The aim of this collection is to provide clear, comprehensive medical information to health professionals for their everyday practice in the broad field of haemostasis.

The first volume was a compilation of the main scores and algorithms used in haemostasis and thrombosis.

The second explores the various aspects of the complex condition of antiphospholipid syndrome. This 74-page manual, authored by a European panel of six leading biologists, summarises our current understanding of antiphospholipid syndrome, with sections on its pathophysiology, clinical manifestations, laboratory diagnosis (including current international recommendations) and treatment.

The manual has been very well received by the scientific community since its launch in late June 2015, in time for the 25th ISTH congress, held in Toronto.

Stago is committed to this collection of manuals with the aim of producing comprehensive, scientific, practical overviews covering the entire field of haemostasis.

If you would like a copy of this Practical Manual - Antiphospholipid Syndrome please email us at info@stago.com
STA Compact Max®²

Innovation born from Expertise

Three years after the launch of the STA Compact Max® designed for all medium size laboratories, Stago is proud to announce the launch of the new analyser: the STA Compact Max®².

The ‘Max Generation’ instrument family is expanding again following the launch of the STA R Max at the beginning of this year for high throughput laboratories. STA Compact Max®² STA Coag Expert software is now totally harmonised with the STA R Max to optimise user-friendliness across multi-site labs.

Max Reliability
Thanks to Stago unique Viscosity-Based (mechanical) Detection System present on all our systems, the RELIABILITY of results is ensured against optical interferences.

The robustness of STA Compact Max®² has also been further improved to reduce user maintenance operations.

Max Innovation
With a new hardware design and improved ergonomics, the STA Compact Max®² will optimise your productivity. INNOVATION is also supported by new software features bringing expertise to every lab: Expert rules to standardise patient results validation and extended traceability to meet quality requirements.

Max Performance
Extensive walkaway capability and true STAT management to ensure a fast Turn-Around-Time, are the main features of the STA Compact Max®² bringing you the performance you can expect from a Stago system.

Max Efficiency
Samples and reagents management have additionally been enhanced and streamlined in the STA Compact Max®² for even better EFFICIENCY: A new cap piercing module extends sample tubes compatibility, and the software provides more flexibility to manage multiple lots and calibration curves on-board.

Discover our extensive reagents line, covering all aspects of Haemostasis from routine to the most specialised tests, including a wide range of liquid ready-to-use products with extended on-board stability, unique pre-calibration feature and fully barcoded management for increased safety.

STA Compact Max®²: Enlarging the Max Generation!
Stago Customer Corner

Stago Customer Corner is available via our newlook website
www.stago.com.au

You simply log-in (clicking the Login button top right) and you will get access to all your data and available services.

The information available includes: your laboratory analysers, orders and ID-card; Material Safety Data Sheets, Package Inserts, Barcode Sheets, Instrument Documents, and Standard Operating Procedures

If you would like access to Customer Corner please contact us for your log-in and password - it's free!

info@stago.com

At the Heart of Haemostasis
Stago are pleased to announce the release of our block buster applications iHemOStasis and Haemoscore. These applications are available free of charge from the Apple App Store and Google play worldwide.

The iHemOStasis tablet application serves as a haemostasis primer for anyone looking to increase knowledge in the area. The uncomplicated user interface offers four areas of interest:

**Coagulation Cascade:** Major coagulation mechanisms are animated along with detailed explanations of each phase, including intracellular and extracellular components.

**Quick Guide:** Detailed descriptions of the most current assays used to examine hemostasis in a global fashion along with various therapies, disease state classifications and decision trees.

**Special Focus:** Product literature supporting Stago’s anticoagulant, thrombin generation and flow cytometry products is housed, along with reference ranges for hemostasis tests in childhood and pregnancy.

**Clinical Cases:** Three case studies are presented, along with quizzes to test the viewer’s knowledge.

The Haemoscore App is available for tablet and smartphone from the Apple Store and Google play.

Clinical scores and algorithms play a central role in modern patient care derived from evidence-based medicine.

Evidence based medicine provides guidelines to physicians aimed at improving efficacy and safety of patient management.

An international expert panel has developed this application that compiles, in a clear and simple way, most recognised and useful clinical scores and diagnosis algorithms in the field of Thrombosis and Haemostasis.

Each algorithm includes the indication and a brief interpretation emphasising the most relevant aspects of each one followed by some representative references.

We hope his application may guide the clinician in the most appropriate diagnostic strategy, answering some of the questions that may arise when treating thrombotic and bleeding problems.
Continuing Education

Diagnostica Stago has a number of websites to assist in the continuing education of your staff. On a regular basis Stago hosts live webinars at a range of times, to suit us in Australia and New Zealand, presented by Key Note Speakers from laboratories from around the world.

These webinars are also available for viewing “on demand” a few weeks after the live presentation.

The topics covered so far include:

1. D-Dimers Its use in the Strategy for VTE exclusion and as a predictor for the risk of VTE recurrence
2. How to diagnose and manage Heparin Induced Thrombocytopenia (HIT)?
3. Laboratory measurement of New oral Anticoagulants
4. New insights in Lupus Anticoagulant Testing
5. Quality Control in the Haemostasis Laboratory. How Quality Control contributes to result reliability.
6. Thrombin Generation: a universal laboratory tool emerging from research to clinical practice
7. How I interpret an APTT result?

The above webinars are currently available to view on demand. All you need to do is go to the Stago ANZ website www.stago.com.au and press the icon Stago Webinars (see below). This link will take you to the webinars website where you register for access and future webinar notifications. The webinars are best viewed using Google Chrome and SD (standard definition) depending on your connection speed.

Our next Webinar is on December 15, 2015 - “The laboratory diagnosis of inherited and acquired Haemophilia.” by Dr Alberto Tosetto (Vincenza, Italy)

Another link on our Stago website “Ed-Vantage Continuing Education” provides access to a huge amount of resources covering topics such as Lab Management, General Coagulation Testing, Case Studies in Hemostasis, Primary Hemostasis, Anticoagulation, Hypercoagulability, Hypocoagulability, and Screening Tests. Some of these talks also attract PACE points.

There are more than 20 educational webcasts available to view.
Coagulation Factor XIII is a transglutaminase that plays an important role in haemostasis since it participates in the final stages of the coagulation cascade. It is an enzyme of the blood coagulation system that cross-links and stabilizes fibrin. By polymerising fibrin monomers, it enables the formation of a firm blood clot.

Factor XIII (FXIII), or fibrin stabilising factor, deficiency was first reported in the literature in 1960. It is an extremely rare factor deficiency, occurring in 1 per 5 million births. It is inherited in an autosomal recessive fashion, meaning that both parents must carry the gene to pass it on to their children; it affects men and women equally. To date only 300 cases have been reported worldwide (Factor XIII registry database) with the greatest number of cases reported in Japan (53 cases) (* http://www.f13-database.de)

FXIII protein stabilises the formation of a blood clot. Without it, a clot will still develop, but will then break down and cause recurrent bleeds. Umbilical cord bleeding is common in factor XIII deficiency, reported in almost 80% of cases.

Up to 30% of patients sustain a spontaneous intracranial hemorrhage, a brain bleed, which is the leading cause of mortality. Other symptoms of FXIII deficiency include bruising, nose and mouth bleeds, muscle bleeds and delayed bleeding after surgery.

Women can experience menorrhagia, long, heavy menstrual periods, and repeat miscarriages. Men with FXIII deficiency may show signs of infertility.

Because patients with FXIII deficiency form a clot, clotting tests come back normal. Instead, diagnosis is made using FXIII assays and a clot solubility test.

**Therapy options:** Fresh Frozen Plasma and cryoprecipitate are the mainstay of therapy for Factor XIII deficiency, but carry risks related to transfusion. Commercially produced factor XIII concentrates are available in some parts of the world. In December 2013, the U.S. Food and Drug Administration approved Tretten, Coagulation Factor XIII A-subunit (Recombinant), the first recombinant product for use in the routine prevention of bleeding in adults and children who have a rare clotting disorder, known as congenital Factor XIII A-subunit deficiency.

Prophylaxis is a practicable option as quite low levels (5-10%) of FXIII in plasma are sufficient for control of bleeding. The longest plasma in-vivo half-life is 11-14 days.

Normal plasma in the adult population is usually between 60 and 150% ** At birth the Factor XIII level is slightly low but reaches the normal level quite rapidly (about 1 month). During pregnancy the Factor XIII level decreases to approximately 50% of normal by the end of the pregnancy.

(** Alexandre P “Les autres déficits héréditaires d’un facteur isolé de la coagulation” Hématologie, 1994)

In Acquired Factor XIII deficiency the FXIII A-subunit levels drop into the range 20-70% ***

Acquired FXIII deficiency is caused by decreased production or increased consumption and is seen in these conditions:

• Acute Leukemia
• Severe liver disease
• DIC
• Inflammatory Bowel disease
• Autoantibodies against FXIII

In Acquired FXIII deficiency, bleeding is rare and rarely requires replacement therapy. (** Kohler et al: “Diagnosis and classification of factor XIII deficiencies” Factor XIII And Fibrinogen SSC Subcommittee of The ISTH. J Thromb Haemost. 2011 Jul;9(7):1404-6)

Factor XIII deficiency severity is typed accordingly:

<table>
<thead>
<tr>
<th>FXIII Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe &lt; 5%</td>
</tr>
<tr>
<td>Moderate 5 to 10%</td>
</tr>
<tr>
<td>Mild &gt; 10%</td>
</tr>
</tbody>
</table>

[An increased level of FXIII is seen in patients with arteriovascular disease and may be a marker to predict prothrombotic state.]

**Factor XIII Deficiency - Lab Testing**

Factor XIII levels are not measured routinely, but should be considered in patients with an unexplained bleeding tendency. Standard laboratory clotting tests PT, aPTT, fibrinogen level, platelet counts, and bleeding time are all normal in FXIII deficiency. The Clot solubility test is a semi quantitative assay and poorly standardised. As a qualitative method it detects only very severe deficiencies.

The **Stago K-Assay® Factor XIII kit** is a fully automated Latex Immunoassay for use on STAR, STAR Max, STA Compact and STA Compact Max.

K-Assay Fact XIII Ref. 01113
K-Assay Fact XIII Cal Ref. 01114
K-Assay Fact XIII Cont Ref. 01115
### Test Principle

Latex particles coated with antibody specific to human Factor XIII form immune complexes in the presence of Factor XIII from the sample. The immune complexes cause an increase in light scattering, which is proportional to the concentration of Factor XIII in the plasma sample. The light scattering is measured by reading turbidity at 500 to 600nm (540nm on Stago analysers). The sample Factor XIII concentration is determined versus dilutions of a Factor XIII calibrator of known concentration.

The measuring range on Stago instruments is 4-200% FXIII. The calibration curve is a 3rd order polynomial.

### K Assay FXIII Performance

Dilution of the International FXIII Standard and George King plasmas shows the following correlation data (see Table 1) with excellent performance at low concentrations (the main area of clinical interest).

### Reagent Stability

Unopened reagents can be used until the expiration date shown on the package and bottle labels if stored at 2-8°C. Once the reagent vial has been opened, store tightly capped at 2-8°C and use within 1 month.

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**Table 1: Correlation Data**

<table>
<thead>
<tr>
<th>Samples</th>
<th>Kamiya</th>
<th>STAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>GK (&lt; 1%)</td>
<td>&lt; 4</td>
<td></td>
</tr>
<tr>
<td>5%</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>10%</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>15%</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>20%</td>
<td>21</td>
<td></td>
</tr>
<tr>
<td>40%</td>
<td>45</td>
<td></td>
</tr>
</tbody>
</table>

If you would like to know more please contact us: info@stago.com
New STA® Liquid D-Di Controls

D-Dimer is an essential parameter for most labs: D-Dimer results are critical for making an appropriate diagnosis and for optimal patient management. It is performed routinely and in an emergency setting (24/7).

Your D-Dimer Quality Controls play an essential role to validate the test system’s performance:

• Check the accuracy and reliability of results reported by your D-Dimer testing system for all patient samples on a daily basis.
• Evaluate the precision in various operating conditions.
• Monitor the consistency of results over a prolonged period of time.
• Comply with quality management recommendations.
• Stago offers a reliable, fully automated, ready-to-use testing system with STA®-Liatest® D-Di Plus and STA®-D-Di Control.

STA®-D-Di Control are:

Compliant with international quality management recommendations featuring 2 assayed quality controls located at ideal levels:
- Control 1 ~0.75 µg/mL FEU
- Control 2 ~2.30 µg/mL FEU

Adapted to your day-to-day D-Dimer testing activity.

Liquid, ready-to-use: convenient for minimising handling procedures errors.

Extended stability: 72h on board STA-R® and STA Compact®, stable for 15 days after opening when stored at 2-8°C.

2 mL vials: allows several QC runs per day.

A key component of your system thanks to barcode-based management of product data:

• Autopopulation of dedicated ranges guarantees the safety of the system.
• Optimal management of volumes, stability, expiry dates, batch numbers etc.

STA®-D-Di Control - Cat. Nr. 00868
(Packaging 2 x 6 x 2 mL - Liquid)

Associated reagents:
STA®-Liatest® D-Di Plus - Cat. Nr. 00662

If you would like to know more please contact us:
info@stago.com
Stago Webinars
Live webinars and available on-demand

We are pleased to advertise the availability of educational resources at not one but two Stago websites.

On a regular basis, keynote speakers present interesting and topical presentations on a variety of topics. The webinar is available to view live at a scheduled time and is available on the website to view on-demand a short time later. The live event allows interaction with the presenter in real time.

To participate all you need to do is register at the website to gain access and reminders of upcoming events.

Webinars on-demand currently available include: DDimer; HIT; NOACs; LA; Thrombin Generation and the latest by Steve Kitchen (UK) on QC in the Haemostasis Laboratory.

Please visit:
http://www.stagowebleinars.com

Educational Website
24 hours per day 7 days per week
Stago-EdVantage.com

New science and the transfer of knowledge leads to new standards of care, better patient outcomes and improved quality of life for the patients we serve.

Diagnostica Stago, has long been committed to providing educational support to haemostasis testing laboratories. Our customers participate by providing feedback and program requests on specific topics that may aid them in the use of our products or provide knowledge to better serve as their institution’s haemostasis resource.

Australian and New Zealand participants can achieve APACE and CPD continuing education credits and certificates by registering and completing the activities on this site.

Please visit:
http://www.stago-edvantage.com

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