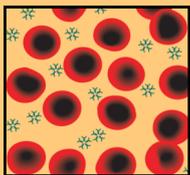


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Inside this issue



Building a haemoglobinopathy library



How to be a Quality Manager



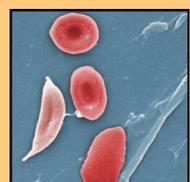
Viapath Contract Research department



IBMS Congress 2017



Enter your work for an Advancing Healthcare Award



A day in life of... A Senior Biomedical Scientist in Viapath's Red Cell Laboratory

Message from the Editor

Quality matters. This is not only true in many aspects of daily life but is also of paramount importance in pathology. In this issue of "pathology@viapath", we explore the role of a Quality Manager in a busy Tissue Sciences laboratory and investigate the need for information to be reliable when interpreting results from patients with haemoglobinopathies. We also discuss the importance of having well-planned clinical trials in order to generate meaningful results.

The media spotlight is currently focused on improving healthcare delivery as the quality of the service offered to patients needs constantly to progress. To recognise the transformational efforts of healthcare scientists in this field, this month the 2018 Advancing Healthcare Awards were announced. Viapath is proud to be sponsoring an award for innovation in healthcare science and hopes this will help to encourage new initiatives in the advancement of high quality patient-centred care.

Building a haemoglobinopathy library

Haemoglobinopathies are a diverse and heterogeneous group of disorders that affect the genes responsible for synthesising globin, an essential component of haemoglobin. They are considered to be one of the most common autosomal recessive disorders affecting humans and can affect either the type of globin produced (haemoglobin variants) or the amount (thalassaemia). In adults, the majority of globin is synthesized by 2 genes, the beta globin gene and the alpha globin gene, both are essential because the main adult haemoglobin (Hb A) is comprised of tetramers formed of two alpha and two beta chains. Although there are a number of common haemoglobin variants such as Hb S, Hb C and Hb E, over 1,000 haemoglobin mutations have been reported.

Most laboratories can identify the common variants but identification of the rare variants is difficult without DNA analysis.

Laboratory tests

Several laboratory tests are available to screen for haemoglobin variants, such as high performance chromatography (HPLC), capillary electrophoresis (CE), alkaline and acid agarose gels, iso electric focusing (IEF), and others. However these methods will only be able to produce a presumptive identification.

With the advances of genetic testing, DNA analysis provided a reliable confirmatory method detecting mutations ranging from a single nucleotide alteration to the loss, duplication or rearrangement of several thousands of nucleotides. An example of these techniques is DNA sequencing by Sanger sequencing.

But, due to the price and processing time, these DNA based methods can't be used routinely to screen all patients for haemoglobin variants and thalassaemias.

Building the resource

Companies try to help the laboratories to provisionally identify variants by offering online library facilities which identify the characteristics of different variants with the equipment in use. This provides a helping hand for the presumptive identification of haemoglobin variants and what further testing is required.

Viapath laboratories offers molecular techniques for all globin genes and mass spectrometry to identify haemoglobin variants, alongside the relevant

expertise required for the interpretation of this complex area.

Trinity Biotech (Bray, Co. Wicklow, Ireland) selected Viapath's Special Haematology Department at Guy's and St. Thomas NHS Foundation Trust for a joint project, aimed at building an online haemoglobinopathy library resource for their Premier Resolution analyser (HPLC). All haemoglobinopathies characterised in the library are confirmed by DNA or mass spectrometry analysis much of which has been carried out at the Viapath laboratories. Furthermore with this partnership, Trinity Biotech can provide a haemoglobinopathy confirmation service for their clients all over the world.

There are a large number of haemoglobinopathies and their combinations. Therefore building the library requires a large number of samples which have been gathered from several countries. Trinity Biotech is shipping samples, they have collected and preserved over the years, to Viapath's laboratory where the necessary testing can be performed to confirm the genotype.

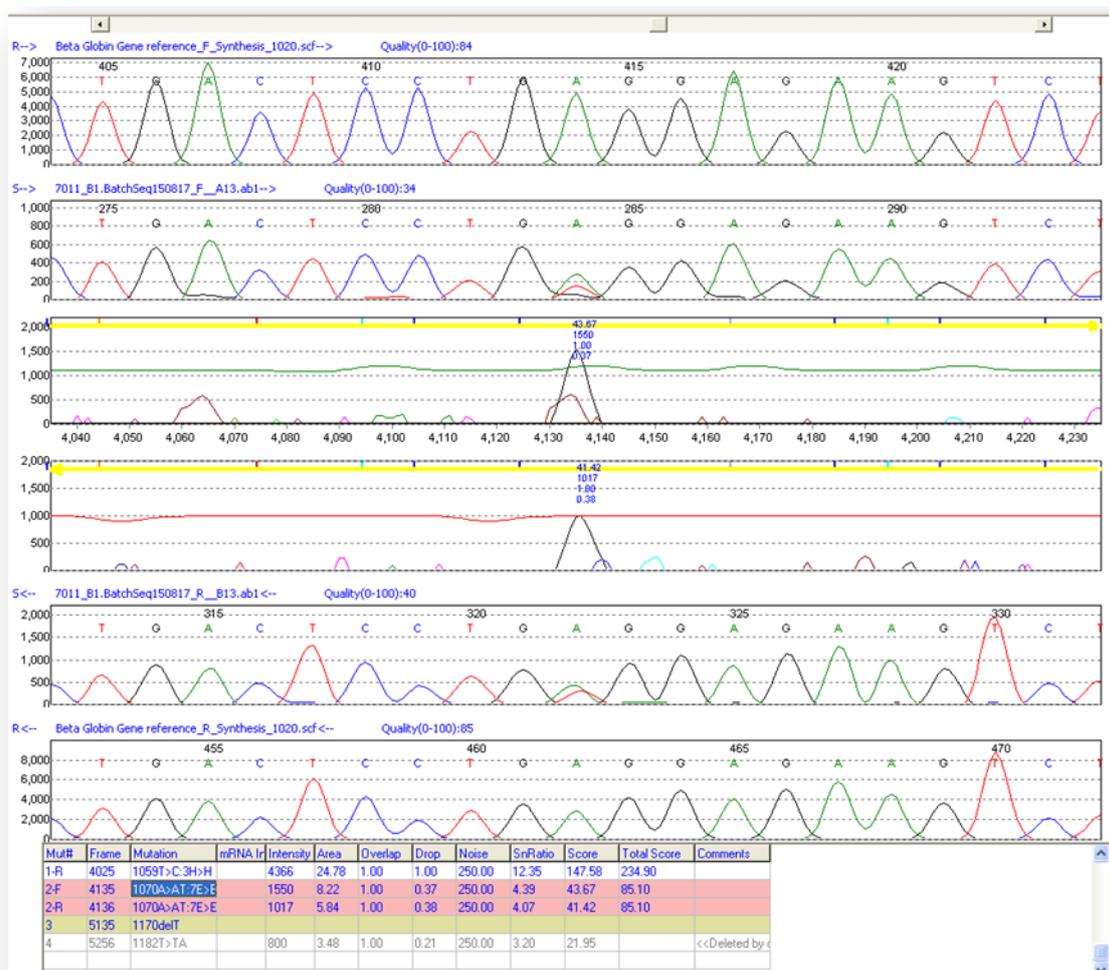


Figure 1 - DNA sequencing software

After confirmation, the results are sent back to Trinity Biotech where they are integrated into the library and facilitated to the end user – the operators of their Premier Resolution Analyser. When an abnormality is found within a given sample, the software compares the peak characteristics present in the patient sample against the examples in the library, the software then suggests a number of possibilities in order to aid the operator in the result interpretation.

The library is comprised of chromatography plots available for each of the samples confirmed by DNA analysis, but also provides information about: the

name and characteristics of each Haemoglobinopathy, its retention time (RT), the globin chain affected and the family origins where they can be found. An example is shown in the schematic below.

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Variant	RRT/F	RRT/A	RRT/A2	RRT/S	RRT/C	CHAIN	%	ETHNICITY
Hounslow			0.89-0.93			Beta	~38	Afghan
D-Iran			0.93-0.97			Beta	35-45	Iranian, Pakistani, Italian Jamaican
Codon 4 ACT > ATT			0.94-0.98			Delta	<2%	Cypriot, Greek
E			0.94-0.98			Beta	20-25	Far East
G-Galveston			0.95-0.99			Beta	~50	African-American
A2			0.98-1.02				1.5-3.5	Normal adult Hb
Osu-Christiansborg			0.98-1.02			Beta	~45	Iranian, Greek, Ghanaian, African-Christian
Inkster			1.01-1.05			Alpha	20-25	African-American, English, German
G-Philadelphia			1.02-1.06			Alpha	30-45	Chinese, African-American, Italian
Korle Bu			1.03-1.07			Beta	40-45	African-American
G-Norfolk			1.06-1.10			Alpha	18-23	English
Manitoba II				0.90-0.94		Alpha	10-20	English, German, Irish, Italian
D-Los Angeles				0.92-0.96		Beta	30-40	Australian, Chinese, Dutch, English, Greek, Turkish, Indian, Pakistani, Yugoslavian
Moabit				0.92-0.96		Alpha	15-20	Turkish
E-Saskatoon				0.97-1.01		Beta	30-40	Scottish, Turkish, Greek, Japanese
S				1.00-1.04		Beta	30-45	African-American, American Indian

Figure 2 - Hb Variant interpretation table

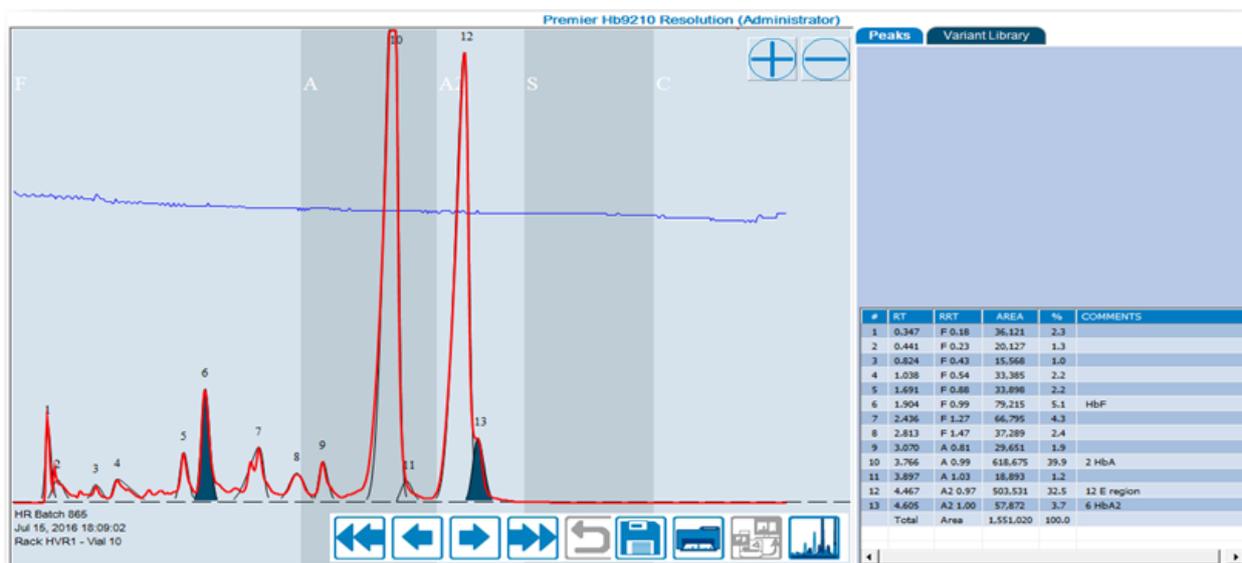


Figure 3 - Premier Hb9210™ Resolution chromatography plot

How to be a Quality Manager

My role as Quality Manager for the Viapath Tissue Sciences laboratories at Guy's and St Thomas' hospitals led me to be invited to speak at this year's IBMS Congress on the topic of 'How to be a successful Quality Manager'. This isn't an easy thing to define; however, here is a review of the approaches I use in my role.

The IBMS define a Quality Manager as '*the individual with responsibility as a management representative for ensuring all aspects of quality within a quality management system function correctly.*'

The role can be wide and varied, but in general it includes:

- Management and oversight of the quality management system (QMS)
- Monitoring and supporting quality improvement
- Ensuring that the requirements of ISO 15189 and any other external assessment and regulatory bodies are met
- Risk management and mitigation
- Investigation of incidents by using root cause analysis and developing action plans
- Representing the laboratory in clinical governance

In other words, the Quality Manager is involved in virtually every aspect of the service, as 'quality' tends to feature in everything! As the role is so diverse, there are different approaches to tackling all the different aspects. Below are the key points that help me succeed in my role:

Qualifications; Questions

Understand; Unbiased

Aims; Approachability

Lead; Learning

Improve; Implement

Team; Teach

You!

Qualifications

A qualification in Quality Management has helped me with the theory to support the practical aspects of my role – this gives me confidence!

Questions

W Edward Deming said: 'In God we trust; all others bring data'. By asking constant questions of the team that I work with, I ensure that quality management procedures are in place in the laboratories and, most importantly, are being followed.

Understand

I am trained in Cellular Pathology so I have experience of working in most of the disciplines that I cover. I find that by understanding what goes on in the laboratories, I can give more in-depth advice to the Operations Managers, and help them to understand how the accreditation standard applies to their service.

Unbiased

Objectivity is vital and to achieve this I try to stand outside of the laboratory operations whenever I can! It is much easier to give an unbiased view if I can look in from the outside as I can gain a clearer view of the areas that need improvement. This is particularly useful when incident investigation is required!

**Be part of a team,
but remain unbiased**

Aims

When I started in this role I took some time to establish where all my laboratories stood in regards to quality management. This helped me to ascertain what was required to improve the QMS and establish some aims for quality improvement.

Approachability

I try to be visible and make sure all members of staff know who I am and what I do. This helps to make quality management accessible to everyone.

Lead

This is particularly important in assessment visits. The Operations Managers in my area rely on me to direct them before and after assessment visits and provide them with action plans.

Learning

Almost every event provides a learning opportunity, be it an audit, an external assessment or an incident. All the Quality Managers in Viapath share learning which drives improvement in each department.

Almost every event provides a learning opportunity

Improve

It is a significant part of my role to keep improving the QMS in order to keep up with new learning and any changes to accreditation standards.

Implement

This is possibly one of the most difficult aspects of the job as all improvements and changes need to be implemented by the laboratories.

Team

As Quality Manager, I am part of the management team. This helps me to know what's going on in our service, as otherwise, the quality/change management aspects of any developments can be easily overlooked. I've also got an excellent team of Quality Officers who support me in implementing changes and making sure compliance is maintained in the laboratories.

Teach

I spend as much time as I can on teaching aspects of the QMS to colleagues. This improves understanding across the laboratories and helps with maintaining compliance.

You!

Quality Managers spend a lot of their time supporting others and reviewing others' work, but I've found that it's vital to make time to complete my own work and projects. This is always challenging, but, achieving my own objectives helps me to stay motivated. This also puts me in a better position to motivate others, and this is essential for achieving success!

I have found that to be a 'successful' Quality Manager you need to:

- Be part of the team, but remain unbiased
- Understand the service, but be prepared to question everything you're told

- Be a leader, but also be approachable
- Be clear on where you're going and how to get there, as well as where you've come from
- Be an authority on the accreditation standards, while remembering there is more to quality management than accreditation!
- Be both a teacher and a student (always learning!)

If you can achieve all that, then maybe Quality Management is for you, too!



Fiona Denham , Quality Manager

References:

1. IBMS. Guidance on Quality Management in Laboratories. 2015.
2. The Deming Institute. <https://deming.org>

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'Quality' tends to feature in every aspect of a laboratory service

Viapath Contract Research Development Department

About us

Viapath's Contract Research and Development Department works with and supports many academic and commercial clinical trials and projects. Our team is experienced particularly in delivering routine and bespoke biomarker research with over 400 assays available by immunoassay (such as Salivary Cortisol, Complement, Cytokines, LPS, Adiponectin, Retinol Binding Protein, Calprotectin, Bile Acids & Periostin) and radioimmunoassay (such as Glucagon, P3NP, 1,5 Anhydroglucitol (1,5-AG), Total Ghrelin & PINP). Additionally, we are able to facilitate most study requirements by utilising the broad wealth of scientific expertise and large repertoire of analytical instrumentation within Viapath's pathology services at Kings College Hospital and Guys and St Thomas' Hospitals which include assays performed in the departments of Biochemical Sciences, Blood Sciences, Diagnostic Immunology and Allergy, Genetics, Haematological Malignancy, Haemostasis and Thrombosis, Reference Biochemistry and Toxicology.

Research & Development Division

Viapath's in-house team of scientists, assistants and administrator are dedicated to offering the highest quality of services and result generation. All staff adhere to the regulatory requirements set out by Good Clinical Practise (GCP) and Human Tissue Authority (HTA). Our experienced scientists are able to help with:

- trial design
- assessing scientific validity

- analytical expertise
- statistical analysis
- methodology write ups



Figure 1 - Contract Research & Development laboratory

For further information, please visit:

<http://www.viapath.co.uk/departments-and-laboratories/contract-research>

Please contact one of our team of experts for more details on how we can help you to take your research study forward:

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Contract Research and Development Team:
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Figure 2 - Contract R&D Immunoassay



Figure 3 - Contract R&D sample processing

IBMS Congress 2017

Kieran Voong—A personal experience

There was a strong Viapath presence at the IBMS Congress this year with many Viapath employees speaking on a variety of topics: Professor Jonathan Edgeworth, Viapath's Medical Director, spoke in the plenary session on **Transformation and Consolidation** and outlined some of the issues that Viapath has faced since its inception.

David Wells, Director of Operations for Reference Services lectured on a range of subjects from **molecular pathology to multi site accreditation**; Erin Mozely talked about **Inherited Metabolic Disease: screening and diagnosis**; Dr Guy Orchard spoke about **Haematoxylin and a pilot EQA scheme for Mohs**; Karolina Wojcik had a talk entitled **A comparison of BRAF V600E immunohistochemistry and molecular screening in 71 cases of malignant melanoma** (for which she won an award for best short paper); Fiona Denham had a lecture entitled **How to be a successful quality manager**; Dr John Mee gave two presentations on **dermatology** and Dr Gary Moore gave a talk called **Beyond textbook diagnosis**.

You can listen to Professor Edgeworth's talk in its entirety at <https://www.mixcloud.com/ViapathFutureLeaders/professor-jonathan-edgeworth-transformation-and-consolidation-a-partnership-model>

Podcasts and posters

I was privileged to attend Congress for the whole four days and as well as attending seminars and viewing posters, I promised to produce podcasts; recording interviews with some of the eminent speakers and poster presenters.

This seemed like a straight forward thing to do until I realised that Congress is spread over 9 conference halls, involving approximately 100 speakers and over

2000 delegates, and has the largest healthcare science trade show in the UK.



Figure 2 - Erin Mozley and Kieran Voong

In preparation, I looked through the list of talks and gave myself the task of setting up at least 3 podcasts each day. As well as liaising with speakers from Viapath, I was able to get in touch with lecturers that I was looking forward to hearing to see if they would be willing to talk to me - I was lucky enough to be able to speak to a few of them!

You can hear all my podcasts from Congress by visiting: <https://www.mixcloud.com/ViapathFutureLeaders>

Winning Posters



Figure 3- Some Viapath poster presenters (clockwise from top right): Volha Klimovich, Devilla Gorman, Debbie Burden, Mohammed Shams, Aimee Rhodes, Elaine Bromidge and Katarzyna Mayer

Viapath had a lot of interesting and informative posters on display over the entirety of Congress, ranging from departments such as clinical chemistry through to haemostasis and dermatology.



Figure 1 - Viapath stand at IBMS



Figure 4 - IBMS poster winners Andi Wilson and Charlotte Lee

These posters are submitted for judging each day with the best ones in their category receiving a cheque for £150.

On Tuesday, the prize for the virology category was won by Viapath's Andrea 'Andi' Wilson from Virology, based at St Thomas' Hospital. This was a fantastic achievement especially as this was the first poster that she had ever produced.

I managed to catch up with Andi for a short chat about the poster too and this can be heard at <https://www.mixcloud.com/ViapathFutureLeaders/compilation-of-ibms-congress-2017-short-podcasts/>

Viapath also had another winner! Charlotte Lee, a trainee biomedical scientist from Immunology at Kings College Hospital, won the immunology category with her post entitled: *Skewed T Follicular Helper Cell Subsets in Common Variable Immunodeficiency*

Enter your work for an Advancing Healthcare Award



The **Advancing Healthcare Awards** is now in its 12th year and aims to recognise and reward projects and professionals that lead innovative healthcare practice and make a real difference to patients' lives. The awards are open to healthcare scientists, allied health professionals and those who work alongside them in support roles. The awards are unique in that they are UK-

wide and cover all these professional and specialists groups whose achievements so often go unnoticed.

There are 14 award categories in total with an overall winner chosen from the category winners. Four of the awards are open to healthcare scientists only and are supported by the Academy for Healthcare Science.

Viapath is sponsoring **The Viapath award for innovation in healthcare science** and is about recognising and rewarding the vital contribution of science to healthcare delivery. We are looking for **innovation that is sustainable, transferable and plays a demonstrable part in delivering service transformation**. The judges will be looking for scientific initiatives for delivering care that have improved the integration of services, speeded up diagnosis and treatment and given patients greater control of their own care.

The deadline for entries is 5pm on Friday 19 January 2018. At least one team member in any entry should be a healthcare scientist working in the UK.

To find out more about the award categories and the Advancing Healthcare Awards 2018 visit www.ahpandhsawards.co.uk and you can download our **Guide to writing a winning entry** [here](#).

A day in the life of...A Senior Biomedical Scientist in Viapath's Red Cell Laboratory

The title of Senior Biomedical Scientist sounds quite lofty and intelligent to non-scientists, yet many people in the position will tell you it is just a job. Whilst at times it may feel this way, the role does require knowledge and experience, an ability to work and communicate effectively with colleagues, and a willingness to move with the changes in technology. In the Red Cell Laboratory, we bring all of this together working as a team to get results out in a timely manner whilst keeping up with the quality standards that we must adhere to in order to produce reliable results.

So here is a brief example of my day, how does it compare to yours?

- Get in early, to get a head start on what I know will be a busy day
- Start performing some laboratory tests such as assays for red cell enzyme deficiencies, EMA for hereditary spherocytosis, HPLC analysis of haemoglobinopathies and sickle screening in newborns
- Answer the phone
- Have a brief staff meeting
- Check some results (answer a query from another staff member in between)
- Start authorising some results (answer a phone query in between)
- Quickly do a quality check that a staff member needs doing before they can continue with their work
- Finish authorising that set of results
- Type up a letter to be sent to counsellors regarding follow-up testing of a patient, and try to get it signed by a manager who is in meetings all day
- Help another staff member with an assay problem and learn that I am surprisingly handy with a screwdriver
- Finish off a PowerPoint presentation for an educational meeting with other laboratories, your clinical lead and some trainees
- Go to lunch
- Return from my brief respite only to find an unexpected sample has arrived which requires

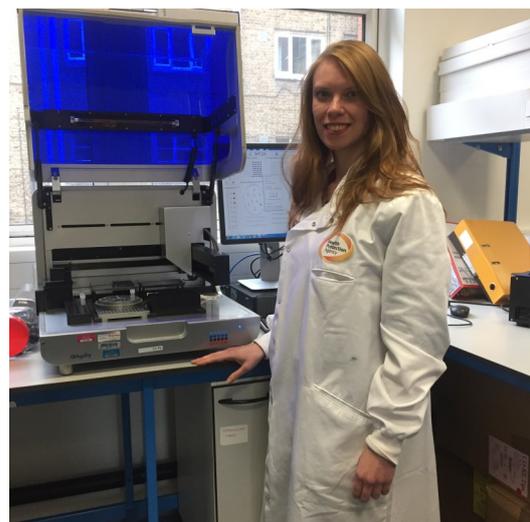
processing that afternoon and collaboration with another department (who are also short-staffed)

- Take a phone call querying a result from a doctor/midwife/counsellor/another laboratory
- Check some more results in between doing that urgent test
- Realise I still haven't checked my emails for the day, or started that weekly results list my colleague (who is on annual leave) usually does
- Get the list done and start planning the next day!

Some of the Red Cell Laboratory samples are urgent, as Viapath serves a large community of sickle cell and thalassaemia patients who sometimes require urgent pain treatment and transfusions, and special measures during operations, as well as providing a selection of other specialist red cell tests.

My brief description above shows how busy and demanding our laboratory can be, yet at the same time it provides a challenge, which is what keeps the work interesting. I have been in this role for over four years, yet I still learned two new things, in passing, today from my colleagues.

There are always new issues to confront, and a variety of people to interact with. And a love of science is a must!



Claire Laas, Senior Biomedical Scientist

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Or visit: <http://www.viapath.co.uk/departments-and-laboratories/red-cell-centre-molecular-diagnostics-laboratory>

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