closed-Tube Sampling)
- **ACL TOP 750 LAS** (Laboratory Automation System)

ACL TOP 750 LAS

- Follows CLSI Guidelines (AUTO 1–5) for electromechanical interfaces
- Provides "Point in space sampling"
- Open system compatible with most laboratory automation track systems
- Eliminates need for costly and slow robotic interface

Connects to LAS-compliant tracks

- Thermo Fisher
- Abbott
- Inpeco
- Beckman Coulter
- Siemens
- IDS
- GLP
- HemoCell



Analyzer automation

- Barcoded reagents
- Continuous onboard reagent stability monitoring
- Automatic QC frequency execution
- Rerun and reflex testing capabilities
- Fully automated reporting of factor assays with Parallelism
- Auto-verification and uploading of results
- Closed-Tube Sampling via cap-piercing (CTS models only)

Continuous operation

- Continual loading and unloading of samples and reagents via racks, with no system interruption
- Uninterrupted cuvette loading
- Uninterrupted waste disposal

Simple maintenance

- Daily maintenance, ordered by user and performed by system, in < 5 minutes
- “Maintenance overdue” notifications alert user
- Remote instrument diagnostics and troubleshooting via web interface in real time* (optional)

Fast turnaround

- Up to 360 PT/hour
- PT from standby in < 3 minutes
- Samples loaded on any rack, in any position, at any time, including STAT

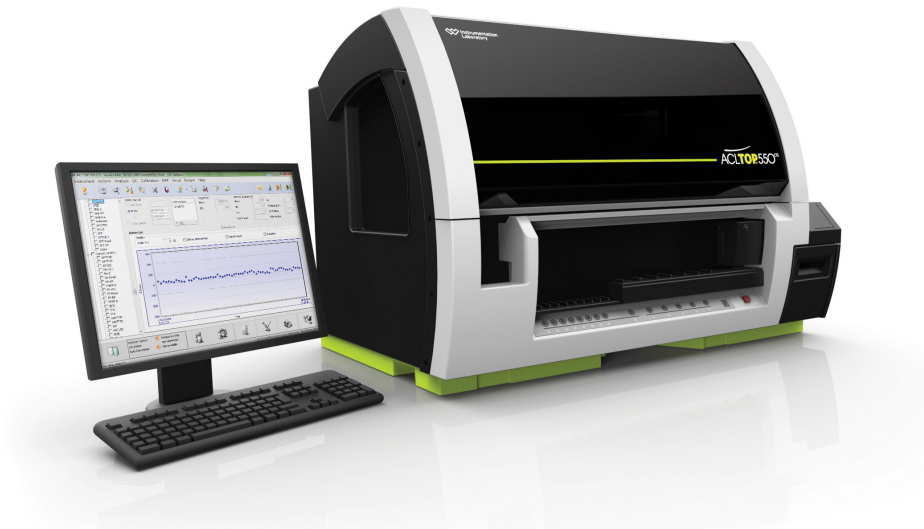
**The ACL TOP 50 Family Series is not available in all countries.*

NEW ACL TOP 550 CTS

Advanced testing automation and quality management for medium- to high-volume labs

Superior functionality at the right size—now with automated assay-specific pre-analytical sample checks

Combines unique testing capabilities with end-to-end automation for simplicity and maximum operator productivity. Its comprehensive menu for routine and specialty assays is ideal for broad-spectrum lab needs and testing volumes. New automated pre-analytical sample checks, advanced automated quality management and accreditation support tools enhance efficiency and patient care.



Analyzer automation

- Barcoded reagents
- Continuous onboard reagent stability monitoring
- Automatic QC frequency execution
- Rerun and reflex testing capabilities
- Fully automated reporting of factor assays with Parallelism
- Auto-verification and uploading of results
- Closed-Tube Sampling via cap-piercing

Continuous operation

- Continual loading and unloading of samples and reagents via racks, with no system interruption
- Uninterrupted cuvette loading
- Uninterrupted waste disposal

Simple maintenance

- Daily maintenance, ordered by user and performed by system, in < 5 minutes
- "Maintenance overdue" notifications to alert user
- Remote instrument diagnostics and troubleshooting via web interface in real time* (optional)

Fast turnaround

- Up to 240 PT/hour
- PT from standby in ~3 minutes
- Samples loaded on any rack, in any position, at any time, including STAT
- High capacity: 800 cuvettes, 80 samples, 40 reagents

**The ACL TOP 50 Family Series is not available in all countries.*

NEW ACL TOP 350 CTS

Advanced testing automation and quality management for medium-volume labs

Small footprint, same user-friendly features—now with automated assay-specific pre-analytical sample checks

Compact in size, yet robust in features, and fully automated for fast and accurate results, with no specialized operator training required. Testing for routine or specialty assays is simple. New automated pre-analytical sample checks, advanced automated quality management and accreditation support tools minimize the risk of errors and enhance efficiency. The ideal solution for medium-volume labs and a perfect complement to the ACL TOP 750 or ACL TOP 550 CTS systems for a fully integrated testing environment.

Analyzer automation

- Barcoded reagents
- Continuous onboard reagent stability monitoring
- Automatic QC frequency execution
- Rerun and reflex testing capabilities
- Fully automated reporting of factor assays with Parallelism
- Auto-verification and uploading of results
- Closed-Tube Sampling via cap-piercing

Continuous operation

- Continual loading and unloading of samples and reagents via racks, with no system interruption
- Uninterrupted cuvette loading
- Uninterrupted waste disposal

Simple maintenance

- Daily maintenance, ordered by user and performed by system, in < 5 minutes
- "Maintenance overdue" notifications to alert user
- Remote instrument diagnostics and troubleshooting via web interface in real time* (optional)

Fast turnaround

- Up to 110 PT/hour
- PT from standby in ~3 minutes
- Samples loaded on any rack, in any position, at any time, including STAT
- High capacity: 800 cuvettes, 40 samples, 26 reagents

**The ACL TOP 50 Family Series is not available in all countries.*

ACL AcuStar

The first specialty-testing analyzer that offers full automation of highly sensitive immunoassays for the Hemostasis lab. Specialty testing can be completed in as little as 25 minutes, with no special training required. Provides superior accuracy and sensitivity to specialty and routine immunoassay testing.

A true breakthrough in specialty testing.
It's about time. And accuracy.

Test panel

- D-Dimer
- aCL IgG
- aCL IgM
- aß$_2$GPI IgG
- aß$_2$GPI IgM
- HIT-IgG$_{(PF4-H)}$
- VWF:Ag*
- VWF:RCo*

Simple to use

- Self-contained, ready-to-use, precalibrated reagent cartridges eliminate reagent handling
- Integrated barcode reader automatically tracks cartridges and samples
- Easy rack loading accommodates up to 30 samples onboard

Chemiluminescent technology.

Highly accurate

- Automated chemiluminescent technology enhances accuracy and sensitivity
- Immunoglobulin isotype differentiation improves specificity
- High sensitivity and broad working range with one- or two-stage immunoassays
- Virtually no optical interference

Fast and efficient

- Unprecedented efficiency for key specialty assays
- Up to 20 different assays onboard and available 24 hours/day, 7 days/week
- 60 tests/hour throughput
- Results in ~30 minutes
- STAT or batch sample processing
- Up to 12-week onboard stability

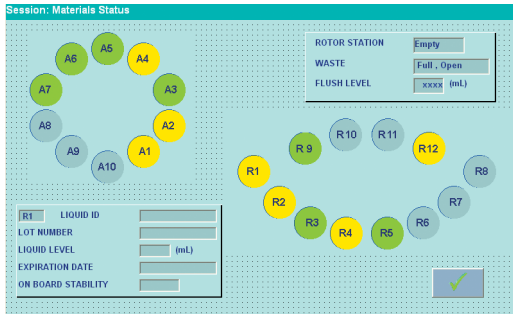
*Not 510(k)-cleared and not Canadian licensed. Not for sale in the US and Canada.

ACL Elite and ACL Elite Pro

Simple, comprehensive solutions for the Hemostasis Laboratory

Enable routine, specialty and STAT testing on compact, convenient and easy-to-use systems. Whether your volume needs are low or high, a host of innovative and valuable performance features include:

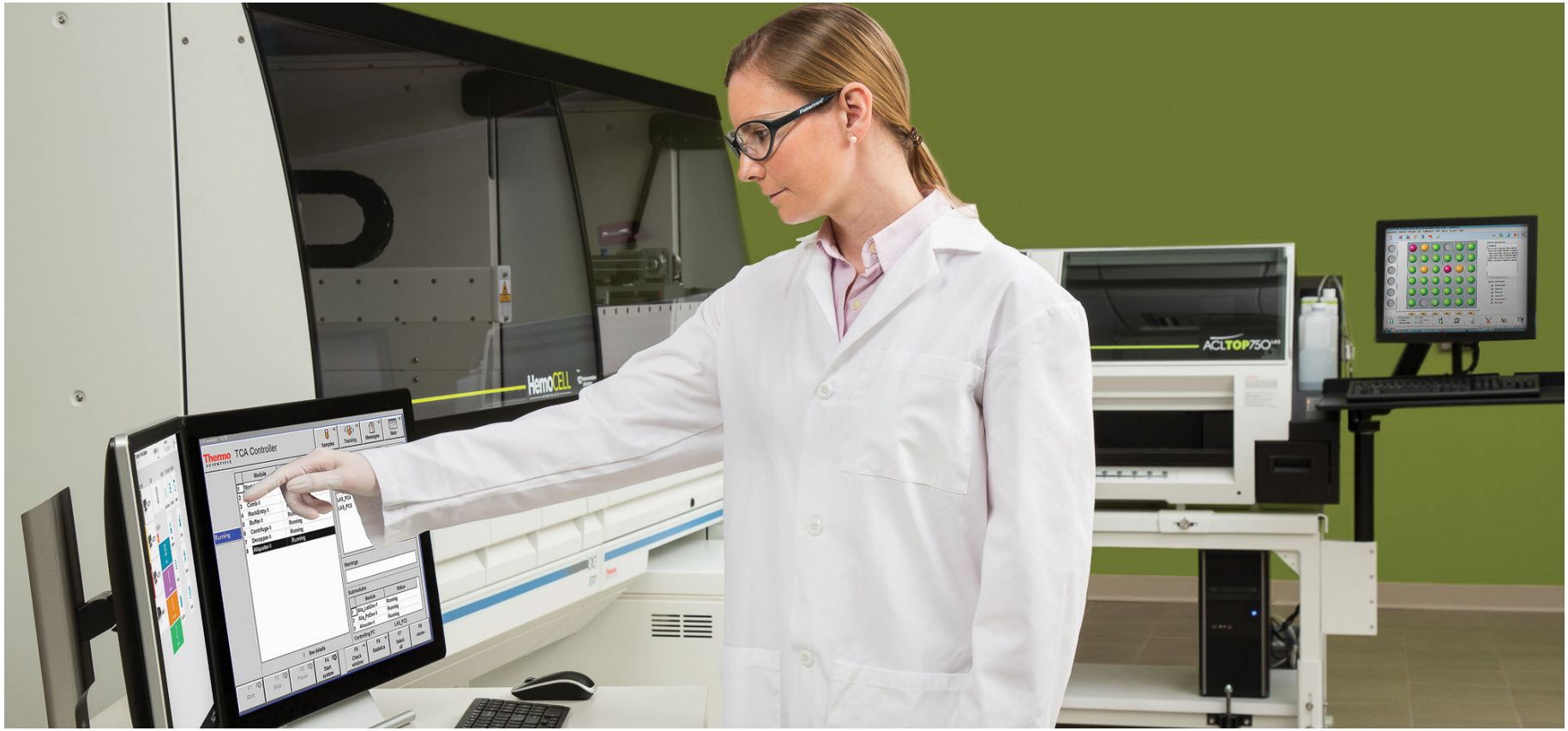
- **Random-access processing** for minimized turnaround time
- **STAT PT and APTT available** in as little as 8 minutes
- **Barcoded reader for reagents** (standard on ACL Elite Pro system)
- **Superior walk-away capacity** for 40 samples and up to 260 cuvettes onboard
- **STAT Interrupt and continuous sample loading** for uninterrupted testing capability
- **Integrated** color touchscreen
- **Intuitive software** streamlines system operation
- **Proven and reliable mechanics** for robust operation with minimal maintenance
- **Comprehensive test menu** makes specialty testing as simple as routine testing



Lab Automation and IT Solutions

Solutions for Hemostasis testing

IL continues to innovate Hemostasis testing to advance patient care and enhance laboratory efficiency. HemoHub Intelligent Data Manager centralizes the entire Hemostasis testing operation from a single workstation, while ProDx Remote Support Suite provides automated remote monitoring and technical support to ensure continuous peak efficiency. HemoCell Specialized Lab Automation is the world's first workcell solution exclusively for Hemostasis testing. It enhances productivity and quality, reducing cost and keeping Hemostasis expertise where it belongs—in your lab.



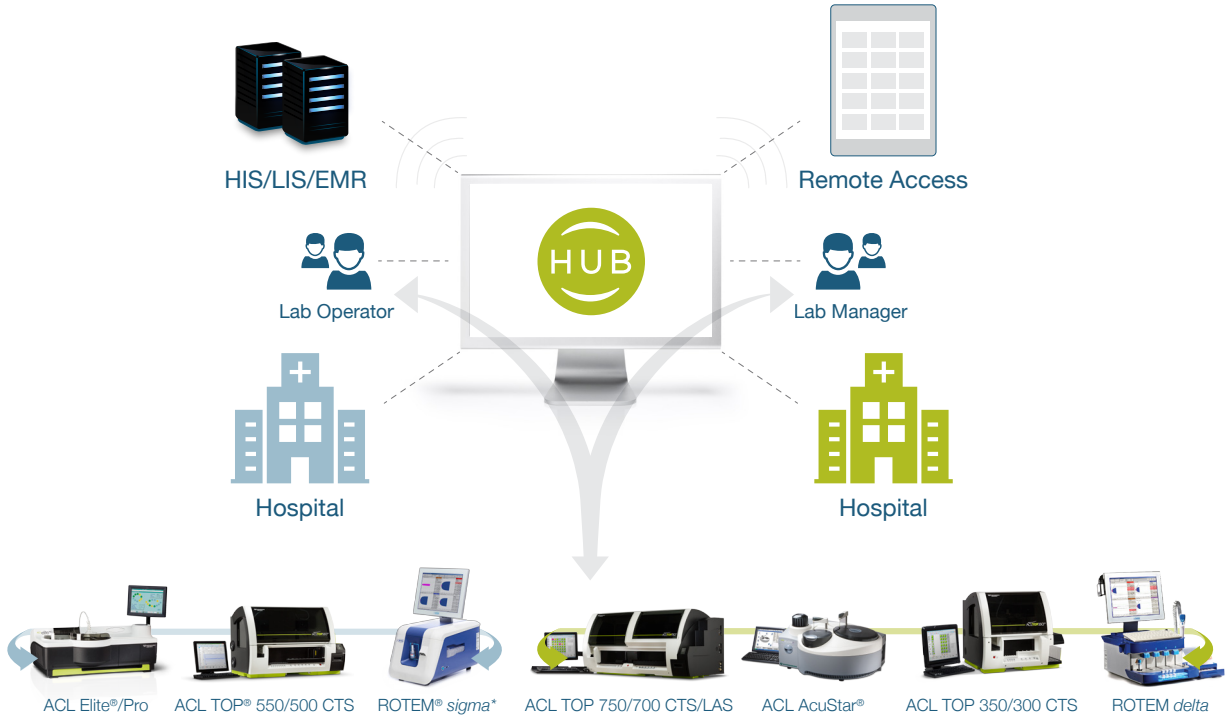
HEMOHUB
INTELLIGENT DATA MANAGER

Centralized management for Hemostasis testing

Unmatched operational performance from a single workstation. Today's Hemostasis testing labs are challenged to do more with less. HemoHub Intelligent Data Manager enhances the efficiency of the entire Hemostasis testing operation, improving workflow, laboratory decision-making, and ultimately, patient care.

Connects all ACL Testing systems and allows users to centrally:

- View critical results and analyzer status in real-time
- Minimize workflow interruptions with flagged sample alerts
- Manage analyzer quality control simply and efficiently
- Support laboratory decision-making by viewing results with patient history
- Set up automatic reruns and reflexes
- Optimize operations and facilitate accreditation
- Run customized reports and track key performance indicators



*Not FDA 510(k)-cleared or Health Canada-licensed. Not saleable in the US or Canada.

NEW ProDx
REMOTE SUPPORT SUITE

Proactive vigilance for peak efficiency

Automated monitoring to ensure continuous peak efficiency and enhanced technical support. ProDx connects your ACL TOP testing systems to our servers, enabling automated continuous monitoring and maximizing instrument uptime.

Continuous monitoring of ACL TOP testing system performance

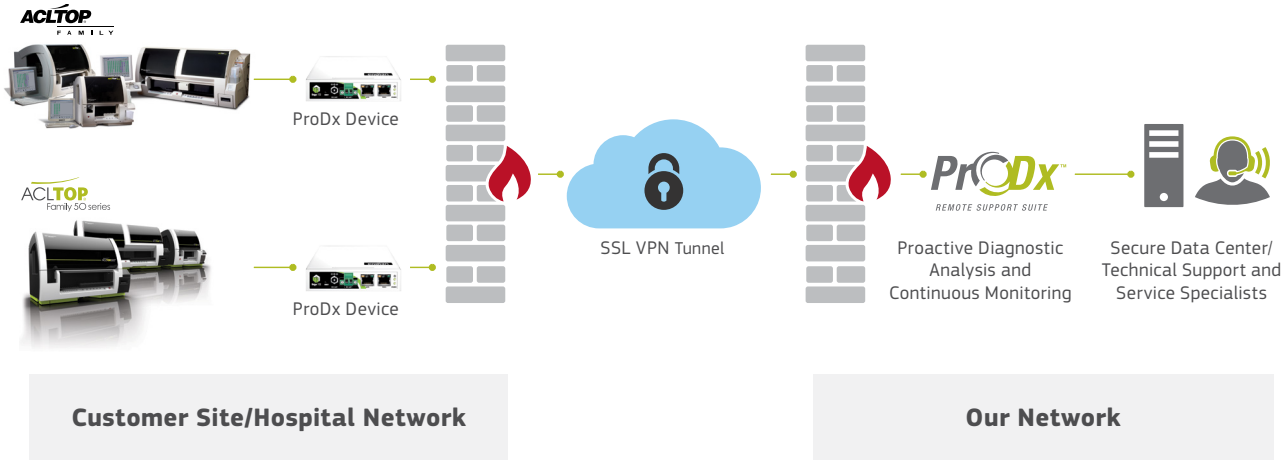
- Identifies issues quickly
- Predicts unexpected system malfunctions and notifies our Technical Support
- Live status monitoring and geographical location of instrument

Remote support for real-time, individually tailored service*

- Guided system software configuration
- Fine-tuning and consultation
- System investigation and troubleshooting
- Scheduled 1-on-1 operator training
- Increases uptime by optimizing preventative maintenance
- Historical data facilitates and expedites root-cause analysis

Maximize uptime for your instrument

- Flags potential problems early, supporting preventative actions
- Identifies root cause and facilitates rapid resolution
- Availability of real-time status information reduces service repair time



*Not available in all countries.

NEW HemoCELL
SPECIALIZED LAB AUTOMATION

For Hemostasis testing—and for your specific needs

Advanced automation of the pre-analytical, analytical and post-analytical phases of Hemostasis testing in high-volume labs. Enhances productivity, improves quality and reduces operating cost. HemoCell Specialized Lab Automation is a workcell solution for Hemostasis testing, customized to your goals.

- Higher throughput
- Shorter turnaround times
- Centralized control of Hemostasis testing
- Retention of Hemostasis expertise in your lab
- Reduced operator exposure to biohazards
- Low implementation impact in the laboratory

Thermo Scientific™
TCAutomation™
Laboratory
Automation System

HemoCELL
SPECIALIZED LAB AUTOMATION

HemoCell integrates the leading Hemostasis testing system with the efficiency of lab automation.

ACL TOP 750 LAS
Hemostasis Testing Syster

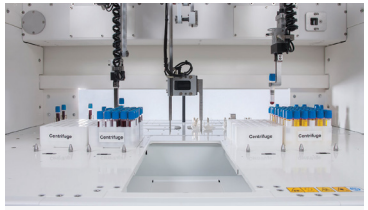
HemoHub
Intelligent Data Manager

Configured for optimal performance

Following a custom analysis from IL, a personalized plan is designed to optimize workflow, analyzers and reagents throughout the track.

EsFlex

- Input/output/sorter
- Cap detection

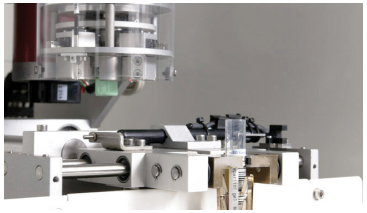


Online centrifuge

- User-configurable centrifugation parameters
- Multiple centrifuges can be installed

Decapper

- Traditional closures and screw caps decapped
- System identifies tube height and diameter, allowing use of a variety of primary tube types



Recapper

- Universal conical cap
- Multi-tube capability

ACL TOP 750 LAS

- Seamless middleware integration and enhanced automation features

HemosIL assay portfolio

- Routine and specialty testing directly from the track

HemoHub Intelligent Data Manager

- Results management, intelligent sample routing and personalized KPIs to help monitor performance

ACL AcuStar
Worklist F2
Results F3
Inventory - Samples
Programmed
Queued
Running
Done
Error
Information
Sampled
Fluid empty
Attention
Status
Sample ID
Assays
1 Ready Q-AB2ML-0712 aB2GPI_IgM
2 Ready Q-AB2MH-0712 aB2GPI_IgM
3 Ready Q-AB2GL-0718 aB2GPI_IgG
4 Ready Q-AB2GH-0718 aB2GPI_IgG
5
6 Ready Q-ACLGL-0717 aCL_IgG
7 Ready Q-ACLGH-0717 aCL_IgG
8 Ready Q-ACLML-0716 aCL_IgM
9 Ready Q-ACLMH-0716 aCL_IgM
10
Samples to Add
Close
Reagent cover unlocked
No work in progress
System Status: Ready
Estimate 49:05
User: operator

Consumables

Product	P/N	ACL TOP Family/ ACL TOP Family 50 Series	ACL Elite/Elite Pro	ACL AcuStar
Cuvettes (2400 cuvettes)	0029400100	•		
CTS filters (12/pkg)	0029403501	•		
Rotors (100 pcs/2000 wells)	0006800000		•	
Sample tray converter (3.5 mL)	0019058600		•	
Sample tray (5 mL)	0018110898		•	
Sample tray (S 11.5)	0018181285		•	
ACL AcuStar cuvettes (1400 pcs)	0009801100			•
ACL AcuStar cuvette waste bin	0009801030			•

Accessories

Product	P/N	ACL TOP 750 ACL TOP	ACL TOP 750 CTS ACL TOP CTS	ACL TOP 750 LAS	ACL TOP 550 CTS	ACL TOP 350 CTS	ACL Elite/ Elite Pro
Magnetic stirrers	0009746606	•	•	•	•	•	•
Sample cups 0.5 mL (polystyrene 1000 pcs)	0006799200						•
Sample cups 2 mL (polystyrene 1000 pcs)	0005575100	•	•	•	•	•	•
Sample cups 4 mL (polystyrene 100 pcs + labels)	0006799400						•
T-connector	0007406800						•
Sample/reagent tubing	0007328901						•
Filter reagent cooling fan	00028617301	•	•	•			
Filter reagent cooling fan	00027333801					•	
Filter reagent cooling fan	00029520901				•		
Air filter moulded	0018181271						•
Waste reservoir	0018181272						•
Needles block	0018110843						•
Needles adjustment tool	0018103941						•
Waste tube	0009909503						•
Waste bottle	0018105769						•
Waste bottle	0018901300	•	•	•	•	•	
Glass vials 20 mL (8 pcs)	0019085463	•	•	•	•	•	
Glass vials 10 mL (10 pcs)	0018924100	•	•	•	•	•	•
Glass vials 4 mL (10 pcs)	0018924104	•	•	•	•	•	•
Plastic bottle (30 mL)	0018902000	•	•	•	•	•	
Tubing extractor kit	0018108065						•
Aliquot tube adapter (10 pcs)	0028533400	•	•	•	•	•	
Paediatric tube adapter (10 pcs)	0028533500	•	•	•	•	•	
Micro tube adapter (10 pcs)	0028533700	•	•	•	•	•	
CTS sample tube adapter (10 pcs)	0028533600		•		•	•	
CTS rack adapter blue (48/pkg)	0027500148		•		•	•	
CTS rack adapter blue (96/pkg)	0027500149		•		•	•	

Product	P/N	ACL TOP 750 ACL TOP	ACL TOP 750 CTS ACL TOP CTS	ACL TOP 750 LAS	ACL TOP 550 CTS	ACL TOP 350 CTS	ACL Elite/ Elite Pro
CTS piercer	0029403601		•		•	•	
CTS probe	0029403701		•		•	•	
CTS sample rack set, 01–12	0029400901		•		•	•	
CTS sample rack set, 13–24	0029400902		•		•	•	
CTS sample rack set, 25–36	0029400903		•		•	•	
CTS sample rack set, 37–48	0029400904		•		•	•	
CTS sample rack set, 49–60	0029400905		•		•	•	
CTS sample rack set, 61–72	0029400906		•		•	•	
CTS sample rack set, 73–84	0029400907		•		•	•	
CTS sample rack set, 85–96	0029400908		•		•	•	
CTS filter replacement tool	0028386300		•		•	•	
CTS sample rack set, 01–08	0029400941		•		•	•	
CTS sample rack set, 09–16	0029400942		•		•	•	
CTS sample rack set, 17–24	0029400943		•		•	•	
CTS sample rack set, 25–32	0029400944		•		•	•	
CTS sample rack set, 33–40	0029400945		•		•	•	
CTS sample rack set, 41–48	0029400946		•		•	•	
CTS sample rack set, 49–56	0029400947		•		•	•	
CTS sample rack set, 57–64	0029400948		•		•	•	
CTS Sarstedt rack set, 16.3 mm 01–08	0000051301		•		•	•	
CTS Sarstedt rack set, 16.3 mm 09–16	0000051302		•		•	•	
CTS Sarstedt rack set, 16.3 mm 17–24	0000051303		•		•	•	
CTS Sarstedt rack set, 16.3 mm 25–32	0000051304		•		•	•	
CTS Sarstedt rack set, 16.3 mm 33–40	0000051305		•		•	•	
CTS Sarstedt rack set, 16.3 mm 41–48	0000051306		•		•	•	
CTS Sarstedt rack set, 16.3 mm 49–56	0000051307		•		•	•	
CTS Sarstedt rack set, 16.3 mm 57–64	0000051308		•		•	•	
CTS Sarstedt rack set, 16.3 mm 65–72	0000051309		•		•	•	
CTS Sarstedt rack set, 16.3 mm 73–80	0000051310		•		•	•	
CTS Sarstedt rack set, 16.3 mm 81–88	0000051311		•		•	•	

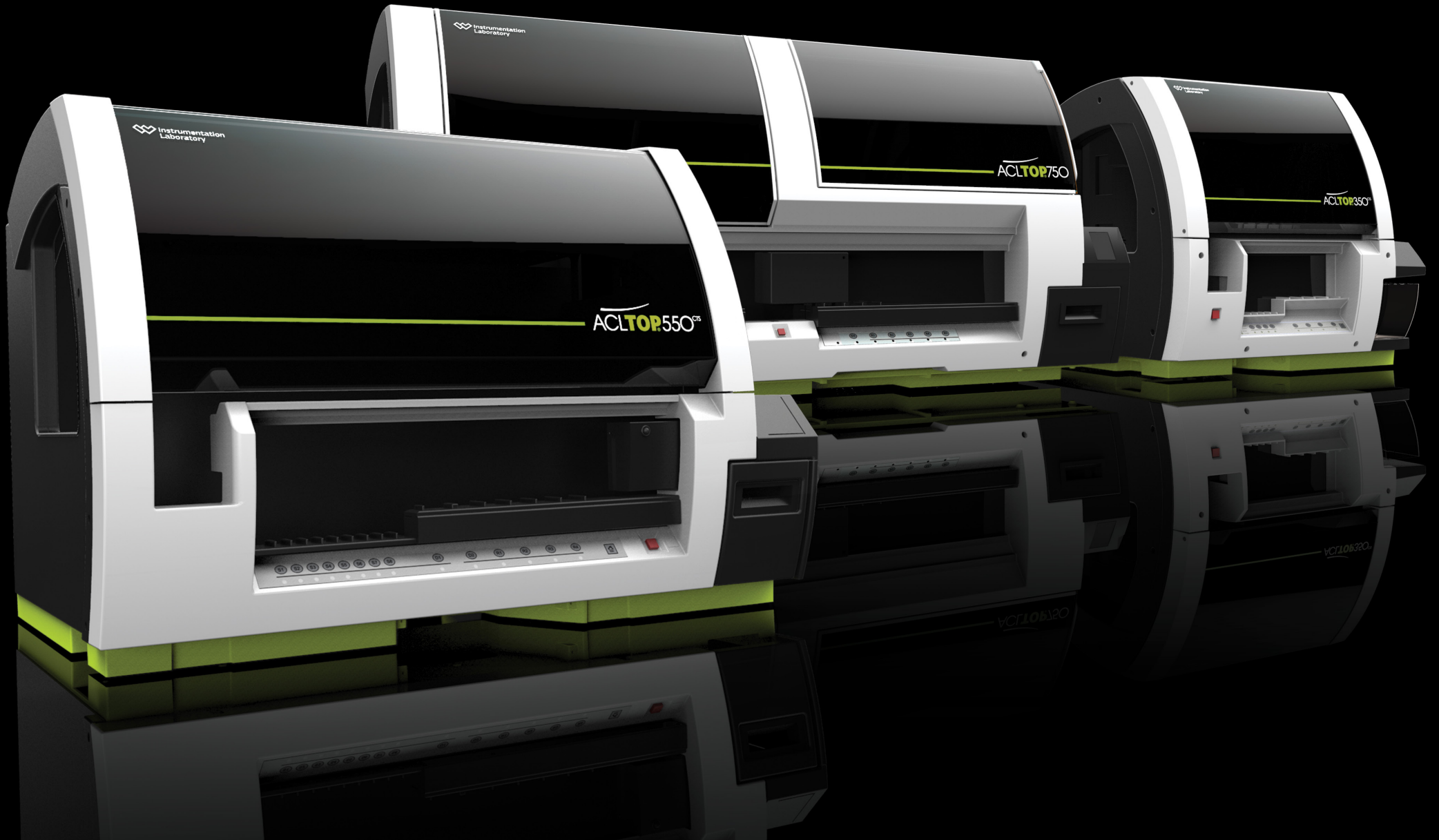
Sarstedt CTS racks and sample adapters may be used on any ACL TOP system with CTS (software version 4.0 or higher). Rack numbering and rack counts vary by set.

Product	P/N	ACL TOP 750 ACL TOP	ACL TOP 750 CTS ACL TOP CTS	ACL TOP 750 LAS	ACL TOP 550 CTS	ACL TOP 350 CTS	ACL Elite/ Elite Pro
CTS Sarstedt rack set, 16.3 mm 89–96	0000051312		•		•	•	
CTS Sarstedt rack set, 14 mm 01–08	0000051401		•		•	•	
CTS Sarstedt rack set, 14 mm 09–16	0000051402		•		•	•	
CTS Sarstedt rack set, 14 mm 17–24	0000051403		•		•	•	
CTS Sarstedt rack set, 14 mm 25–32	0000051404		•		•	•	
CTS Sarstedt rack set, 14 mm 33–40	0000051405		•		•	•	
CTS Sarstedt rack set, 14 mm 41–48	0000051406		•		•	•	
CTS Sarstedt rack set, 14 mm 49–56	0000051407		•		•	•	
CTS Sarstedt rack set, 14 mm 57–64	0000051408		•		•	•	
CTS Sarstedt rack set, 14 mm 65–72	0000051409		•		•	•	
CTS Sarstedt rack set, 14 mm 73–80	0000051410		•		•	•	
CTS Sarstedt rack set, 14 mm 81–88	0000051411		•		•	•	
CTS Sarstedt rack set, 14 mm 89–96	0000051412		•		•	•	
CTS Sarstedt rack set, 16.3 mm 01–12	0000051501		•		•	•	
CTS Sarstedt rack set, 16.3 mm 13–24	0000051502		•		•	•	
CTS Sarstedt rack set, 16.3 mm 25–36	0000051503		•		•	•	
CTS Sarstedt rack set, 16.3 mm 37–48	0000051504		•		•	•	
CTS Sarstedt rack set, 16.3 mm 49–60	0000051505		•		•	•	
CTS Sarstedt rack set, 16.3 mm 61–72	0000051506		•		•	•	
CTS Sarstedt rack set, 16.3 mm 73–84	0000051507		•		•	•	
CTS Sarstedt rack set, 16.3 mm 85–96	0000051508		•		•	•	
CTS Sarstedt rack set, 14 mm 01–12	0000051601		•		•	•	
CTS Sarstedt rack set, 14 mm 13–24	0000051602		•		•	•	
CTS Sarstedt rack set, 14 mm 25–36	0000051603		•		•	•	
CTS Sarstedt rack set, 14 mm 37–48	0000051604		•		•	•	
CTS Sarstedt rack set, 14 mm 49–60	0000051605		•		•	•	
CTS Sarstedt rack set, 14 mm 61–72	0000051606		•		•	•	
CTS Sarstedt rack set, 14 mm 73–84	0000051607		•		•	•	
CTS Sarstedt rack set, 14 mm 85–96	0000051608		•		•	•	
ACL AcuStar Sample Rack (6 pcs)	0009801006						•
ACL AcuStar Sample Rack Adapters (30 pcs)	0009801020						•
ACL AcuStar Narrow Tube Adapters (30 pcs)	0009801025						•
Sample racks	0019007000		•				
Sample rack set, 01–08*	0029400541	•	•	•	•	•	
Sample rack set, 09–16*	0029400542	•	•	•	•	•	
Sample rack set, 17–24*	0029400543	•	•	•	•	•	
Sample rack set, 25–32*	0029400544	•	•	•	•	•	
Sample rack set, 33–40*	0029400545	•	•	•	•	•	

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.
**Open tubes or cup. Rack sets compatible with all ACL TOP Family systems. Rack numbering and rack counts vary by set.*

Product	P/N	ACL TOP 750 ACL TOP	ACL TOP 750 CTS ACL TOP CTS	ACL TOP 750 LAS	ACL TOP 550 CTS	ACL TOP 350 CTS	ACL Elite/ Elite Pro
Sample rack set, 41–48*	0029400546	•	•	•	•	•	
Sample rack set, 49–56*	0029400547	•	•	•	•	•	
Sample rack set, 57–64*	0029400548	•	•	•	•	•	
4 mL diluent bottle adapter (2 pcs)	0028526001	•	•	•	•	•	
10 mL diluent bottle adapter (2 pcs)	0028526101	•	•	•	•	•	
20 mL diluent bottle adapter (2 pcs)	0028526201	•	•	•	•	•	
Rotor insertion tool	0018181277						•
Reagent adapters 10 mL vial (stirred)	0018181265						•
Reagent adapters 10 mL vial (not stirred)	0019076200						•
Reagent adapters 4 mL vial (not stirred)	0019076100						•
Sample tray cup adapters	0019076400						•
Sample tray 4 mL vial adapters	0019076300						•
4 mL reagent bottle adapters	0028520500	•	•	•	•	•	
10 mL reagent bottle adapters	0028520900	•	•	•	•	•	
Reagent rack set, RA-RF	0029400601	•	•	•	•	•	
Reagent rack set, RG-RM	0029400602	•	•	•	•	•	
Rack set reagent, RA-RD ACL TOP	0029400641	•	•	•	•	•	
Rack set reagent, RE-RH ACL TOP	0029400642	•	•	•	•	•	
ACL TOP diluent rack set, DA-DB	0029400741	•	•	•	•	•	
ACL TOP diluent rack set, DC-DD	0029400742	•	•	•	•	•	
Diluent rack DA-DC	0029400701	•	•	•	•	•	
Diluent rack DD-DF	0029400702	•	•	•	•	•	
Sample rack set, 01–12*	0029400501	•	•	•	•	•	
Sample rack set, 13–24*	0029400502	•	•	•	•	•	
Sample rack set, 25–36*	0029400503	•	•	•	•	•	
Sample rack set, 37–48*	0029400504	•	•	•	•	•	
Sample rack set, 49–60*	0029400505	•	•	•	•	•	
Sample rack set, 61–72*	0029400506	•	•	•	•	•	
Sample rack set, 73–84*	0029400507	•	•	•	•	•	
Sample rack set, 85–96*	0029400508	•	•	•	•	•	
Cuvette waste liner, 10 pack (ACL TOP 500)	0029506900				•		
Cuvette waste liner, 10 pack (ACL TOP 700)	0029401100	•	•	•			
Cuvette waste bin, 10 pack (ACL TOP 300)	0027344900					•	
Tray, 6-sample racks	0028780200	•	•	•	•	•	

**Open tubes or cup. Rack sets compatible with all ACL TOP Family systems. Rack numbering and rack counts vary by set.*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Instrument Specifications/Tests

Specifications	ACL TOP 750 CTS ACL TOP CTS	ACL TOP 750 LAS	ACL TOP 550 CTS	ACL TOP 350 CTS	ACL Elite/ Elite Pro	ACL AcuStar
Turbidimetric (clotting) channel	•	•	•	•	•	
Absorbance (chromogenic) channel	•	•	•	•	•	
Immunological tests	•	•	•	•	•	•†
Samples onboard (maximum)	120	90	80	40	40	30
Reagents onboard (maximum)	44 (+16)	44 (+16)	40	26	18/22	20
Cuvettes onboard (maximum)	800	800	800	800	240	280
Sample predilution	•	•	•	•	•	•
Calibration curve predilution	•	•	•	•	•	
STAT capability	•	•	•	•	•	•
Quality control	•	•	•	•	•	•
Patient data storage	•	•	•	•	•	•
Reaction curves availability	•	•	•	•	•	
Liquid (sample/reagent) sensor	•	•	•	•	•	•
Primary tube capability	•	•	•	•	•	•
External barcode reader	*	•	*	*	*	•
Internal barcode reader	•	•	•	•	•	•
Throughput up to PT/hour	360/270		240	110	150	††
APTT/hour	320/270		180	110	100	††
Automatic downloading	•	•	•	•	•	•
Automatic validation	*	*	*	*		•
Automatic uploading	*	*	*	*	•	•
Automatic printing on internal printer					•	•
Automatic printing on external printer	•	•	•	•	•	•
Interface to host computer	Bidirectional	Bidirectional	Bidirectional	Bidirectional	Bidirectional	Bidirectional
Sample ID	•	•	•	•	•	•
Preheating	•	•	•	•	•	
Open applications	•	•	•	•	•	
Cap-piercing	•		•	•		

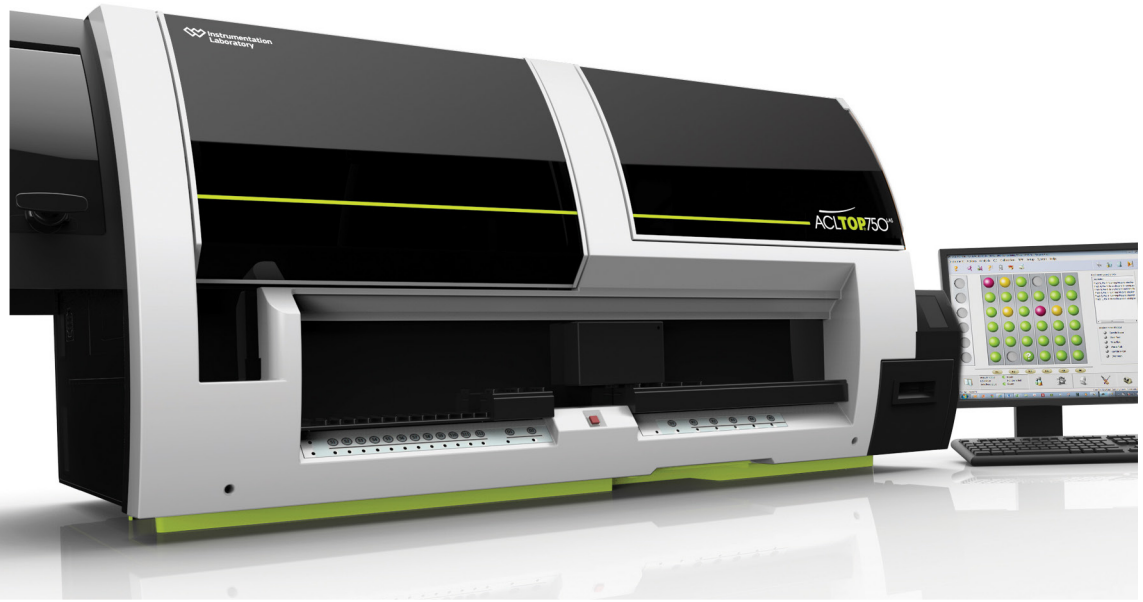
**Optional. †Chemiluminescent technology. †† ACL AcuStar throughput is 60 tests/hour. PT/APTT are not applicable. For supported assays, refer to page 56.*

Instrument Specifications/Tests

Tests	ACL TOP Family	ACL Elite/Elite Pro	ACL AcuStar
PT	•	•	
PT-Fib based	•	•	
APTT	•	•	
TT	•	•	
Fibrinogen-C	•	•	
Pro-IL-Complex*	•	•	
Hepatocomplex*	•	•	
Heparin	•	•	
Liquid Anti-Xa	•	•	
D-Dimer	•	•	•
D-Dimer 500*	•	•	
D-Dimer HS	•		
D-Dimer HS 2000*	•		
D-Dimer HS 500	•		
FDP*	•		
HIT-Ab$_{(PF4-H)}$	•		
HIT-IgG$_{(PF4-H)}$			•
Antithrombin	•	•	
Protein C (chromogenic)	•	•	
ProClot (clotting)	•	•	
Protein S Activity	•	•	
Free Protein S	•	•	
Factor V Leiden (APC-R V)	•	•	
Homocysteine	•	•	
dRVVT Screen & Confirm	•	•	
Silica Clotting Time	•	•	
Anti-Cardiolipin IgG			•
Anti-Cardiolipin IgM			•
Anti-β_2 GPI Domain 1			•
Anti-β_2 Glycoprotein-I IgM			•
Anti-β_2 Glycoprotein-I IgG			•
Factor II (clotting)	•	•	
Factor V (clotting)	•	•	
Factor VII (clotting)	•	•	
Factor VIII (clotting)	•	•	
Factor IX (clotting)	•	•	
Factor X (clotting)	•	•	
Factor XI (clotting)	•	•	
Factor XII (clotting)	•	•	
Factor VIII (chromogenic)		•	
Factor XIII Antigen**	•		
von Willebrand Factor Antigen	•	•	•
von Willebrand Factor Activity	•	•	
von Willebrand Factor Ristocetin Cofactor Activity*	•		•
von Willebrand Factor Collagen Binding Activity*			•
Plasminogen	•	•	
Plasmin Inhibitor	•	•	

**Not 510(k)-cleared. Not saleable in the US. Not available in all countries.*
***FXIII assays are exempt from 510(k)-clearance.*

Hemosil® AcuStar
VWF:RCo
Hemosil® AcuStar
VWF:Ag


Instrumentation Laboratory
ACL TOP 750

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