Haemostasis Product Catalogue

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Biosciences Europe

Introduction to Helena Biosciences

Helena Biosciences is a world-leading IVD manufacturer based in the North East of England selling to end-users, distributors and OEM clients. Our global development, distribution and support operation is run from three European sites, housing our specialised R&D, manufacturing, sales and support teams.

Gateshead, UK

- Sales and marketing
- Design team
- Assay development
- Quality Assurance
- Software team
- Service and support
- Warehousing
- Logistics
- Administration

Sunderland, UK

- Research and Development
- Reagent manufacture
- Quality Assurance
- Documentation
- Packaging
- Regulatory Affairs
- Customer support
- Warehousing and logistics

Emmen, Netherlands

- Instrumentation specialists
- Analyser, assay and software R&D
- Multi-disciplinary engineering and manufacturing teams
- Sales, marketing and support
- Warehousing, logistics and distribution

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Haemostasis experts for over forty years

Helena Biosciences are proud to serve B2B, B2C and OEM customers of all sizes with bespoke and off-the-shelf reagent, controls and instrumentation solutions.

Haemostasis Solutions



Complete portfolio of reagents for determination of blood coagulation and platelet function with support for many major brand analysers.

Reagent Portfolio:
Routine Screening Tests • Factor Assays • Fibrinolysis Thrombophilia • Platelet Disorders • Controls • Calibrators

Semi-Automated Analysers:
1/2/4 Channel Coagulometers • Platelet Aggregometers

Reagent OEM



Tailored kit and vial formats and reagent properties to suit your exact requirements, whether for specific B2B purposes or via a full OEM agreement. Our dedicated team of application specialists can develop bespoke packages and provide the application notes for use of our full panel of Helena reagents on all coagulation instrument platforms.

Product Portfolio:
Routine Assays • Specialist Assays • Calibrators • Controls Platelet Function Assays

Third Party Controls

A range of quality controls allowing for the independent verification of a laboratory's QC régime, monitoring for any shift in analyser performance.

Routine Controls • Speciality Assayed Controls • LA Positive Control • D-Dimer (high/low) • Ristocetin Cofactor Abnormal Control

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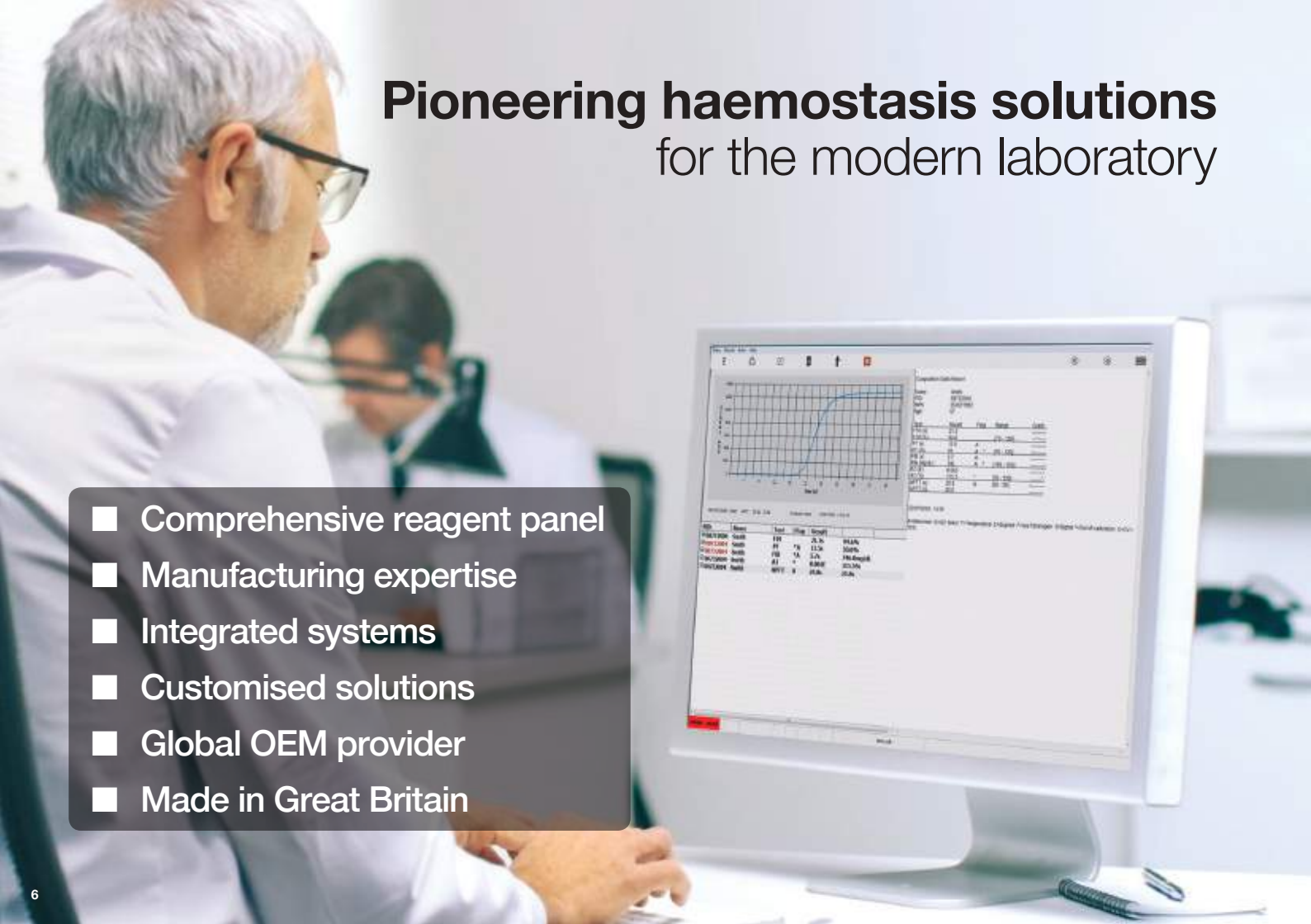
Key: CE = *CE marked* ◆ = *Lyophilised*

Pioneering haemostasis solutions
for the modern laboratory



- Comprehensive reagent panel
- Manufacturing expertise
- Integrated systems
- Customised solutions
- Global OEM provider
- Made in Great Britain

Routine Assays

Factor Deficient Plasma

Chromogenic Assays

Specialist Assays

Calibrators and Quality Control Material

Platelet Function

Instruments

Thromboplastin L

REF: 5265HL, 5265L, 5267L

Intended Use:

Thromboplastin L is calcified Rabbit Brain Thromboplastin Suspension used for the determination of Prothrombin Time, investigation of the extrinsic pathway and monitoring of oral anticoagulant therapy in citrated human plasma.

Main Features:

- Low ISI ~ 1.1
- Calcified liquid ready to use reagent
- Calibrated against WHO international reference preparation
- Insensitive to Heparin up to 2U/mL

Kit Contents:

Component	REF	Volume	Stability
Thromboplastin L (Liquid)	5265HL	2 × 5 mL	Store at +2 –+8°C and is stable until the expiry date indicated on the label. DO NOT FREEZE
Thromboplastin L (Liquid)	5265L	8 × 5 mL	Store at +2 –+8°C and is stable until the expiry date indicated on the label. DO NOT FREEZE
Thromboplastin L (Liquid)	5267L	10 × 10 mL	Store at +2 –+8°C and is stable until the expiry date indicated on the label. DO NOT FREEZE

APTT Si L Minus

REF: 5562SLQ, 5558SLQ, 5559SLQ, 5560SLQ

Intended Use:

APTT Si L Minus contains phospholipid extract and a near-colloidal particle activator. It is for use in the determination of Activated Partial Thromboplastin Times (aPTT), related coagulation factor assays, pre-surgical screening and monitoring of Heparin therapy using citrated plasma. The reagent can be used on manual, semi-automated and automated methods.

Main Features:

- Ready to use liquid components
- Silica contact activator
- Insensitive to low levels of Lupus
- Sensitive to Heparin
- Excellent factor sensitivity

Kit Contents:

Component	REF	Volume	Stability
APTT Si L Minus	5562SLQ 5560SLQ 5558SLQ 5559SLQ	5 × 5 mL 10 × 5 mL 5 × 10 mL 10 × 10 mL	Store at +2 –+8°C DO NOT FREEZE Stable for 30 days after opening
Calcium Chloride: 0.025M	5562SLQ 5560SLQ 5558SLQ 5559SLQ	5 × 5 mL 10 × 5 mL 5 × 10 mL 10 × 10 mL	Store at +2 –+8°C DO NOT FREEZE Stable for 30 days after opening

Calcium Chloride

REF: 5386

Intended Use:

0.025M Calcium Chloride for use in conjunction with Helena Biosciences Thromboplastin and APTT reagents.

Kit Contents:

Component	REF	Volume	Stability
◊ Calcium Chloride 0.025M	5386	10 × 10 mL	Stored at +2 –+8°C and is stable until the expiry date indicated on the label DO NOT FREEZE

Clauss Fibrinogen 35

REF: 5376/35R

Intended Use:

Clauss Fibrinogen 35 is intended for the quantitative determination of Fibrinogen based on the Clauss method, in human citrated plasma on IL/ACL Coagulation Systems. Thrombin is added to human plasma to convert Fibrinogen to Fibrin, the clot time is directly proportional to the fibrinogen concentration.

Main Features:

- Bovine Thrombin
- 35 NIH Units/mL
- Specifically designed for IL/ACL Coagulation systems
- Linear calibration from 0.7-7g/L on the ACL 3000 Plus instrument
- Insensitive to Heparin levels up to 1 U/mL on the ACL 3000 Plus

Kit Contents:

Component	REF	Volume	Stability
◈ Thrombin: 35 NIH/mL	5376/35R	5 × 2 mL	Once reconstituted: 8 hours at +15 –+30°C 1 week at +2 –+8°C
◈ Fibrinogen Calibrator	5376/35R	1 × 1 mL	Once reconstituted: 4 hours at +2 –+8°C
◊ Imidazole Buffer	5376/35R	1 × 25 mL	Unopened bottles are stable until the given expiry date when stored under conditions indicated on the bottle label.

Clauss Fibrinogen 50

REF: 5556

Intended Use:

Clauss Fibrinogen 50 is intended for the quantitative determination of Fibrinogen in citrated human plasma, utilising Owren's Buffer. An excess of Thrombin (>30 NIH units/mL) is added to human plasma to convert Fibrinogen to Fibrin, the clot time is directly proportional to the Fibrinogen concentration.

Main Features:

- Bovine Thrombin
- 50 NIH Units/mL
- Specifically designed for use on Helena Biosciences' C-Series (old design) and AC-4 instruments
- Linear calibration from 1.5-6.5 g/L

Kit Contents:

Component	REF	Volume	Stability
◆ Thrombin: 50 NIH/mL	5556	5 × 4 mL	Once reconstituted: 8 hours at +15 –+30°C 1 week at +2 –+8°C 1 month at -20°C
◆ Fibrinogen Calibrator	5556	2 × 1 mL	Once reconstituted: 4 hours at +2 –+8°C
◊ Owren's Buffer	5556	2 × 25 mL	Store at +2 –+8°C once opened

Clauss Fibrinogen 50

REF: 5556R

Intended Use:

Clauss Fibrinogen 50 is intended for the quantitative determination of Fibrinogen in citrated human plasma, utilising Imidazole Buffer. An excess of Thrombin (>30 NIH units/mL) is added to human plasma to convert Fibrinogen to Fibrin, the clot time is directly proportional to the Fibrinogen concentration.

Main Features:

- Bovine Thrombin
- 50 NIH Units/mL
- Specifically designed for use on Helena Biosciences' C-Series (old design) and AC-4 instruments
- Linear calibration from 1.5-6.5 g/L

Kit Contents:

Component	REF	Volume	Stability
◆ Thrombin: 50 NIH/mL	5556R	5 × 4 mL	Once reconstituted: 8 hours at +15 –+30°C 1 week at +2 –+8°C 1 month at -20°C
◆ Fibrinogen Calibrator	5556R	2 × 1 mL	Once reconstituted: 4 hours at +2 –+8°C
◊ Imidazole Buffer	5556R	2 × 25 mL	Unopened bottles are stable until the given expiry date when stored under conditions indicated on the bottle label.

Clauss Fibrinogen 100

REF: 5376

Intended Use:

Clauss Fibrinogen 100 is intended for the quantitative determination of Fibrinogen in citrated human plasma, utilising Owren's Buffer. An excess of Thrombin (>30 NIH units/mL) is added to human plasma to convert Fibrinogen to Fibrin, the clot time is directly proportional to the Fibrinogen concentration.

Main Features:

- Bovine Thrombin
- 100 NIH Units/mL
- Linear calibration from 1.5-6.5 g/L
- Suitable for use on most manual, semi-automated and automated instruments

Kit Contents:

Component	REF	Volume	Stability
◆ Thrombin: 100 NIH/mL	5376	5 × 2 mL	Once reconstituted: 8 hours at +15 –+30°C 1 week at +2 –+8°C 1 month at -20°C
◆ Fibrinogen Calibrator	5376	2 × 1 mL	Once reconstituted: 4 hours at +2 –+8°C
◊ Owren's Buffer	5376	2 × 25 mL	Store at +2 –+8°C once opened
◊ Kaolin Suspension 0.5g/L	5376	2 × 5 mL	Store at +2 –+8°C once opened

Clauss Fibrinogen 100

REF: 5376R

Intended Use:

Clauss Fibrinogen 100 is intended for the quantitative determination of Fibrinogen in citrated human plasma, utilising Imidazole Buffer. An excess of Thrombin (>30 NIH units/mL) is added to human plasma to convert Fibrinogen to Fibrin, the clot time is directly proportional to the Fibrinogen concentration.

Main Features:

- Bovine Thrombin
- 100 NIH Units/mL
- Linear calibration from 1.5-6.5 g/L
- Suitable for use on most manual, semi-automated and automated instruments

Kit Contents:

Component	REF	Volume	Stability
◆ Thrombin: 100 NIH/mL	5376R	5 × 2 mL	Once reconstituted: 8 hours at +15 –+30°C 1 week at +2 –+8°C 1 month at -20°C
◆ Fibrinogen Calibrator	5376R	2 × 1 mL	Once reconstituted: 4 hours at +2 –+8°C
◊ Imidazole Buffer	5376R	2 × 25 mL	Unopened bottles are stable until the given expiry date when stored under conditions indicated on the bottle label.
◊ Kaolin Suspension 0.5g/L	5376R	2 × 5 mL	Store at +2 –+8°C once opened

Clauss Fibrinogen (Thrombin only) CE

REF: 5374, 5378

Intended Use:

Clauss Fibrinogen (Thrombin only) is intended for use in the quantitative determination of Fibrinogen in human plasma using the Clauss Method.

Main Features:

- Thrombin only component
- Bovine Thrombin
- 100 NIH Units/mL

Kit Contents:

Component	REF	Volume	Stability
◆ Thrombin: 100 NIH/mL	5374 5378	10 × 2 mL 10 × 5 mL	Once reconstituted: 8 hours at +15 – +30°C 1 week at +2 – +8°C 1 month at -20°C

Imidazole Buffer CE

REF: 5375R

Intended Use:

Imidazole can be used with Clauss Fibrinogen and Factor assays to dilute standards, control plasma and patient plasma for manual, semi-automated and fully automated methods.

Kit Contents:

Component	REF	Volume	Stability
◊ Imidazole Buffer	5375R	10 × 25 mL	Unopened bottles are stable until the given expiry date when stored under conditions indicated on the bottle label.

Owren's Buffer

REF: 5375

Intended Use:

Owren's Buffer can be used with Clauss Fibrinogen and Factor assays to dilute standards, control plasma and patient plasma for manual, semi-automated and fully automated methods.

Kit Contents:

Component	REF	Volume	Stability
Owren's Buffer	5375	10 × 25 mL	Unopened bottles are stable until the given expiry date when stored under conditions indicated on the bottle label

Kaolin Suspension

REF: 53765

Intended Use:

Kaolin Suspension is used to reconstitute Thrombin where instrument methodology indicates Kaolin reconstitution of the Thrombin reagent is required for use in Clauss Fibrinogen assays.

Kit Contents:

Component	REF	Volume	Stability
Kaolin Suspension 0.5g/L	53765	1 × 100 mL	Unopened bottles are stable until the given expiry date when stored under conditions indicated on the bottle label

Thrombin Time

REF: 5392, 5377

Intended Use:

The Thrombin Time reagent is intended to give a qualitative indication of abnormal Fibrinogen levels, or the presence of interfering substances such as FDPs or Heparin. Quantitative evaluation of the possible causes of prolonged Thrombin Times should be performed as follow-up studies.

Main Features:

- Bovine Thrombin
- 10 NIH Units/mL
- Multiple kit formats
- Suitable for use on manual, semi-automated and fully automated methods

Kit Contents:

Component	REF	Volume	Stability
◆ Thrombin Time	5392 5377	10 × 2 mL 10 × 5 mL	Once reconstituted, the reagent is stable for 14 days at +2 –+8°C or 1 month at -20°C

Thrombin Time

REF: 5380

Intended Use:

The Thrombin Time reagent is intended to give a qualitative indication of abnormal Fibrinogen levels, or the presence of interfering substances such as FDPs or Heparin on IL TOPS Coagulation Systems. Quantitative evaluation of the possible causes of prolonged Thrombin Times should be performed as follow-up studies.

Main Features:

- Bovine Thrombin
- 10 NIH Units/mL
- Suitable for use on IL TOPS

Kit Contents:

Component	REF	Volume	Stability
◆ Thrombin Time	5380	4 × 5 mL	Once reconstituted, the reagent is stable on-board the IL TOPS for 3 days
◊ Thrombin Time Diluent	5380	1 × 27 mL	

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Factor Deficient Plasma

Chromogenic Assays

Specialist Assays

Calibrators and Quality Control Material

Platelet Function

Instruments

Put your trust in a proven partner.

Complete your laboratory's QC process with Helena's high quality range of controls

Routine Controls • Speciality Assayed Controls • LA Positive Control
D-Dimer (high/low) • Ristocetin Cofactor Abnormal Control

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Intrinsic Factor Deficient Plasmas CE

REF: 5193, 5194, 5793, 5794, 5796, 5797

Intended Use:

The intrinsic factor deficient plasmas are intended for the quantitative determination of specific factor activity in citrated human plasma. This one stage method requires an appropriate APTT reagent and any instrument capable of performing APTT-based factor assay testing.

Main Features:

- Residual factor activity < 1%
- All other factor activity optimal
- Human plasma
- Congenital and immunodepleted plasmas available
- Intrinsic factor assay linearity from 10-150%

Kit Contents:

Component	REF	Volume	Stability
◈ Factor VIII Deficient Plasma (Congenital)	5193	10 × 1 mL	Once reconstituted, the reagent is stable for 8 hours when kept at +2 –+8°C
◈ Factor IX Deficient Plasma (Congenital)	5194	10 × 1 mL	
◈ Factor VIII Deficient Plasma (Immunodepleted)	5793	10 × 1 mL	
◈ Factor IX Deficient Plasma (Immunodepleted)	5794	10 × 1 mL	
◈ Factor XI Deficient Plasma (Immunodepleted)	5796	10 × 1 mL	
◈ Factor XII Deficient Plasma (Immunodepleted)	5797	10 × 1 mL	

Extrinsic Factor Deficient Plasmas CE

REF: 5191, 5192, 5195, 5790, 5791, 5792, 5795

Intended Use:

The extrinsic factor deficient plasmas are intended for the quantitative determination of specific factor activity in citrated human plasma. This one stage method requires an appropriate PT reagent and any instrument capable of performing PT-based factor assay testing.

Main Features:

- Residual factor activity < 1%
- All other factor activity optimal
- Human plasma
- Congenital and immunodepleted plasmas available
- Extrinsic factor assay linearity from 10-150%

Kit Contents:

Component	REF	Volume	Stability
◈ Factor V Deficient Plasma (Congenital)	5191	10 × 1 mL	Once reconstituted, the reagent is stable for 8 hours when kept at +2 –+8°C
◈ Factor VII Deficient Plasma (Congenital)	5192	10 × 1 mL	
◈ Factor X Deficient Plasma (Congenital)	5195	10 × 1 mL	
◈ Factor II Deficient Plasma (Immunodepleted)	5790	10 × 1 mL	
◈ Factor V Deficient Plasma (Immunodepleted)	5791	10 × 1 mL	
◈ Factor VII Deficient Plasma (Immunodepleted)	5792	10 × 1 mL	
◈ Factor X Deficient Plasma (Immunodepleted)	5795	10 × 1 mL	

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Routine Assays

Factor Deficient Plasma

Chromogenic Assays

Specialist Assays

Calibrators and Quality Control Material

Platelet Function

Instruments

Antithrombin Xa

REF: 5502, 5507

Intended Use:

The Antithrombin Xa kit is a chromogenic assay intended for the quantitative determination of Antithrombin III (AT-III) activity in human citrated plasma. This two-stage method utilises Factor Xa, added to a patient plasma dilution containing AT-III in the presence of excess heparin and calcium. After an initial incubation period (stage 1), residual Factor Xa is determined with a Factor Xa-specific chromogenic substrate (stage 2). The residual Factor Xa activity is inversely proportional to the AT-III concentration.

Main Features:

- Factor Xa assay
- Insensitive to Heparin Cofactor II
- Linear calibration from 7.5 - 150%
- Excellent open vial stability

Kit Contents:

Component	REF	Volume	Stability
◆ Factor Xa Substrate	5502 5507	3 × 10 mL 5 × 2 mL	Once reconstituted: 2 months at +2 –+8°C
◆ Factor Xa	5502 5507	3 × 10 mL 5 × 2 mL	Once reconstituted: 2 months at +2 –+8°C
◊ Sample Diluent	5502 5507	4 × 10 mL 5 × 3 mL	Once opened: 2 months at +2 –+8°C

Protein C

REF: 5543

Intended Use:

The Protein C kit is intended for the quantitative determination of Protein C in citrated human plasma. Protein C in the patient plasma is activated by a specific fraction from the *Agkistrodon Contortrix* snake venom (Protac®). The amount of activated protein C (APC) is determined by monitoring the rate of hydrolysis of a Protein C specific chromogenic substrate. The release of pNA is measured and is proportional to the Protein C level in the patient's plasma.

Main Features:

- Activates endogenous Protein C
- Excellent open vial stability

Kit Contents:

Component	REF	Volume	Stability
◆ Protein C Substrate	5543	6 × 2 mL	Once reconstituted: 1 week at +2 –+8°C 1 month at -20°C
◆ Protein C Activator	5543	6 × 2 mL	Once reconstituted: 1 week at +2 –+8°C 1 month at -20°C
◊ Protein C Diluent	5543	3 × 5 mL	Store at +2 –+8°C

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Routine Assays

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Instruments

Auto Blue D-Dimer 400

REF: 5552

Intended Use:

The Auto Blue D-Dimer 400 is an immunoturbidimetric assay for the quantitative determination of D-Dimer fragments in citrated human plasma using semi-automated and fully automated instruments with wavelengths in the range of 350-600nm.

Main Features:

- Latex based assay
- Fully quantitative
- Liquid, ready to use components
- No prozone effect below 100,000 ng/mL
- 99% Negative predictive value using 200ng/mL cut off

Kit Contents:

Component	REF	Volume	Stability
◊ D-Dimer Blue Latex	5552	2 × 3 mL	Once opened, the reagent is stable for 4 weeks at +2 –+8°C or 2 weeks at +20°C
◊ D-Dimer Blue Buffer	5552	2 × 7 mL	Once opened, the reagent is stable for 4 weeks at +2 –+8°C or 2 weeks at +20°C
◊ D-Dimer Diluent	5552	1 × 7 mL	Store at +2 –+8°C and use within 4 weeks of opening
◆ D-Dimer Calibrator	5552	1 × 1 mL	Once reconstituted, the reagent is stable for 12 hours at +4 –+25°C

Auto Blue D-Dimer 400

REF: 5553IL

Intended Use:

REF: 5553IL Auto Blue D-Dimer 400 is an immunoturbidimetric assay for the quantitative determination of D-Dimer fragments in citrated human plasma on the ACL Elite Pro analyser.

Main Features:

- Latex based assay
- Fully quantitative
- Liquid, ready to use components
- 99% Negative Predictive Value using 200ng/mL cut off

Kit Contents:

Component	REF	Volume	Stability
◊ D-Dimer Blue Latex	5553IL	2 × 5 mL	Once opened, the reagent is stable for 4 weeks at +2 –+8°C or 2 weeks at +20°C
◊ D-Dimer Blue Buffer	5553IL	2 × 7 mL	Once opened, the reagent is stable for 4 weeks at +2 –+8°C or 2 weeks at +20°C
◊ D-Dimer Diluent	5553IL	3 × 7 mL	Store at +2 –+8°C and use within 4 weeks of opening
◆ D-Dimer Calibrator	5553IL	1 × 1 mL	Once reconstituted, the reagent is stable for 12 hours at +4 –+25°C
◆ D-Dimer Control Plasma (High)	5553IL	2 × 1 mL	Once reconstituted, the reagent is stable for 12 hours at +4 –+25°C
◆ D-Dimer Control Plasma (Low)	5553IL	2 × 1 mL	Once reconstituted, the reagent is stable for 12 hours at +4 –+25°C

Auto Red D-Dimer 700

REF: 5501

Intended Use:

The Auto Red D-Dimer 700 is an immunoturbidimetric assay for the quantitative determination of D-Dimer fragments in citrated human plasma using semi-automated and fully automated instruments with wavelengths in the range of 600-900nm.

Main Features:

- Latex based assay
- Fully quantitative
- Liquid, ready to use components
- No prozone effect below 130,000 ng/mL
- 98% Negative predictive value using 200ng/mL cut off

Kit Contents:

Component	REF	Volume	Stability
◊ D-Dimer Red Latex	5501	4 × 4 mL	Once opened, the reagent is stable for 4 weeks at +2 –+8°C or 2 weeks at +20°C
◊ D-Dimer Red Buffer	5501	4 × 7 mL	Once opened, the reagent is stable for 4 weeks at +2 –+8°C or 2 weeks at +20°C
◊ D-Dimer Diluent	5501	2 × 7 mL	Store at +2 –+8°C and use within 4 weeks of opening
◆ D-Dimer Calibrator	5501	2 × 1 mL	Once reconstituted, the reagent is stable for 12 hours at +4 –+25°C.

Manual D-Dimer

REF: 5250, 5250H

Intended Use:

The Manual D-Dimer is a semi-quantitative latex agglutination assay for the determination of fibrin D-Dimer in human citrated plasma to aid in the exclusion of DVT, PE and DIC. Serum samples suited for FDP analysis can also be used.

Main Features:

- Qualitative and semi-quantitative method
- Results in less than 4 minutes
- No automation required
- Positive and negative controls included in kit

Kit Contents:

Component	REF	Volume	Stability
◊ Manual D-Dimer Latex	5250 5250H	1 × 1.7 mL 1 × 0.85 mL	Store at +2 –+8°C and use within the indicated expiry date
◆ Positive Control Plasma	5250 5250H	1 × 1 mL 1 × 1 mL	Once reconstituted the reagent is stable for one week at +2 –+8°C or one month at -20°C
◆ Negative Control Plasma	5250 5250H	1 × 1 mL 1 × 1 mL	Once reconstituted the reagent is stable for one week at +2 –+8°C or one month at -20°C
◊ Saline Solution	5250 5250H	2 × 8 mL 1 × 8 mL	Store at +2 –+8°C and use within the indicated expiry date
Test Cards	5250 5250H	16 × 6 8 × 6	N/A
Mixing Sticks	5250 5250H	50 25	N/A

Free Protein S

REF: 5525

Intended Use:

The Free Protein S kit is a latex immunoassay based method for the quantitative determination of Free Protein S in human plasma. It is suitable for use on automated instruments with a 600-800nm wavelength.

Main Features:

- Latex based assay
- No prozone effect below 500%
- Liquid ready to use components

Kit Contents:

Component	REF	Volume	Stability
◊ Free Protein S Latex	5525	4 × 2.5 mL	8 weeks after opening at +2 –+8°C
◊ Free Protein S Buffer	5525	4 × 4 mL	8 weeks after opening at +2 –+8°C
◊ Free Protein S Diluent	5525	4 × 7 mL	8 weeks after opening at +2 –+8°C
◆ Free Protein S Calibrator	5525	3 × 1 mL	12 Hours at +2 –+8°C once reconstituted

Protein S (Clot)

REF: 5511

Intended Use:

Protein S is used for the determination of functional Protein S levels in citrated human plasma using a clotting method.

Main Features:

- Linear calibration from 10-150%
- Functional free Protein S assay
- Suitable for all clot based detection methods

Kit Contents:

Component	REF	Volume	Stability
◆ Protein S Activator	5511	2 × 1 mL	Once reconstituted: 1 week at +2 –+8°C or 8 hours at room temperature DO NOT FREEZE
◆ Protein S Deficient Plasma	5511	2 × 1 mL	Once reconstituted: 8 hours at +2 –+8°C or 4 hours at room temperature 1 month at -20°C
◆ Protein S Substrate	5511	2 × 1 mL	Reconstituted vials are stable for up to 8 hours at +2 –+8°C or 3.5 hours at room temperature DO NOT FREEZE
◊ Substrate Diluent	5511	1 × 2 mL	Opened vial should be stable until the given expiry date DO NOT FREEZE
◊ Calcium Chloride 0.025M	5511	1 × 5 mL	Opened vial should be stable until the given expiry date DO NOT FREEZE
◊ Saline Solution: 0.9%	5511	1 × 25 mL	Opened vial should be stable until the given expiry date DO NOT FREEZE

DRVVT Screen

REF: 5484

Intended Use:

The DRVVT Screen kit is intended for the qualitative determination of Lupus Anticoagulants "LAs" in citrated human plasma. Russell's Viper Venom directly activates Factor X to Factor Xa in the presence of phospholipids and calcium, leading to detectable clot formation in plasma. The DRVVT Screen kit is intended to be used in conjunction with the DRVVT Confirm kit.

Kit Contents:

Component	REF	Volume	Stability
◈ DRVVT Screen	5484	10 × 2 mL	Reconstituted vials are stable for 24 hours at +15 –+30°C 5 days at +2 –+8°C 2 weeks at -20°C The reagent should be frozen in plastic test tubes and thawed at +37°C before use

DRVVT Confirm

REF: 5485

Intended Use:

The DRVVT Confirm kit is designed to be used in conjunction with the DRVVT Screen test kit to discriminate between Lupus Anticoagulants, factor deficiencies (II, V or X) or other inhibitors. If the clot time of the patient samples with the DRVVT Screen procedure are greater than 3 standard deviations above the mean of the normal range and are not corrected by mixing studies, a lupus anticoagulant may be present. Under these circumstances, samples should be re-tested using the DRVVT Confirm Reagent. The increased concentration of phospholipid in this reagent is designed to neutralise lupus anticoagulants.

Kit Contents:

Component	REF	Volume	Stability
◈ DRVVT Confirm	5485	10 × 1 mL	Reconstituted vials are stable for 24 hours at +15 –+30°C 5 days at +2 –+8°C 2 weeks at -20°C The reagent should be frozen in plastic test tubes and thawed at +37°C before use

PCA Ratio

REF: 5546

Intended Use:

The PCA Ratio Kit is a clot based assay used in determination of resistance to activated Protein C caused by Factor V Leiden mutation. This APTT based assay creates a clotting time ratio of PCA.APTT/APTT which determines APC resistance.

Main Features:

- Activates endogenous Protein C (using Protac®)
- Excellent discrimination between APC resistant and normal samples
- Superior result discrimination compared to traditional APC methods
- Compatible with all instrumentation capable of carrying out APTT assays
- Negates Lupus and Heparin interference

Kit Contents:

Component	REF	Volume	Stability
◆ Factor V Depleted Plasma	5546	4 × 2 mL	Reconstituted Factor V Depleted Plasma should be discarded after use, or can be frozen at -20°C and thawed once
◆ APTT	5546	2 × 2 mL	Reconstituted APTT Reagent is stable for 2 weeks at +2 –+8°C
◆ PCA.APTT	5546	2 × 2 mL	Reconstituted PCA.APTT Reagent is stable for 2 weeks at +2 –+8°C
◆ APC Resistant Plasma	5546	1 × 0.5 mL	Reconstituted APC Resistant Plasma can be frozen and thawed
◊ Calcium Chloride 0.025M	5546	2 × 8mL	Store at +2 –+8°C, and is stable until the expiry date indicated on the label

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Routine Assays

Factor Deficient Plasma

Chromogenic Assays

Specialist Assays

Calibrators and Quality Control Material

Platelet Function

Instruments

Helena Third Party Controls

Quality Control (QC) testing is implemented in laboratories in order to ensure continuing, high analytical quality of a test system. It is of critical importance to detect any changes or inaccuracies of the test system which could lead to anomalous results. As such, the use of quality controls is essential to prevent patient misdiagnosis.

"Third party" controls are those which are manufactured without the intention of being used on a particular instrument/ with specific reagents, in order to give a completely unbiased performance assessment of a test system. Helena Biosciences' third party controls are manufactured independently of the calibrators and reagents used in the intended test system, allowing completely impartial assay verification. These controls are manufactured using human plasma as the base material, giving a product similar in composition to the patient samples to be tested. Controls are manufactured to give results at multiple levels, including within the normal reference interval, as well as close to medical decision limits.

Our third party controls have a long shelf life so that the same lot can be used over multiple changes in reagents and calibrators, allowing the laboratory to detect any shifts in results which may occur with changes to the test system.

Many instrument manufacturers provide both calibrators and control materials for their own systems, often manufactured under the same processes. Consequently, the control may mimic the calibrator, making it less sensitive to changes in device performance. This could lead to inaccurate reporting of patient test results, and potentially incorrect diagnoses. A laboratory using an instrument manufacturer or in-kit control may receive a control lot specific for each new reagent lot, which does not provide the laboratory with the same benefits of long-term QC monitoring afforded by third party control material.

Regulatory Requirements Emphasise the Need for Using Third Party Quality Controls

". . . quality control materials should be different from the calibrator materials to ensure that the QC procedure provides an independent assessment of the measurement procedure's performance in its entirety, including the procedure for calibration of the measurement."

CLSI C24-A3, Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline—Third Edition, 6.2.1 Relation to Calibrators

"Use of independent third party control materials should be considered either instead of, or in addition to, any control materials supplied by the reagent or instrument manufacturer."

Medical Laboratories — Requirements for quality and competence (ISO 15189:2012).

Setting Your Own Assay Ranges: Easier Than You Think

"Collect at least 20 measurements over at least 2 weeks or 10 working days, and preferably over at least 4 weeks or 20 working days. You do this by including control materials as part of your daily work for a long enough period to observe the variation expected in your laboratory.

Too short a period leads to too small an estimate of the standard deviation. Longer estimates will include pre and post maintenance performance, changes in reagent lot numbers, sample probes or pipettes, etc…"

James O. Westgard, P. (2015). QC - The Calculations - Westgard. [online] Westgard.com. Available at: https://www.westgard.com/lesson14.htm [Accessed 28 Aug. 2015].

Quality Control and Reference Plasma Compatibility Matrix

The following matrix illustrates Helena Bisociences' extensive control and reference plasma assay compatibility.

Test	Coagulation control plasmas			Speciality Assayed Controls					Reference Material		
	Routine Control N	Routine Control A	Routine Control SA	Speciality Assayed Control N	Speciality Assayed Control A	LA Positive Control S	D-Dimer Control H/L	Ristocetin Cofactor Abnormal Control	Calibration Plasma 5185	Fibrinogen Calibrator	Calibration Plasma 5504R
PT	■	■	■	■	■	■					■
APTT	■	■	■	■	■	■					
TT	■	■	■								
Fibrinogen	■	■	■	■	■				■	■	
Antithrombin III	■	■	■	■	■				■		
Factor II				■	■				■		
Factor V				■	■				■		
Factor VII				■	■				■		
Factor VIII				■	■				■		
Factor IX				■	■				■		
Factor X				■	■				■		
Factor XI				■	■				■		
Factor XII				■	■				■		
Chromogenic Protein C				■	■				■		
Free Protein S				■	■						
Protein S Clotting				■	■				■		
D-Dimer							■				
DRVVT Screen						■					
DRVVT Confirm						■					
Ristocetin Cofactor				■	■			■	■		

Calibration Plasma

REF: 5185

Intended Use:

Calibration Plasma is prepared from normal human plasma and may be used as a reference plasma for the following assays: Factors II, V, VII, VIII, IX, X, XI, XII, Fibrinogen, von Willebrand Factor, antigenic and functional Protein C, Protein S (total and free), as well as the chromogenic assays including Antithrombin Xa, Protein C and Plasminogen.

Main Features:

- Single calibrator for multiple assays
- Sourced from human plasma
- Factor II, VII, VIII, IX and X values and the chromogenic AT III and Protein C values are traceable to World Health Organisation standards

Kit Contents:

Component	REF	Volume	Stability
◆ Calibration Plasma	5185	10 × 1 mL	Unopened vials are stable until the given expiry date when stored under conditions indicated on the vial or kit label. Values for Factor VIII, von Willebrand factor and ristocetin co-factor are stable for 2 hours at +2 –+8°C. All other factors are stable for 4 hours at +2 –+8°C

Calibration Plasma

REF: 5185IL

Intended Use:

Calibration Plasma is prepared from normal human plasma and may be used as a reference plasma for the following assays: Factors II, V, VII, VIII, IX, X, XI, XII, Fibrinogen, von Willebrand Factor, antigenic and functional Protein C, Protein S (total and free), as well as the chromogenic assays including Antithrombin Xa, Protein C and Plasminogen.

Main Features:

- Single calibrator for multiple assays
- Sourced from human plasma
- Factor II, VII, VIII, IX and X values and the chromogenic AT III and Protein C values are traceable to World Health Organisation standards
- Suitable for use on IL TOPS

Kit Contents:

Component	REF	Volume	Stability
◆ Calibration Plasma	5185	10 × 1 mL	Unopened vials are stable until the given expiry date when stored under conditions indicated on the vial or kit label. Values for Factor VIII, von Willebrand factor and ristocetin co-factor are stable for 2 hours at +2 –+8°C. All other factors are stable for 4 hours at +2 –+8°C

Fibrinogen Calibrator

REF: 5379

Intended Use:

For use as a calibrator in the assay of fibrinogen in human plasma. May be used in conjunction with Helena Biosciences' Clauss Fibrinogen (Thrombin Only) (REF 5374, 5378) or Clauss Fibrinogen 100 (REF 5376, 5376H).

Kit Contents:

Component	REF	Volume	Stability
◆ Fibrinogen Calibrator	5379	10 × 1 mL	Once reconstituted, the plasma is stable for 4 hours at +2 –+8°C

Calibration Plasma

REF: 5504R

Intended Use:

The Calibration Plasma set is designed to simplify the laboratory calculation of Thromboplastin ISI values when using automated and semi-automated instruments for the determination of Prothrombin Time. It used for: generating a %PT Calibration Curve; generating an INR Reference Curve for the direct INR determination of a patient sample; generating specific ISI and MNPT values for the system, reagent and instrument combination used by the laboratory.

Main Features:

- Traceable to WHO standard reference Thromboplastin.
- Direct INR determination
- Increased calculation efficiency of INR, ISI and MNPT values

Kit Contents:

Component	REF	Volume	Stability
◆ PT Calibrant 1	5504R	1 × 1 mL	Reconstituted plasma must be used within 1 hour
◆ PT Calibrant 2	5504R	1 × 1 mL	Reconstituted plasma must be used within 1 hour
◆ PT Calibrant 3	5504R	1 × 1 mL	Reconstituted plasma must be used within 1 hour
◆ PT Calibrant 4	5504R	1 × 1 mL	Reconstituted plasma must be used within 1 hour

Routine Control N, A and SA

REF: 5186, 5187, 5183

Intended Use:

Routine Control N, Routine Control A and Routine Control SA are for use as normal, moderately prolonged and markedly prolonged controls for PT and aPTT assays. They are also assayed for Class Fibrinogen, Thrombin Time and Antithrombin Xa and are prepared from normal human plasma.

Main Features:

- Instrument specific ranges for market leading instruments such as: Helena Biosciences' AC-4, Helena Biosciences' C-Series, Helena Biosciences' CoaDATA family, Helena Biosciences' Thrombostat, Sysmex Series, ACL Series, Coalab, and KC-10
- Sourced from human plasma
- Suitable for use on all manual, semi-automated and fully automated methods

Kit Contents:

Component	REF	Volume	Stability
◆ Routine Control – N	5186	10 × 1 mL	Once reconstituted: 8 hours at +2 –+8°C or 4 weeks at -20°C when flash frozen
◆ Routine Control – A	5187	10 × 1 mL	Once reconstituted: 8 hours at +2 –+8°C or 4 weeks at -20°C when flash frozen
◆ Routine Control – SA	5183	10 × 1 mL	Once reconstituted: 8 hours at +2 –+8°C or 4 weeks at -20°C when flash frozen

Speciality Assayed Control N, A

REF: 5301, 5302

Intended Use:

Speciality Assayed Control N (SAC - N) and Speciality Assayed Control A (SAC-A) may be used as a normal control and abnormal control when assaying for Factors II, V, VII, VIII, IX, X, XI, XII, Fibrinogen, von Willebrand Factor, antigenic and functional Protein C and Protein S (total and free), as well as the chromogenic assays including Antithrombin Xa, Protein C and Plasminogen.

Main Features:

- Factor II, VII, VIII, IX and X values, Antithrombin III and Protein C values are traceable to World Health Organisation standards
- Control ranges for routine and specialist assays
- Sourced from human plasma
- Suitable for use on all manual, semi-automated and fully-automated methods

Kit Contents:

Component	REF	Volume	Stability
◆ SAC – N	5301	10 × 1 mL	Values for Factor VIII, von Willebrand factor and ristocetin co-factor are stable for 2 hours at +2 –+8°C. All other factors are stable for 4 hours at +2 –+8°C or 4 weeks at -20°C when flash frozen
◆ SAC – A	5302	10 × 1 mL	Values for Factor VIII, von Willebrand factor and ristocetin co-factor are stable for 2 hours at +2 –+8°C. All other factors are stable for 4 hours at +2 –+8°C or 4 weeks at -20°C when flash frozen

Speciality Assayed Control N, A

REF: 5301IL, 5302IL

Intended Use:

Speciality Assayed Control N (SAC - N) and Speciality Assayed Control A (SAC-A) may be used as a normal control and abnormal control assaying for PT, aPTT, TT, Fibrinogen as well as the chromogenic assays including Antithrombin Xa and Protein C.

Main Features:

- Values are traceable to World Health Organisation standards
- Control ranges for routine and specialist assays
- Sourced from human plasma
- Suitable for use on IL fully-automated methods

Kit Contents:

Component	REF	Volume	Stability
◆ SAC – N	5301IL	10 × 1 mL	Values for Factor VIII, von Willebrand factor and ristocetin co-factor are stable for 2 hours at +2 –+8°C. All other factors are stable for 4 hours at +2 –+8°C or 4 weeks at -20°C when flash frozen
◆ SAC – A	5302IL	10 × 1 mL	Values for Factor VIII, von Willebrand factor and ristocetin co-factor are stable for 2 hours at +2 –+8°C. All other factors are stable for 4 hours at +2 –+8°C or 4 weeks at -20°C when flash frozen

LA Positive Control S

REF: 5486

Intended Use:

LA Positive Control S is prepared from human donor plasma positive for Lupus anticoagulants. The control gives results typical of a Lupus Anticoagulant patient in DRVVT Screen, DRVVT Confirm and APTT-based tests.

Main Features:

- Sourced from human plasma
- Ranges for PT, APTT, Normalised DRVVT Screen ratio, Normalised DRVVT Confirm ratio and Lupus ratio

Kit Contents:

Component	REF	Volume	Stability
◆ LA Positive Control S	5486	1 × 1 mL	Reconstituted vials of plasma should be kept on ice and are stable for 4 hours at +2 –+8°C

D-Dimer Control H/L

REF: 5509

Intended Use:

The D-Dimer Control H/L kit contains plasmas with low and high levels of D-Dimer. The plasmas are intended to be used in conjunction with the Helena Biosciences' latex immunoassays for D-Dimer.

Main Features:

- Suitable for use with Auto Red D-Dimer 700 and Auto Blue D-Dimer 400
- Assay ranges defined for multiple market leading coagulometers such as: Helena Biosciences' AC-4, Helena Biosciences' C-Series, Sysmex CA and CS Series, IL TOPS and Behnk

Kit Contents:

Component	REF	Volume	Stability
◈ D-Dimer Control - L	5509	5 × 1 mL	Reconstituted vials are stable for 5 days at +2 –+8°C, or 3 months at -20°C Do not freeze /thaw more than once
◈ D-Dimer Control - H	5509	5 × 1 mL	Reconstituted vials are stable for 5 days at +2 –+8°C or 3 months at -20°C Do not freeze/thaw more than once

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Routine Assays

Factor Deficient Plasma

Chromogenic Assays

Specialist Assays

Calibrators and Quality Control Material

Platelet Function

Instruments

Platelet Agonists

REF: 5364, 5366, 5367, 5368, 5199

Intended Use:

For use in platelet aggregation studies to confirm specific platelet disorders.

Main Features:

- Full agonist panel available
- Suitable for use with any Platelet Aggregometer
- High stock concentrations allow for high and low dose dilutions recommended by CLSI guidelines

Kit Contents:

Component	REF	Volume	Stability
◆ Arachidonic Acid: 5 mg/mL	5364	2 × 1 mL	The reconstituted reagent is stable for 24 hours when stored at +2 –+8°C or 8 weeks at -20°C when flash frozen
◆ Adenosine Diphosphate: 200 µM	5366	2 × 1 mL	Reconstituted reagent is stable for 1 week when stored at +2 –+8°C or 8 weeks at -20°C when flash frozen
◆ Epinephrine: 3 mM	5367	2 × 1 mL	Reconstituted reagent is stable for 1 week when stored at +2 –+8°C or 8 weeks at -20°C when flash frozen
💧 Collagen: 100 µg/mL	5368	2 × 1 mL	Reconstituted reagent is stable for 4 week when stored at +2 –+8°C or 8 weeks at -20°C when flash frozen
◆ Ristocetin: 15mg/mL	5199	10 × 0.5 mL	Once reconstituted, the reagent is stable for 8 hours at +2 –+8°C or or 8 weeks at -20°C when flash frozen

Ristocetin Cofactor Kit

REF: 5370

Intended Use:

The Ristocetin Cofactor Kit is intended for use in the quantitative determination of von Willebrand Factor activity in citrated human plasma. It is used to measure the ability of the patients' plasma to agglutinate formalin fixed platelets in the presence of Ristocetin.

Main Features:

- Gold standard method for vWD testing
- High activity platelets
- Complete kit format
- Suitable for use with all light transmission aggregometers

Kit Contents:

Component	REF	Volume	Stability
◆ Lyophilised Platelets	5370	4 × 5 mL	Once reconstituted, the reagent is stable for 1 day (24 hours) at +2 –+8°C
◆ Ristocetin: 10 mg/mL	5370	2 × 1.5 mL	Once reconstituted, the reagent is stable for 8 hours at +2 –+8°C or 30 days at -20°C
◆ Calibration Plasma	5370	2 × 1 mL	Once reconstituted, the reagent is stable for 2 hours at +2 –+8°C
◆ Ristocetin Cofactor Abnormal Control	5370	2 × 0.5 mL	Once reconstituted, the reagent is stable for 8 hours at +2 –+8°C or 30 days at -20°C
💧 Tris-Buffered Saline	5370	1 × 35 mL	Opened bottle must be stored at +2 –+8°C

Ristocetin

REF: 5372

Intended Use:

Ristocetin is used in conjunction with Lyophilised Platelets for use in the quantitative determination of von Willebrand Factor activity in plasma.

Kit Contents:

Component	REF	Volume	Stability
◈ Ristocetin: 10 mg/mL	5372	5 × 1.5 mL	Once reconstituted: 8 hours at +2 – +8°C 30 days at -20°C

Lyophilised Platelets

REF: 5371

Intended Use:

Lyophilised Platelets are intended for use in the quantitative determination of von Willebrand Factor activity in plasma. They are used to measure the ability of a patient's plasma to agglutinate formalin-fixed platelets in the presence of Ristocetin.

Main Features:

- Gold Standard method for vWD testing
- High activity platelets
- Suitable for use with all light transmission aggregometers
- Multi kit formats

Kit Contents:

Component	REF	Volume	Stability
◈ Lyophilised Platelets	5371	5 × 5 mL	Once reconstituted, the reagent is stable for 1 day (24 hours) at +2 – +8°C

Ristocetin Cofactor Abnormal Control

REF: 5373

Intended Use:

For use as an abnormal control in the Ristocetin Cofactor Assay of human plasma.

Kit Contents:

Component	REF	Volume	Stability
Ristocetin Cofactor Abnormal Control	5373	5 × 0.5 mL	Once reconstituted: 8 hours at +2 –+8°C 1 month at -20°C

Tris-Buffered Saline

REF: 5365

Intended Use:

For use in the dilution of standards, patient samples and controls used in conjunction with the Ristocetin Cofactor Kit.

Kit Contents:

Component	REF	Volume	Stability
Tris-Buffered Saline	5365	1 × 125 mL	Opened bottle must be stored at +2 –+8°C

Platelet Scale Set

REF: 1479

Intended Use:

The Platelet Scale Set is intended to be used to calibrate the Helena Biosciences AggRAM at 650nm.

Kit Contents:

Component	REF	Volume	Stability
Scale set 1	1479	1 × 7 mL	Stored at +2 –+8°C and are stable until the expiration date indicated on the package DO NOT FREEZE
Scale set 2	1479	1 × 3 mL	Stored at +2 –+8°C and are stable until the expiration date indicated on the package DO NOT FREEZE

AggRAM

Light Transmission Aggregometer

Platelet aggregation testing for the modern laboratory

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Biosciences Europe

Routine Assays

Factor Deficient Plasma

Chromogenic Assays

Specialist Assays

Calibrators and Quality Control Material

Platelet Function

Instruments

C-Series

A new generation of high-performance, versatile and affordable multi-channel coagulometers, offering powerful optical detection in conjunction with Helena's superior reagent range.

C-Series REF C-1X, C-2X, C-4X

CE

Semi-automated Coagulometers

Main features:

- **Flexible platform with 1, 2 or 4 optical channels**
  High-performance analysis with no requirement for mechanical stirring
- **Sensitive detection with small sample volumes**
  High-resolution optical measurement, even with only 75µL sample and reagent volume
- **User-friendly operation**
  Touchscreen workflow allows simple programming and automatic start
- **Automatic optical adjustment**
  Ensures reliable results across all channels when sample quality varies
- **Powerful connectivity**
  Patient and sample ID tracking with optional external bar code scanner
- **High quality construction**
  Tried-and-tested analytical platform, designed and manufactured in EU

Patient management and result software

Dedicated TECAM Smart software package allows for extensive result database accessibility.

- Designed for the analysis, control, management and storage of test results generated by the C-1, C-2 and C-4
- Intuitive and user-friendly software platform with personalised settings
- Single-screen navigation displaying reaction curve and patient info
- Quantitative and graphical data for patient diagnosis and QC monitoring
- Uni-directional interface for Laboratory Information and Management Systems (LIMS)

Specifications:

	Helena C-1	Helena C-2	Helena C-4
REF	C-1X	C-2X	C-4X
Optical measurement channels	1	2	4
Optical wavelength	405 nm (UV)		
Automatic light level adjustment	✔		
Reagent/optic warming	✔		
Cuvette pre-warm	10×	20×	20×
Reagent pre-warm, 24mm	1×	1×	1×
Reagent pre-warm, 22mm	2×	2×	2×
Microtubes pre-warm	2×	2×	2×
Reagent stirrer	No	1×	1×
Cuvettes	Single-format 75 µL cuvettes, activated online		
Auto-start	Yes, on reagent addition		
Patient ID	No	✔	✔
Double determination	No	200 results	200 results
Whole-blood testing	No		
Dual reagent lots	No	✔	✔
Global clotting assays	PT, aPTT, Fibrinogen, TT		
Special clotting assays	Intrinsic and Extrinisic Factors		
Chromogenic assays	AT, Protein C		
Latex-enhanced assays	Auto D-Dimer (Blue)		
Multi-language display	4.3” (480×272 pixels) capacitive touchscreen		
Printer	Optional external printer (RS232)		
Barcode scanner	Optional external 1D barcode scanner (RS232)		
LIMS connectivity	Yes, via TECAM software		
Dimensions	225 mm × 150 mm × 90 mm (L × W × H)		
Power supply	Input 110–240V at 50–60 Hz; output 5V, 3.3A		

AC-4

Fully Automated Coagulometer

Detection principle:

- Photo-optical
- 4 x laser optics utilising 405 nm wavelength
- Suitable for icteric and lipaemic samples

Measurement:

- Clotting
- Chromogenic
- Immunoturbidimetric

Sample processing:

- Plasma sample
- Cap piercing
- 24 position sample rack
- Up to 110 PT/Hour
- Up to 45 APTT/Hour
- Stat sample position
- Suitable for spun primary sample tubes
- Integrated barcode for primary patient IDs

AC-4 REF AC4100

CE

Fully-automated Coagulometer

The Helena AC-4 is a fast, flexible, accurate photo-optical, fully automated coagulometer suitable for clotting, chromogenic and immunoturbidimetric assays using plasma.

Main features:

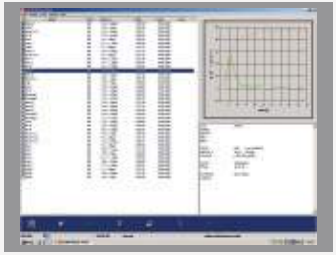
- Simple, comprehensive, walk away operation
- 4 independent measurement channels (405 nm)
- 110 tests/hour (PT), 45 tests/hour (PTT)
- STAT position for quick and easy emergency sample analysis
- Cap piercing ensures operator safety with direct access to sealed primary tubes (includes needle guard)
- Complete positive patient ID
- Integrated bar code reader for fast, accurate sample loading
- Automatic plasma dilutions
- Automatic calibration curves and quality control
- Single or duplicate sample analysis
- Micro volume procedures
- Flexible reagent positions:
  - 4 positions at 37°C
  - 2 positions at room temperature
  - 6 positions at 15...18°C
  - 3 pre-warming positions 1 position for cleaner
  - 2 positions for buffer
  - 1 stirred position at 37.2°C
- Reagent dead volumes less than 300 µL
- Low consumption of consumables: Rinse (<1 mL/test) Clean (<15 mL/day)
- Fully programmable, allowing optimisation of existing tests and design of new test protocols
- Dedicated TECAM software
- Integrated thermal printer

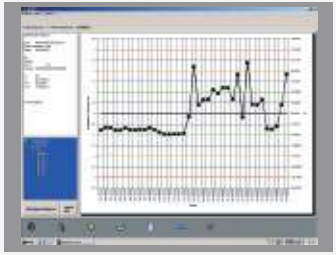
Dedicated patient management and result software: TECAM

Dedicated Tecam software allows patient identification, management and extensive result database accessibility.

- Bi-directional communication by partnering of the AC-4 to the patient management software TECAM PRO brings additional sophistication to the system for data handling and reporting, results transfer, storage, and patient monitoring over time
- Quality Control and auto-flagging of erroneous results is achieved through monitoring of control values against fixed ranges and analysis according to Levey-Jennings graphics.

  In addition Westgard Rules may be applied to the results for the determination of trends and removal of subjectivity
- Bi-directional communication to Hospital LIMS/LIS systems is achieved by TECAM PROLIS software via fast and reliable international standard ASTM protocols





AggRAM

Light Transmission Aggregometer

Detection principle:

- Light transmission
- 4 channel laser optics utilising 650 nm wavelength

Measurement:

- Aggregation
- Agglutination

Sample processing:

- Plasma sample
- Micro-volume testing — minimum cuvette volume of 150 µL
- 4 or 8 patient samples per run
- 12 sample incubation positions
- 4 ambient reagent positions

AggRAM REF 1487

CE

Light transmission Aggregometer

The Helena AggRAM offers fully customisable platelet aggregation and Ristocetin cofactor testing using light transmission aggregometry on plasma.

Main features:

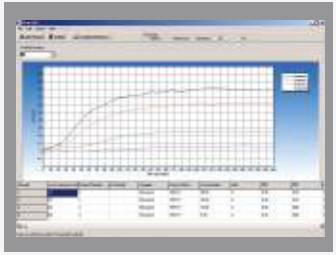
- **Flexibility**: customise your assay test sequence, calibration, dilutions, volumes, run times, display parameters, input additional agonists and create new screens
- **Half-volume**: fully optimised half volume settings, including programmable stirrer speed
- **Powerful data handling**: automatic calculation of slope, max% aggregation, time to max aggregation, lag phase, secondary slope and area under the curve (research use only) with full manual edit options
- **Security**: operator log on with password level protection
- **Database**: extensive database for patient results, quality control and standards. Data retrieval with the safety of full automatic backup
- **Interface**: LIMS uni-directional host interface
- **Quality control**: Levey-Jennings display of QC data based on assigned Westgard rules with integrated corrective action log
- Available PC/Printer option

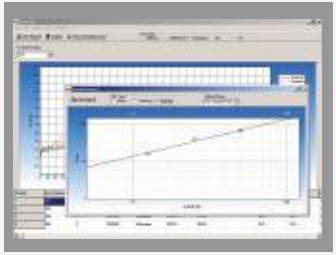
Starter Set:

Starter Set contents: REF 1487	Qty
AggRAM Module	1
A and B Module Labels	1
Optic cover	1
Sample holder	1
Module interface cable	1
Pack of cuvettes	1
Pack of stir bars	1
HemoRAM Disc	1
CD (Operators Manual)	1
Installation verification report	1
Power cable	1

Patient management and result software: HemoRAM

- Overlay and compare up to 20 previous results with the current test — determine ranges for normal results using normal/abnormal data
- Export result data to CSV, TXT, QRK, HTM, XLS, RTF, PDF formats, allowing free interchange of results with colleagues
- Flexible working — enter patient demographics either before or after results, allowing you to include diagnoses in reports
- Customised reports — include data from one channel or four, one patient or the whole run, retrieve archived data to profile individual patients





Helena C-Series

2020 models (new design) only

Consumables

A standardised range compatible with Helena C-1, C-2 and C-4.

REF	Description	Qty
C-101V	Single cuvettes	500
AC4300	Reagent container Ø 22.5 mm	100
AC4302	Stirring magnets (Helena C-2 and C-4)	4
C-104	Reagent container Ø 11 mm	100
C-011	Reagent adapter Ø 22.5–24.2 mm	1
C-012	Micro tubes, safe-lock, with cap Ø 11 mm	100
C-013	Display protection foil set	1
C-014	Barcode scanner for new C-Series	1
C-01	Thermal printer	1
C-015	Printer cable for printer	1
C-016	Thermal paper for printer	5
C-02	TECAM Smart Software	1

Helena C-Series

2008–2019 models (old design) only

Consumables

Ensure the correct instrument-specific catalogue numbers are selected.

Description	C-1	C-2	C-4	Qty
Single cuvettes	C-101	-	-	250
Reagent container Ø 11 mm	C-104	-	-	100
Double cuvettes	-	C-241	C-241	250
Reagent containers Ø 22.5 mm	-	AC4300	AC4300	100
TECAM SMART software	C-02	C-02	C-02	1
Thermal printer	C-01	C-01	C-01	1
Thermal paper	C-04	C-04	C-04	5
Stirring magnets	-	AC4302	AC4302	4
4 stage auto-pipette (20/50/100/200µl)	-	C-010	C-010	1
Reagent adapter Ø 11.0 mm	C-05	-	-	1
Reagent adapter Ø 22.5 mm	-	AC4601	AC4601	1
Reagent adapter Ø 22.8 mm	-	AC4602	AC4602	1
Reagent adapter Ø 24.2 mm	-	AC4603	AC4603	1
Reagent adapter Ø 18.0 mm	-	C-06	C-06	1
Reagent adapter Ø 27.8 mm	-	C-07	C-07	1
Reagent adapter Ø 25.2 mm	-	C-08	C-08	1
Barcode scanner	-	C-09	C-09	1

AC-4

Consumables

REF	Description	Qty
AC4200	Cuvette block (4 wells/each) 100 Pieces.	400
AC4205	Cuvette block (4 wells/each) 200 Pieces.	800
AC4210	Cuvette block (4 wells/each) 1000 Pieces.	4000
AC4401	Rinse solution 3 × 1.25 L	3 × 1.25 L
AC4402	Cleaning solution 1 × 500 mL	1 × 500 mL
AC4404	Thermal paper 80mm	5
AC4405	AC-4 INSTRUMENT TROLLEY	1
AC4501	WASTE BOX LARGE	1
AC4502	WASTE CONTAINER 5L	1
AC4503	WASTE BOX,CAP WITH TUBE CONNECTORS	1
AC4400	Cap-piercing pipette probe with tubing	1
AC4302	Stirring magnets	4

AggRAM

Consumables

REF	Description	Qty
1473	AGGRAM Cuvettes (×200)	200
1479	Platelet scale set	1
1489	AGGRAM Stir Bars (×30)	30

CoaDATA 501

Obsoleted instruments

Consumables

CoaDATA 501

REF	Description	Qty
211-07-010-00	Helena CuvCARD cuvettes with mixer, Dispo-System	500
211-01-090-00	Cuvette with Mixer Dispo System (Original)	500
211-070-030-00	Cuvettes Micro Cuvcard 5 × 500 Dispo	500
C-01	Thermal Printer	1
C-016	Thermal Printer Paper	1
30.00.2767	Reducer ring	1
30.000.1032	Teflon Mixer in Plastic Vial (13mm)	1

CoaDATA 2001, 4001

Obsoleted instruments

Consumables

CoaDATA 2001, 4001

REF	Description	Qty
211-07-010-00	Helena CuvCARD cuvettes with mixer, Dispo-System	500
211-01-090-00	Cuvette with Mixer Dispo System (Original)	500
211-070-030-00	Cuvettes Micro Cuvcard 5 × 500 Dispo	500
30.600.0982	Thermo Printer Paper (10 rolls)	1
30.00.2767	Reducer ring	1
30.000.1032	Teflon Mixer in Plastic Vial (13mm)	1

Application Guides

Helena Biosciences' reagent portfolio has been specifically designed and modified for high performance compatibility on a range of market leading instruments. Test dependent application notes and in use stability information are available for the following instrumentation platforms on request:

Helena Biosciences :
- AC-4
- C-Series
- AggRAM

Sysmex:
- CA500 Series
- CA1500
- CA6000
- CA7000
- CS2100
- CS5100

IL:
- Classic series
- ACL Futura
- ACL Top
- Elite Pro

STAGO:
- STA Compact
- STA-R Evolution

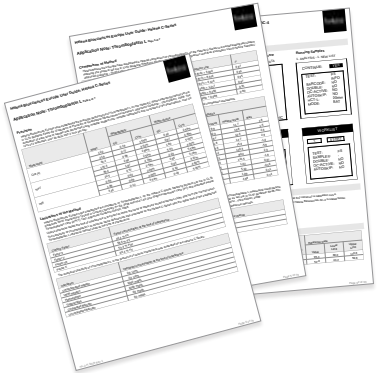
Dade Behring:
- BCT
- BCS

Hitachi:
- 910
- 911

CoaLAB:
- 2000

Behnk:
- Thrombostat
- Compact X / XRM

Amelung:
- KC-1
- KC-4
- KC-10



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- Integrated systems
- Customised solutions
- Global OEM provider
- Made in Great Britain

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