

HEMOSTASIS REAGENTS



HEMOSTASIS REAGENTS AND CONTROLS



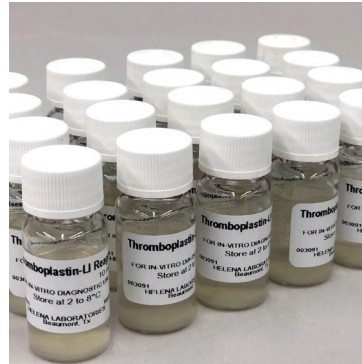
Helena offers a complete line of reagents for routine clotting assay – PTs, aPTTs, thrombins, fibrinogens and factor assays – ideal for automated, semi-automated, and manual instrumentation.

Prothrombin Time Assays

Thromboplastin-LI Reagent Kit

- 5248 Thromboplastin-LI Kit, 250 tests (10 x 5 mL)
- 5249 Thromboplastin-LI Kit, 500 tests (10 x 10 mL)

Thromboplastin-LI is a stable liquid, ready for use. With a low ISI assignment less than 1.50, this reagent offers reliable sensitivity to liver disease, depression of Vitamin K dependent factors, and coumarin-induced coagulation, even in the presence of high-dose heparin therapy.



Activated Partial Thromboplastin Time

aPTT-SA Reagent with Soluble Ellagic Acid Activator

- 5388 aPTT-SA Reagent Kit / 250 tests Ellagic Acid Activated Reagent (5 x 5 mL) / 0.025 M Calcium Chloride (5 x 5 mL)
- 5389 aPTT-SA Reagent Kit / 500 tests Ellagic Acid Activated Reagent (5 x 10 mL) / 0.025 M Calcium Chloride (5 x 10 mL)
- 5387 aPTT-SA Reagent, 1000 tests (10 x 10 mL)
- 5386 0.025 M Calcium Chloride, 1000 tests (10 x 10 mL)

aPTT-SA Reagent uses a soluble ellagic acid activator to provide a more optically clear reagent, an important consideration for automated analyzers with sensitive photo-optical detectors. Ellagic acid reagents also offer excellent precision and sensitivity. aPTT-SA reagent is a stabilized liquid available in three convenient kit sizes.

Fibrinogen Assays

Fibrinogen Kit

- 5376 Fibrinogen Assay Kit, 100 tests / Thrombin Reagent (5 x 2 mL) / Fibrinogen Calibrator (2 x 1 mL) / Owren's Veronal Buffer (2 x 25 mL) / Fibrinogen Assay Graph Paper (1 sheet)
- 5374 Thrombin Reagent, 200 tests (10 x 2 mL) / 0.025 M Calcium Chloride (5 x 10 mL)
- 5379 Fibrinogen Calibrator (10 x 1 mL)

The Fibrinogen Assay kit is for quantitation of fibrinogen in plasma. The kit uses a relatively high working concentration of thrombin (100 NIH units/mL) and low fibrinogen concentration to minimize effects of heparin and FDPs. Reagents and calibrator are also available as individual items.

Thrombin Time Assays

Helena Thrombin Clotting Time (TCT) Regent

- 5377 Thrombin Time Reagent, 250 tests (10 x 5 mL)
- Helena's TCT assay uses a low concentration of thrombin (3 NIH units/mL) with undiluted plasma. It is sensitive to fibrinogen levels below 70 mg/dL.

Owren's Veronal Buffer

- 5375 Owren's Veronal Buffer (10 x 25 mL)
- Owren's Veronal Buffer is used as a diluent in preparing patient sample dilutions for Factor and Fibrinogen Assays.

CASCADE M4

Optical Hemostasis Analyzer

Cascade M4 is an optical hemostasis analyzer that is ideal for all routine clotting assays - PTs, aPTTs, thrombins, fibrinogens and factor assays. Designed for easy, inexpensive, low-volume testing, the analyzer is small in size but big on features, offering time and labor saving benefits. Operation is simple and economical.

Compact, Lightweight

With a benchtop footprint smaller than 14" wide by 14" deep and a weight of approximately 21 pounds, Cascade M4 is sized to fit any lab. Compact size, dependability and versatility make Cascade M4 an excellent choice as a primary analyzer for smaller laboratories or as a backup unit for larger coagulation analyzers.

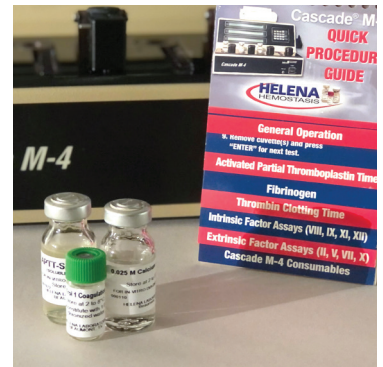
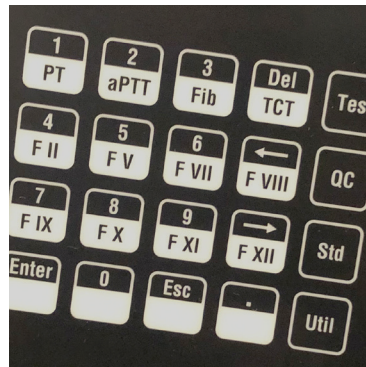
Easy-to-Use Keypad, On-Screen Prompts

All tests are clearly enumerated on the keypad for fast, easy test selection - there's no guess work caused by "hidden" function keys. Computer prompts appear on the screen to conveniently step the user through testing. Default settings are preprogrammed but can easily be changed, if desired.

Computerized Features, On-Board QC

Cascade M4 stores standard curves and calculates patient results, INRs and aPTT ratios. The Cascade M4 makes quality control tasks easy by calculating the mean, SD and CV. Plus it can plot and print Levey-Jennings QC charts. Four independent photo-optic detection sources read all samples, regardless of turbidity.

- 1711 Cascade M4, 4-channel analyzer, 110V / 220V
- 1718 Cascade M4 Cuvettes (5 pkgs of 100)
- 1720 Cascade M4 Printer Paper (5 rolls)
- 1475 Disposable Pipette Tips, 50-200 μ L (1000 pkg)
- 9167 Service Manual for Cascade M4



The Cascade M4 optical hemostasis analyzer is compact and economical, offering a wide range of assay options for all your hemostasis needs.

HEMOSTASIS CONTROLS AND REFERENCE PLASMAS

Hemostasis Controls

Controls for PT, aPTT

- 5186 Norm-Trol 1 (10 x 1 mL)
- 5187 Ab-Trol 2 Borderline Control (10 x 1 mL)
- 5183 Ab-Trol 3 High Control (10 x 1 mL)

Norm-Trol 1, Ab-Trol 2 and Ab-Trol 3 are prepared from human plasma. Norm-Trol 1 represents a normal patient result range while Ab-Trol 1 and Ab-Trol 2 are in the abnormal spectrum.

Hemostasis Controls

S.A.C.-1 and S.A.C.-2 Assayed Controls

- 5301 S.A.C.-1 (10 x 1 mL)
- 5302 S.A.C.-2 (10 x 1 mL)

S.A.C.-1 is a normal control plasma assayed for a broad spectrum of hemostasis tests including PT, aPTT, fibrinogen, Proteins C and S, Ristocetin Cofactor, vWF:Ag, plus Factors II, V, VII, VIII, IX, X, XI and XII. S.A.C.-2 is an abnormal control (values < 60% of normal) assayed for the same parameters as S.A.C.-1.

Reference Plasma

S.A.R.P. Specialty Assayed Reference Plasma

- 5185 S.A.R.P. (10 x 1 mL)

Coagulation S.A.R.P. was the first reference plasma fully assayed for virtually all coagulation studies. S.A.R.P. is prepared from a frozen pool of citrated plasma from healthy donors. S.A.R.P. is assayed for these parameters: PT, aPTT, Fibrinogen, Factors II, V, VII, VIII, IX, X, XI, XII, Protein C, Protein S (free & total), Ristocetin Cofactor, and vWF:Ag.

Factor Deficient Substrates

Congenital Factor Deficient Substrate Plasmas

- 5190 Factor II Deficient Substrate (10 x 1 mL)
- 5191 Factor V Deficient Substrate (10 x 1 mL)
- 5192 Factor VII Deficient Substrate (10 x 1 mL)
- 5193 Factor VIII Deficient Substrate (10 x 1 mL)
- 5194 Factor IX Deficient Substrate (10 x 1 mL)
- 5195 Factor X Deficient Substrate (10 x 1 mL)
- 5196 Factor XI Deficient Substrate (10 x 1 mL)
- 5197 Factor XII Deficient Substrate (10 x 1 mL)

Quality laboratory testing is essential for diagnosis and treatment. Helena offers quality factor deficient substrates with < 1% residual factor activity. All substrates (except Factor II) are prepared from human congenitally deficient donors.



Our controls and reference plasmas offer a sensible means to monitor accuracy and precision in hemostasis testing.



■ ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA)

ELISA kits offer sensitive and specific assays with faster turnaround times, greater ease of use, and clear-cut standardized results using established reference preparations. Antigen assays employ 6-point reference curves with accurate detection as low as 5% of normal.

■ von Willebrand Factor Antigen (vWF:Ag)

5290 vWF:Ag ELISA Kit, 96 tests

Kit includes: 12 x 8-well vWF:Ag Microwell Plate, 60 mL Sample Diluent, 3 x 0.5 mL ELISA Reference Plasma, 12 mL vWF:Ag Conjugate Solution, 13 mL Substrate, 15 mL Stopping Solution, 30 mL Phosphate Buffered Saline Concentrate

Using an ELISA antibody capture sandwich technique to quantitate vWF:Ag in human plasma, this assay is standardized against established reference preparations. Assay time is about an hour and final results are read at 450 nm. vWF:Ag is important in evaluating the pro-coagulant system, and von Willebrand Disease in particular.

■ Protein C Antigen

5291 Protein C ELISA Kit, 96 tests

Kit includes: 12 x 8-well Protein C Microwell Plate, 60 mL Sample Diluent, 3 x 0.5 mL ELISA Reference Plasma, 12 mL Protein C Conjugate Solution, 13 mL Substrate Solution, 15 mL Stopping Solution, 30 mL Phosphate Buffered Saline

The Protein C ELISA assay uses an antibody sandwich capture technique to quantitate Protein C in human plasma. This assay is complete in about 90 minutes and read at 450 nm. Its fast turnaround time and ease of use are clear advantages. Quantitative deficiencies of Protein C are associated with an increased tendency for thrombosis.

■ Free and Total Protein S Antigen

5292 Protein S (Free & Total) ELISA Kit, 96 tests

Kit includes: 12 x 8-well Protein S Microwell Plate, 60 mL Sample Diluent, 2 mL Free Protein S Reagent (PEG), 3 x 0.5 mL ELISA Reference Plasma, 12 mL Protein S Conjugate Solution, 13 mL Substrate Solution, 15 mL Stopping Solution, 30 mL Phosphate Buffered Saline

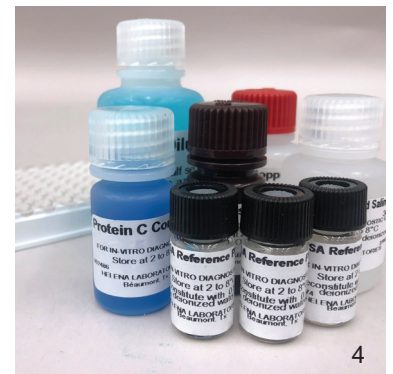
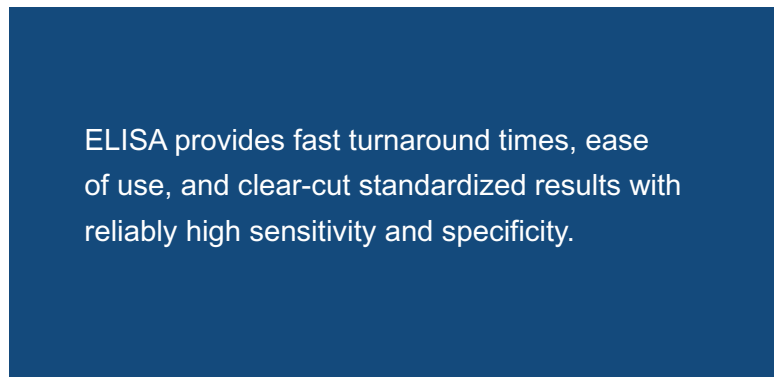
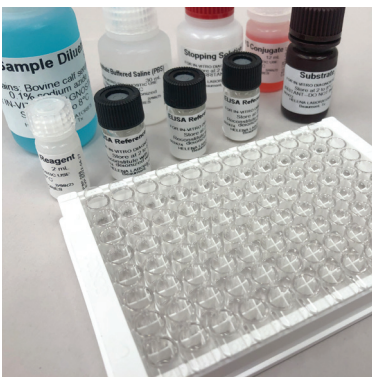
This 90-minute ELISA assay for quantitation of free and total Protein S in human plasma is easy to perform. To determine free Protein S, the physiologically active form, the sample is pretreated with PEG to precipitate the C4b-binding protein complex. The assay is read at 450 nm. Deficiencies of Protein S are associated with increased thrombosis.

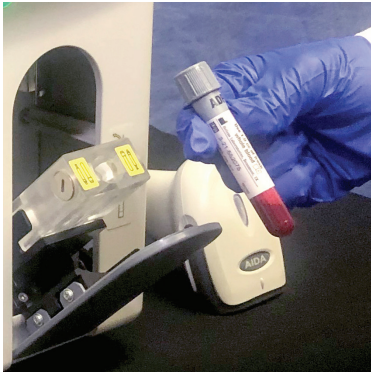
■ Monoclonal Free Protein S Antigen

5293 Monoclonal Free Protein S ELISA Kit, 96 tests

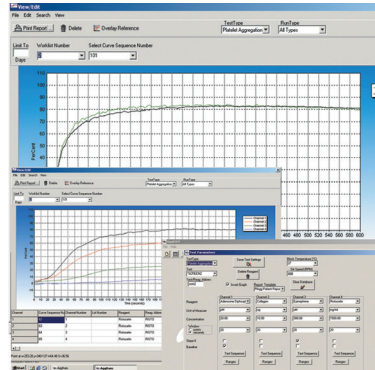
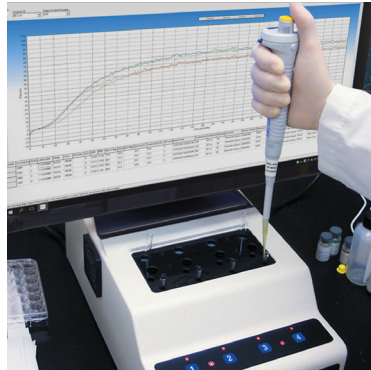
Kit includes: 12 x 8-well Free Protein S Microwell Plate, 60 mL Sample Diluent, 3 x 0.5 mL ELISA Reference Plasma, 12 mL Protein S Conjugate Solution, 13 mL Substrate Solution, 15 mL Stopping Solution, 30 mL Phosphate Buffered Saline

This assay uses a monoclonal antibody specific for Free Protein S in an ELISA format to measure Free Protein S directly without PEG precipitation. Incubation times for this procedure total 1 hour, allowing timely completion of testing. Results are read at 450 nm and calculated by comparison to an internationally recognized reference plasma.





AggRAM couples four-channel laser optic modules with a powerful, easy to use Microsoft® Windows interface for aggregometry like has never been seen before.



PLATELETS

POC Rapid Platelet Function Screening

- Functional Platelet Count
- Platelet Inhibition
- Platelet Aggregation
- CBC

Plateletworks effectively determines functional platelet count and true platelet aggregation or inhibition using traditional ADP, Collagen or Arachidonic Acid agonists. All that's needed is an impedance cell counter and Plateletworks reagent tubes to screen pre-surgical and trauma patients for adequate platelet function and to monitor effects of anti-platelet therapies. The Mindray BC3600 analyzer is a small, economical desktop CBC analyzer that brings testing to the smallest of areas near patient care.

- Efficient pre-surgical screen
- Monitor anti-platelet therapies
- Determine best use of transfusion resources
- Uses traditional ADP, collagen and arachidonic acid agonists
- No specialized training or equipment
- Use whole blood at the point of care

- 5850 Plateletworks Combo-15 Kit
- 5852 Plateletworks Combo-25 Kit
- 5854 Plateletworks Combo-10 Kit
- 5860 Plateletworks ADP Kit
- 5862 Plateletworks Collagen Kit
- 5864 Plateletworks Arachidonic Acid Kit
- 5890 Mindray BC-3600 Analyzer

AGGRAM

Modular Platelet Aggregometer

- Data Handling Features
- Customized Reports
- Quality Control
- Quality Reagents

The AggRAM utilizes LTA, the gold standard, for platelet aggregation and ristocetin cofactor testing and offers unsurpassed precision, ease of use and flexibility. Up to two modules can be run per Remote Analyzer computer, providing up to eight channels to handle your workload. The AggRAM's advanced laser diode optics provide beautiful precision across all channels, plus an improved algorithm for slope calculation greatly improves precision for ristocetin cofactor testing.

- Gold standard technology
- High precision optics
- On-screen prompts
- Barcode and L.I.S. capable
- Auto curve calculation and smoothing
- Reference overlay

- 1484 AggRAM Analyzer
- 1486 AggRAM Module
- 1487 AggRAM for Export
- 1667 Barcode Reader and Cabling
- 1473 Siliconized Cuvettes for AggRAM and PACKS-4
- 1479 Scale Set Solutions (650 nm) for Platelet Assays
1 each Low and High Calibrator
- 1489 AggRAM Stir Bars – 30/pkg



Helena's platelet reagents provide outstanding stability and performance at affordable pricing. Reagents are optimized for use with the AggRAM, but may be used on any turbidometric aggregometer of similar quality.

PLATELET AGGREGATION

Platelet aggregation is performed to identify abnormal platelet function, to quantitate platelet response, and to monitor platelet inhibition by drug therapy. Helena's platelet reagents provide outstanding stability and reasonable pricing. Reagents are optimized for use with Helena's AggRAM, but may be used on any turbidometric aggregometer of similar quality.

ADP

- Lyophilized preparation of adenosine-5-diphosphate
- Reconstitutes to a 20 µM stock solution

Collagen

- One of the world's best collagen preparations
- Clear stabilized liquid prepared from equine tendon
- 10 µg/mL concentration

Epinephrine

- Lyophilized preparation of L-epinephrine bitartrate
- Reconstitutes to 300 µM

Arachidonic Acid

- Lyophilized preparation of sodium arachidonate
- Useful in evaluating aspirin-induced platelet dysfunction
- It has been suggested that this test be performed before other testing to screen for drugs effecting platelet responsiveness

Ristocetin

- Derived from the actinomycete *Nocardia lurida*
- For use in ristocetin-induced platelet aggregation (RIPA) assays
- Concentration post-reconstitution is 15 mg/mL

- 5364 Arachidonic Acid, 2 x 1 mL
- 5366 ADP, 2 x 1 mL
- 5367 Epinephrine, 2 x 1 mL
- 5368 Collagen, 2 x 1 mL
- 5369 Platelet Aggregation Kit (5366, 5367, 5368)
- 5199 Ristocetin (for RIPA), 10 x 0.5 mL
- 5365 Tris-Buffered Saline, 1 x 125 mL



RISTOCETIN COFACTOR ASSAY

The Ristocetin Cofactor assay measures the ability of vWF in the patient's plasma to agglutinate formalin-fixed (metabolically inactive) platelets in the presence of ristocetin. This assay is more sensitive than RIPA to mild reductions in vWF and more often used to monitor therapy in vWD patients.

- The Ristocetin Cofactor Assay Kit, Cat. No. 5370, includes
 - Ristocetin (10 mg/mL; 2 x 1.5 mL)
 - Formalinized platelets (~200,000/mL; 4 x 5 mL)
 - S.A.R.P. reference plasma (2 x 1 mL)
 - Abnormal control (R:Co <50%; 2 x 0.5 mL)
 - Tris-buffered saline (1 x 35 mL)
- Items also available separately
- Platelets in Cat. No. 5356 show a slower reaction rate than platelets in Cat. No. 5371

- 5370 Ristocetin Cofactor Kit, 50 tests
- 5356 Lyophilized Platelets, 5 x 10 mL
- 5371 Lyophilized Platelets, 5 x 5 mL
- 5373 Ristocetin Cofactor Abnormal Control, 5 x 0.5 mL
- 5372 Ristocetin (10 mg/mL), 5 x 1.5 mL
- 5365 Tris-Buffered Saline, 1 x 125 mL



Activated Clotting Time (ACT) testing is the gold standard for monitoring heparin therapy during cardiac procedures.



■ ACTALYKE® POC HEPARIN ASSESSMENT

Actalyke Activated Clotting Time

The Actalyke Activated Clotting Time test system takes a bold step forward in the management of heparin anticoagulation. Actalyke analyzers are for use at the point of care during cardiopulmonary bypass, cardiac catheterization, angioplasty, hemodialysis and other procedures where heparin monitoring with accurate ACT results is needed. For enhanced user flexibility and cost-effectiveness, Actalyke instruments and test tubes are interchangeable with other ACT systems using electromagnetic clot detection principles.

Actalyke Reagent Tubes

MAX-ACT, C-ACT, K-ACT, G-ACT – Helena offers a full line of Actalyke ACT tubes, including traditional glass bead, kaolin, celite plus new MAX-ACT. MAX-ACT uses a blend of celite, kaolin and glass bead. Factor XII has been found to be multi-species in nature and may not be fully activated by one type of activator. By using a cocktail of activators, MAX-ACT provides maximal activation of Factor XII resulting in greater heparin specificity and exceptional linearity.

Two-Point Clot Detection

All premiere Actalyke systems use a two-point clot detection mechanism - one at 0° and another at 90°. This two-point system enables Actalyke to detect a clot at early fibrin formation and is less affected by clot stability. The end result is greater test result reliability, especially on highly heparinized and diluted samples.

- Gold standard technology
- 2-point early clot detection
- Extensive data management
- Onboard barcode reader; L.I.S. connectivity
- Celite, Kaolin, Glass or MAX-ACT tests

5772	Actalyke Ultra Analyzer
5763	Actalyke Mini II Analyzer
XL-ECT	Actalyke Electronic Clotting Tube
C-ACT	Celite ACT Reagent Tubes (50/box)
K-ACT	Kaolin ACT Reagent Tubes (50/box)
G-ACT	Glass Bead ACT Reagent Tubes (50/box)
MAX-ACT	MAX-ACT Reagent Tubes (50/box)
AQC-HP	Level 1 and 3 Controls for MAX-ACT, C-ACT, K-ACT
AQC-LP	Level 1 and 2 Controls for G-ACT



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