Collaboration boosts regulatory compliance for centre of excellence

Elite specialist haemostasis unit in the NHS partners with Stago UK to improve patient outcomes through innovation, workflow efficiency and confidence in results reporting.

The quality of life and life expectancy for haemophilia patients has improved significantly over the past 30 years. This has led to demand for greater and more easily accessible diagnostic testing and monitoring services. To respond to this demand, the NHS established the Comprehensive Care Centres (CCC), a nationwide network of 22 centres of excellence.

The haemophilia and thrombosis centre run by East Kent Hospitals University NHS Foundation Trust is one of these centres of excellence and now treats more than 500 patients from across Kent and parts of East Sussex. The trust is one of the largest hospital trusts in England, with five hospitals serving a local population of around 759,000 people.

Its haemophilia unit fosters a multidisciplinary approach involving clinicians, physiotherapists, paediatricians, obstetrics and gynaecology – all based around the specialist haemostasis laboratory at the Kent and Canterbury Hospital. The laboratory offers a full range of specialist investigations for patients with inherited and acquired disorders of haemostasis and thrombosis. While routine blood testing takes place across three hospital sites, all specialist coagulation work is handled by Canterbury, normally running 50 specialist investigations a day.

The unit has been accredited by the Department of Health for more than 18 years and, although one of the smaller specialist units in the UK, it is the only national centre to be selected that is not located in a university teaching hospital.

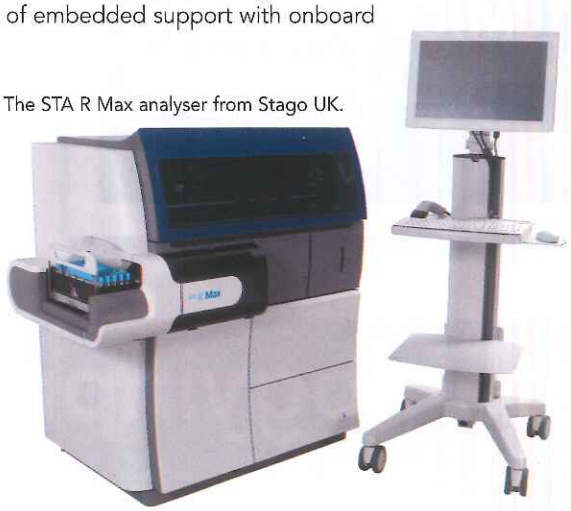
Effortless compliance support

Maintaining its position requires consistently high standards of workflow efficiency, innovative attitudes and confidence in results reporting. To help make this possible, the laboratory service turned to Stago UK and its next-generation STA R Max system both for routine and specialist assays. Six STA R analysers have been installed across the trust in three sites, with two Star R Max systems in the haemophilia and thrombosis centre, in Canterbury.

"The STA R Max gives us an edge," said head biomedical scientist Jo Nightingale. "It is fast, very much quieter than its predecessor and intuitive to use, so easy for staff to learn. We already see a significant improvement in turnaround times (TATs), enabling staff to meet performance targets."

The STA R Max has a great deal of embedded support with onboard resources such as the extended traceability function, providing full traceability (including sample, reagents, consumables and operator), method validation and verification, as well as all aspects of quality control management. The Stago STA Coag Expert, which is part of the STA R Max and STA Compact Max 2 software, provides autovalidation tools and rules to speed up TATs even further.

The STA R Max analyser from Stago UK.



The NHS focus on process improvement is driven in part by the need for compliance with ISO 15189:2012 quality requirements. The new accreditation requirements are time-intensive and place a significantly increased burden on laboratories. For example, measurement of uncertainty was first introduced in engineering and manufacturing processes to characterise the dispersion of values attributed to a measured quantity. The ISO 15189 standard now requires laboratories to assess and report variability and, similar to manufacturing processes, to attribute a measurement of uncertainty to laboratory results. For example, what variability the laboratory would expect if an assay were to be repeated.

Unfortunately, assessing uncertainty is not a straightforward process with coagulation as a lot of the tests are multi-parametric. As Jo explained: "Stago has excelled in creating a system that not only improves our workflow but enables our compliance obligations to be handled quickly and easily, with far greater accuracy than we believed possible.

"Longer term, I see the quality of Stago's accreditation tools becoming our biggest ally. Its software and its quality management systems are

fabulous. Whatever the standard, it enables us to demonstrate how well this laboratory complies. The STA R Max simply takes the compliance burden off our shoulders."

Scalable analyser

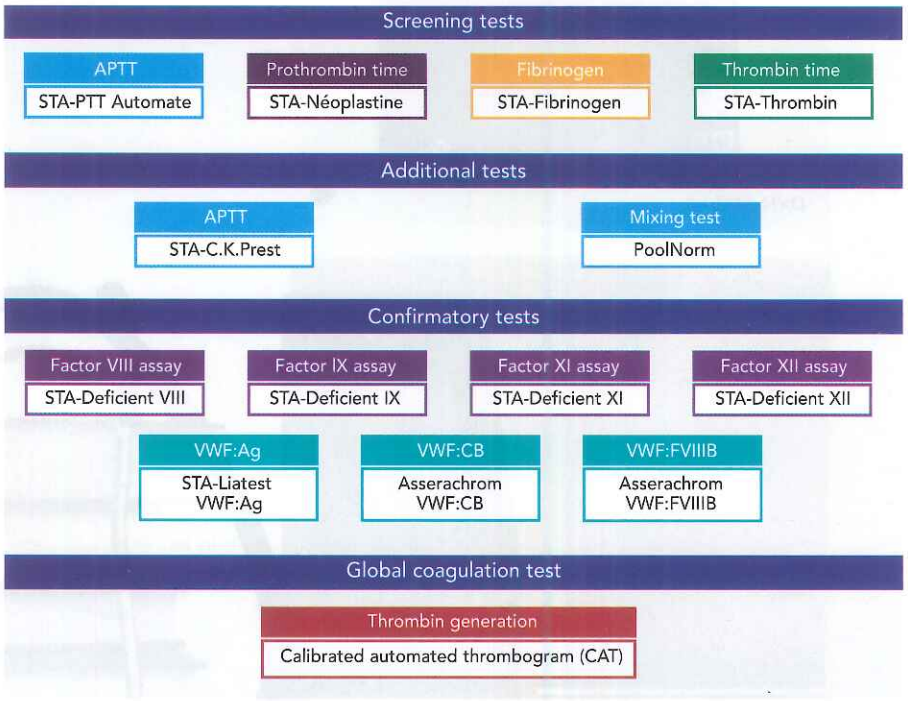
This emphasis on high standards and being a centre of excellence requires the laboratory to operate the STA R Max 24 hours a day, seven days a week, ready to run tests such as prothrombin time (PT) and activated partial thromboplastin time (APTT) throughout.

The STA R Max can be adapted to any laboratory set-up, delivering the same high-throughput performance whether connected to an automation track system or in standalone operation. Designed for high-volume laboratories, this scalable system is a good fit for the expanding NHS hub-and-spoke network of laboratories.

Stago has designed its Max Generation haemostasis analysers (including the STA Compact Max and Max 2) to be operationally efficient, running 24/7 without needing start-up time and delivering a STAT turnaround time of less than 10 minutes. Pre-calibration is a feature of Stago haemostasis analysers, saving both time and cost and ensuring the analysers are always ready to use. With a high load capacity both for consumable and samples, the STA R Max takes 1000 cuvettes, up to 215 samples and has 70 cooled reagent positions. The unit is also able to handle paediatric tubes and small-volume samples.

Its environmentally friendly design provides savings because of the use of a limited and contained fluidic waste system and it minimises solid contaminated waste disposal (one cuvette equals one test). Live performance can be monitored, utilising the integrated TAT monitoring report. This helps laboratories manage their targets for delivering patient results.

In addition, its viscosity-based (mechanical) detection system enables immediate delivery of accurate and precise results. Advantages include insensitivity to any type of coloured plasma, maximum precision for weak clot detection and standardisation between Stago systems.



Tests performed for detecting haemophilia.

Expert rules for multiple dilution analysis

To improve the detection of inhibitors, Stago has recently developed a set of specialist rules that can be activated within the Coag Expert to carry out multi-dilution analysis which aims for 100% reliability. The rules were developed in compliance with the revised CAP Guidelines, (2011 Haematology Guideline 37980), setting down the following:

- perform at least three dilutions
- the results of each individual dilution should be within 15% of one another to be considered linear or parallel
- in situations of non-parallelism, the highest value obtained with dilution should be reported with a comment about dilution effect
- to be valid, at least one value must fall within the upper and lower limits of the standard curve used for the calculation of the results.

Improving patient outcomes

The laboratory runs a number of educational programmes for clinicians as well as the county's GPs and other healthcare professionals. Not only do these seek to raise awareness about thrombosis prevention as well as other blood disorders, but it also sets down guidelines for improving standards and compliance before the samples reach the laboratory.

Jo Nightingale sees the work of the laboratory as integral to the successful delivery of care and improved outcomes for patients. "We are a highly regarded unit within the NHS haemophilia service, and work in a very collaborative way with other disciplines in the trust. We are supported by a clinical lead who encourages the laboratory to be proactive in the best interests of our patients."

Another example of the laboratory's proactive approach relates to von Willebrand disease (VWD), for which, unlike other centres, Jo's team routinely

Haemophilia

Haemophilia was only defined in 1928 but it was first noted as early as the second century AD when a rabbi correctly identified a maternal link in sons who bled to death after circumcision. Most cases are due to an inherited link passed down by the mother. However, in the most famous carrier, Queen Victoria, it was likely to have resulted from a 'spontaneous' mutation, as her father, the Duke of Kent, was not affected, nor were children from her mother's earlier marriage.

The clotting activity of factor VIII needs to be determined to establish the diagnosis and the severity of the disease. The gene for factor VIII is located on the long arm of the X chromosome. A single allele is present in males compared with two in females. Carriers are generally non-symptomatic, although some may have reduced plasma activity of factor VIII (below 50%, ie 50 units/dL) and can transmit this anomaly to their offspring.

Infectious complications are associated with the human origin of certain blood products used in the treatment of haemophilia A. In the past, viral transmission (HIV, hepatitis B and C) was a major complication of haemophilia A therapy, but since the introduction of effective viral inactivation processes towards the end of the 1980s, this risk has become minimal.

tests. This disease has special implications for patients facing surgery and for menstruating women, and research indicates that as many as nine out of 10 people with VWD have not been diagnosed. The disease can also be acquired as a result of other medical conditions and certain drug therapies.

Venous thromboembolism (VTE) is an international patient safety issue and a clinical priority for the NHS in England. Alongside its work with bleeding disorders, the team's other main focus is actively supporting the VTE Prevention Programme campaign.

Around half of all cases are associated with hospitalisation, with many events occurring up to 90 days after admission. "We need to address the 25% of preventable deaths that occur in NHS hospitals each year from thrombosis," said Jo Nightingale. "With the support of our clinicians and managers, the laboratory is able to take a very proactive approach to improving outcomes for patients. The objective is to assess and manage every patient's risk of developing a VTE when they enter hospital for treatment."

Collaborative working

Another example of the haemophilia and thrombosis centre's successful multidisciplinary approach is the award of a prestigious £250,000 grant to lead an NHS research 'first' into haemophilia. The study is the first randomised clinical trial of its type for physiotherapy intervention in children with haemophilia. The study will take the first step in establishing links between exercise, weak muscles and joint damage caused by bleeding in children with the condition. The grant has been awarded by the National Institute for Health Research (NIHR). Funders said the unit's involvement of patients and the public in the research programme was exceptional and considered the findings would provide robust evidence likely to have a marked impact on treatment and the quality of patients' lives.

The partnership between Stago UK and the Canterbury-based haemophilia and thrombosis centre echoes the unit's approach to collaborative working. Jo Nightingale summed up the way the company works with customers as "proactive and committed to thinking how it can best deliver a systems solution that fits the needs of your specific laboratory; with brilliant aftersales support to ensure it works".

Testing pathway for identifying clotting activity.

1	Activated partial thromboplastin time (APTT)
2	Mixing test
3	Prothrombin time (PT)
4	Fibrinogen
5	Thrombin time (TT)
6	Bleeding time

About Stago

Stago UK offers a complete system of haemostasis instrumentation and optimised reagent kits for research as well as for routine analysis. It provides the means and the tools for scientists and clinicians to diagnose and to understand the reasons for thrombosis or bleeding disorders.

The company was first created in 1945 as an IVD company to develop and market reagents and automated systems for the investigation of blood coagulation disorders. It now has 2000 employees worldwide and products are available in more than 100 countries. Its global headquarters, as well as research and development (R&D), manufacturing and logistics activities are located mainly in Paris, France.

For more information about Stago, its products or services, go to the company's website (www.stago-uk.com).