

ACB News

The Association of Clinical Biochemists • Issue 486 • 20th October 2003



**CE Marking
an In-House
Assay for
Real**

**MRCPath
Success Tips
Part II**

**Dextro
Headache
Solution**



The **New** Force in Global Diagnostics



AIA 21
Automated
Immunoassay
analyser



AIA 600 II
Table-top Automated Immunoassay
analyser



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High throughput Automated
Immunoassay analyser



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G7
Automated HbA1c and Thalassemia
Analyser



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The Editor is responsible for the final content. Views expressed are not necessarily those of the ACB.

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Front cover:

The Bull sculpture at Bullring, Birmingham (Laurence Broaderrick, 2003)

focus2004

ICC • BIRMINGHAM • 18-20 MAY

The Association of Clinical
Biochemists National Meeting

ICC, Birmingham

Tel: 01223 404830 Fax: 01223 404841

Email: info@focus-acb.org Web: www.focus-acb.org

Big Bull and More in Brum . . .

ACB News brings you the Invitation to Participate for Focus 2004 this month. For those downloading ACB News you can of course also get the PDF of the Focus 2004 brochure from www.focus-acb.org

This year the meeting returns to Birmingham and is held at the International Convention Centre in the heart of the city.

Delegates will find that Birmingham has changed since the last visit of Focus in 1997. A radical new Bullring area has opened up in the centre of the city. The Bull, which features on the front cover of ACB News, is just one of a number of items of public art in Bullring and has made a great front page photo for the Focus Programme.

The Selfridges store is also featured in the Invitation to Participate. This has been the cause of huge interest around

the world, with its bold aluminium disc cladding and curvaceous shape making it quite stunning. Some of the social events, including a

walking tour of the city will enable delegates to look in more detail at the architecture and public art of this new part of Birmingham. ■



David Vallance and Ann Bowron preview the scientific programme at Focus 2004 at a recent organising meeting



Jonathan Berg, Focus 2004 Local Organising Committee Chairman, with the Selfridges building

Who was the UK's Number 1 Immunochemistry company in 2002?



The latest independent market survey confirms that Roche
Diagnostics are the new **UK market leader in Immunochemistry**
whilst retaining their position at number 1 in Clinical Chemistry.

MODULAR ANALYTICS E systems offer many advantages including:

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ACB News Stimulates CE Marking Debate

ACB News has received considerable feedback on the ten pages of editorial looking at the issue of CE marking in-house assays published in September. Views vary markedly but at present the Editor has not resigned! Here are a selection of comments that we have received, either on email or in more direct communications:

"NHS laboratories have had plenty of time to get up to speed with CE marking. The MDA held seminars last year and ACB members attended. No one in the NHS environment has done anything until ACB News went big on it"

Corporate Member

"The whole thing is ridiculous and will be overturned. We are not going to do anything about CE marking"

Regional Service Scientist

"No longer can laboratories ignore the kit insert and modify reagents to serve their own ends. Nowhere else in Europe do professionals do that to our kits to save a few pennies"

Company Representative

"Clinical laboratories in the UK are reeling from shock following the open publication by the Medicines and Healthcare Products Agency of two letters dictating the need to CE mark some IVDs that are made in-house that put at risk thousands of "home-brew" IVDs. It seems that most laboratories were totally unaware until they read the MHRA's statements of the fact that the IVD Directive applied to them and are now rushing to establish where they stand and what rules they need to comply with."

Clinica Editorial 9th September 2003

"We are getting on with it right now and I am working flat out to CE mark the assays we need to."

Quality Officer, Northern Teaching Trust

"Everyone should read the ACB News, September edition"

Comment at CPA AGM

"Laboratories think they are in trouble . . . they should talk to some of the companies!"

Company Representative

"No other European country is applying the IVD Directive like this. Other European societies have not even heard of this issue"

ACB Committee Member

" We are dropping assays and stopping to support several of our older machines because of CE marking. The virologists are not very happy"

Representative of a Large Diagnostics Company

"We learnt a lot getting to grips with the FMEA risk analysis. Even better a couple of weeks later it came up as an exam question in the Part I MRCPATH"

Exam Candidate, MRCPATH Part 1,
September 23rd 2003

" We will get our tandem mass-spec methods in place before 7th December and at least then we have got two years grace"

Consultant in a Lab with a "Big Boy's Toy"

"CE marking our first in-house assay has to be a "win-win", as it has both improved our procedures and potentially makes the assay more marketable".

Editor, ACB News - October 2003

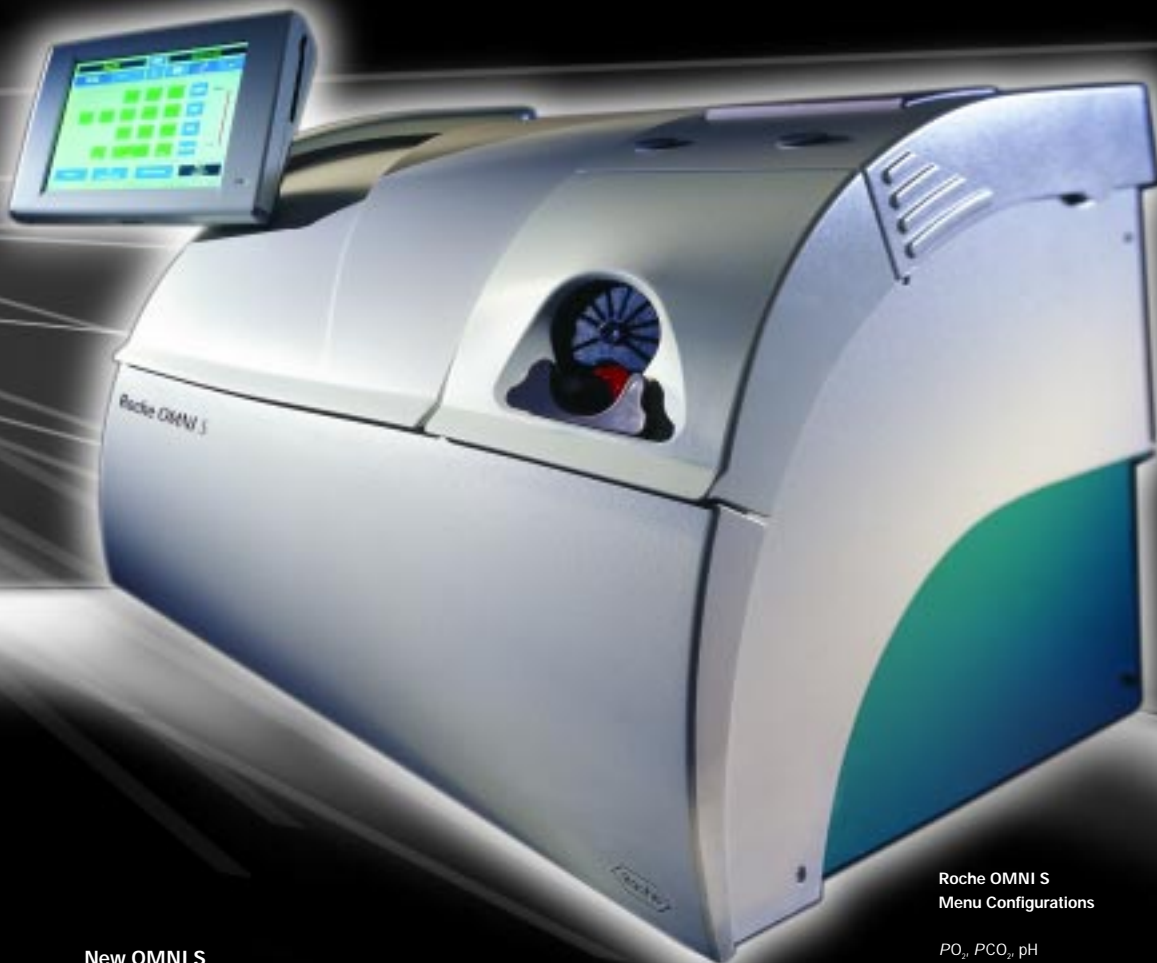
For those who want to keep up-to-date about CE Marking the National Audit Meeting on 27th November will have a substantive talk by Sue Spencer, one of very few professional consultants in the UK on the CE marking process. ■

Focus Dates to Remember

Abstract Submission Deadline: 9th January 2004

Late booking fee applied after: 1st April 2004

One giant leap for Critical Care control



New OMNI S

Critical Care testing has evolved: meet the intuitive new blood gas analyser from Roche Diagnostics. Designed for maximum ease of use and reliability, OMNI S has many new features that will reduce demands on your time:

- New reagent concept using RF transponders - going beyond bar code technology
- New availability of Bilirubin and low sample volume ideal for neonatal units
- Flexibility to meet the needs of your Critical Care setting through extended parameter portfolio and modularity
- High quality readings with minimised user interaction frees up time to focus on what really matters - your patient
- Can be linked directly with OMNILINK management system for constant assessment and troubleshooting from remote PC

Roche OMNI S Menu Configurations

*PO₂, PCO₂, pH
Na⁺, K⁺, Ca²⁺, Cl
Glu, Lac, Urea, Bilirubin
O₂, Hb, HHb, COHb, MetHb
Total Haemoglobin tHb
Oxygen Saturation SO₂
Haematocrit Hct*

**Please contact your local
Roche HosPOC representative
for further information**



Diagnostics

Roche Diagnostics, Bell Lane,
Lewes, East Sussex BN7 1LG
Tel: 01273 480444
www.rochehospoc.co.uk

Point of Care Testing and Informatics

**A One Day Meeting
organised by the
ACB Informatics Group**

4th December 2003

**The Conference Room
Association of Clinical
Biochemists
130-132 Tooley Street
London**

POCT: What Might the
Future Hold?

Joan Pearson, Leeds

POCT Connectivity:
Present and Future

Doug Hirst, Bradford

The Oxford Experience:

Successes and "Issues Still
to be Resolved"

Jonathan Kay, Oxford

The Need for Unique Patient ID:
A Scottish Approach
Ian Godber, Wishaw

Full details will be available at:
www.acb.org.uk/meetings/POCT.htm

Places are limited to 60,
and will be allocated on a first-come,
first-served basis.

Cost including lunch:

£80 - ACB Members

and £100 non-ACB Members.

For further details please contact:

Association of Clinical Biochemists
130-132 Tooley Street, London SE1 2TU

Tel: 0207-403-8007

Email: bookings@acb.org.uk

West Midlands ACB Region Screening for Health

**Clinical Sciences Building
Walsgrave Hospital, Coventry
Wednesday 21st January 2004**

- 14:00-14:30 Registration and coffee
Chairman: Dr Jonathan Berg,
Chairman, West Midlands ACB
- 14:30-15:20 Robert Gaddie Memorial Lecture:
Consent or be damned
Professor Jean McHale, Professor of
Law, Leicester University
- 15:20-15:50 The UK Colorectal Cancer
Screening Pilot – the English Arm
Mr Ron Parker, Director of
Screening and Consultant Surgeon,
University Hospitals of Coventry
and Warwickshire
- 15:50-16:10 High tea
- 16:10-16:40 Toley Testing!
Dr Steve Smith, Consultant Clinical
Biochemist, University Hospitals of
Coventry and Warwick
- 16:40-17:20 Screening for Health: is Genetics
the Answer?
Dr John Archer, Geneticist,
Cambridge University
- 17:20-17:45 Conclude and depart

*Registration for this meeting is free and open to
ACB members and other interested professionals.*

*To register please contact Dr David Kennedy,
Meetings Secretary, ACB West Midlands Region,
Good Hope Hospital, Rectory Road, Sutton Coldfield,
West Midlands B75 2RR. Tel: 0121-378-2211
Email: meetings@acbwm.org.uk*

Delegate Costs are Down . . .

The Focus 2004 committee are keen that as many delegates as possible attend the whole meeting and to this end costs of the full delegate package have been kept extremely low. Indeed, for just £400 you can have registration, accommodation and the full social programme – compare that with other meetings and you are getting a really brilliant deal! Great science, a terrific exhibition and a fantastic exhibition – what an absolute bargain! ■

ACB (Southern Region) Meeting

University of Sussex, 9th December 2003

A programme to celebrate the opening of the Brighton and Sussex Medical School

Morning session: Chair, Dr Gary Firth

- | | |
|-------------|--|
| 09.55-10.00 | Introduction and welcome |
| 10.00-10.45 | Endotoxins
<i>Professor J Cohen</i> |
| 10.45-11.30 | Developments in cardiac medicine
<i>Professor Richard Vincent</i> |
| 11.30-12.00 | Osteoprotegerin in health and disease
<i>Suki Sankaralingam</i> |
| 12.00-12.15 | Retirement presentations |
| 12.15-13.15 | Lunch |

Afternoon session: Chair, Elizabeth Hall

- | | |
|-------------|--|
| 13.15-14.00 | Responding to the threat of bioterrorism
<i>Angela Iversen, Dr Peter Sharp</i> |
| 14.00-14.45 | Control of hepatic carbohydrate metabolism in endotoxic shock
<i>Dr Mike Titheradge</i> |
| 14.45-15.15 | Tea/coffee |

Education session: Chair, Dr Bernie Rocks

- | | |
|-------------|--|
| 15.15-15.45 | Modern approaches to undergraduate medical education: implications for diagnostic medicine
<i>Dr John Kay</i> |
| 15.45-16.15 | Education of Clinical Scientists into the 21st century
<i>Janet Smith</i> |
| 16.15-16.30 | Discussion |

The meeting is £15 for members (free to Grade As). Please send applications and cheque (payable to ACB Southern Region) to Dr Maria Firth, Hurstwood Park Neurological Centre, The Princess Royal Hospital, Haywards Heath, Sussex, RH16 4EX by Wednesday 3rd December.

Associate Editor Required

Judith Burrows, who has been the Associate Editor of ACB News for several years leaves for New Zealand at the end of the year.

We are now looking for a new person to join the team. Duties include proof-reading and working on editorial. This can include some investigative journalism and reporting of scientific events.

If you are interested then please contact the Editor at: Tel: 0121-507-5353 or Editor.ACBNews@ACB.org.uk



Applying for a CE Mark

By Jonathan Berg, Editor

Audit of In-House Assays

Prior to undertaking a test CE mark registration we audited the in-house assays throughout our Pathology Department. In Clinical Biochemistry we had seven assays that were clearly in-house. There are more if we include situations where we are using alterations to commercial kits, for example by using different standards or reagent volumes which is particularly applicable to some of our specific protein assays. However, we await more detailed guidance on such aspects and are just sticking to the “barn door” situations. Four in-house assays were based on chromatographic techniques in our Vitamin laboratory and three were specialist enzyme activity assays.

Careful Choice of Test to Pilot

We decided to make life simple by choosing a new in-house assay which has been developed over the last eight months in our department. It had been worked up by two of us and we have kept comprehensive day books on all aspects of the assay development, even down to review meetings where we looked at approaches to getting the assay working and robust. The assay has the following components:

- Preparation of red blood cell lysate and determination of haemoglobin content.
- Enzyme incubation with substrates in a controlled environment.
- HPLC determination of product.

Lysate haemoglobin is determined using a micro-method developed by us on a clinical biochemistry analyzer. It uses a commercial haemoglobin reagent supplied for our main analysers in the Haematology Department and is clearly an in-house procedure when used in our modified application. We manufacture a number of reagents for the enzyme assay, including mobile phase, standards, control materials and a reagent mix which includes substrates in buffer. We took professional advice on all this and our approach was to apply for one CE mark for the method in totality. This does mean, for example, that our lysate haemoglobin method is only CE marked as part of the overall method and probably not as a stand alone technique.

Technical File Contents

The technical file is the way forward. It contains everything required to keep a potential inspector happy in the future. This is what it contains:

Essential requirements checklist: We modified an essential requirements checklist that we found on a website of a Primary Care Trust! This is based

Following extensive coverage of the Medical and Healthcare Products Regulatory Agency (MHRA) guidance letters on CE marking last month, we report on the work involved in applying for a CE Mark for one in-house assay

on the IVD Directive. Each essential requirement was reviewed for its relevance and we then responded on a table as to whether everything was in place for each item. From this review we were able to examine any areas that needed further work prior to sending in our form for CE mark self-certification to MHRA.

Data Section: In the data section of our technical file we have included evidence that the assay had been properly established in all technical areas. Key components of our data included the full text of a paper describing our method, already submitted to the Journal of Chromatography, comparisons with another assay at a reference laboratory and citations in the laboratory day-books where the work-up of the method can be found. We also included our Standard Operating Procedure, information sheet to users of the service and of course the details on our website.

Risk Analysis Exercise

This is the area that took the most work and needed us to reach a higher level of understanding prior to starting. We soon realised that we needed to perform a Failure Mode and Effects Analysis (FMEA) relevant to a medical device. FMEA is a bottom up approach, where each component of the system is analysed with regard to the potential for failure. One can then go up one level at a time and assess the risk of failure as components are brought together. There is a huge amount on the internet about this approach and it is a really interesting area to research – if only we had more time!

We looked at commercial software packages available as demo models on the internet and indeed tried out one, Sabaton (www.sydvest.com) in detail. It was easy to understand the software once the concepts of a “bottom-up” risk analysis became more familiar. However, once we got our risk entries into double figures Sabaton decided this was beyond the remit of a demo programme! We finally designed our own Excel spreadsheet which would enable us to perform the risk analysis.

The risk analysis included an assessment of the chance of a failures occurring and then offers solutions. Once this process was complete we prioritised the risks and looked at modifications that could reduce risk in the system. Getting to a level of understanding and performing the risk analysis probably took one working week of research before two of us spent an afternoon actually performing it. However, further risk analyses will be much quicker. For those with large numbers of analyses to undertake, a commercial software package would be useful. Of course if you are looking at a lot of similar assays then there will be considerable overlap and a time saving.

Quality System

Our laboratory is fully CPA accredited and our new test had already been notified to CPA. However, to comply with CE marking we certainly identified some areas to improve, from both the risk analysis and our reading of the IVD Directive, that meant we needed to introduce new elements, as follows:

Reagent Manufacture: We have made a number of changes here. For example, while we used to write the date mobile phase was made up on the bottle this is clearly not adequate for a CE Mark. We have had to put in place a system for recording all facets of how, when and who has made up reagents, standards and internal quality control materials for our in-house assay. We have had to decide upon expiry dates for all these items and also stipulate more fully than before the storage conditions. All this detail is now in our SOP, which has become one of the longer ones in the Department!

Vigilance System: We have introduced a vigilance system, such that any problems with our in-house assay are properly noted through written comments and referred back to the “manufacturer” which of course is ourselves. The vigilance system includes a checklist

form with an area for feedback comments and notes of daily readings, which can help us monitor any change in performance of the in-house assay. For example we now record in writing readings such as the HPLC pump pressure and water bath temperature and have an area for operators to comment on anything unusual on a daily basis. Of course it is commonsense that an in-house assay should have all this in the same way we record signals from electrodes on a blood gas analyser. However, we did not do this and would guess that very few laboratories operated their in-house assays to this degree of rigor.

Introduction and other evidence: The technical file included an introduction, and a “CE declaration of conformity”. Again, we found a number of examples of a conformity declaration on other people’s websites and modified one for our own use. The Technical File is a living document, just like an SOP, and further risk analyses and updates to the method will need to go in the file on a regular basis

Submission to MHRA

As a self-certification assay we completed the MHRA form RG3 and submitted it with the standard fee of £70. Of course we could have submitted all our in-house assays at one time for a total of £70 if we had been ready! Within 5 working days, we received a letter from MHRA informing us that our registration was progressing and a few days latter we received a receipt. There was no relevant Group Code for our assay and therefore we had to describe it in the free text box on the form. This seems to have delayed things at the MHRA as the technical team had to decide an appropriate coding for our in-house assay.

CE Marking Lessons

The process of building up the evidence in a technical file for submission of one in-house assay for CE self-certification appeared daunting. In practice we quickly acquired the knowledge and skills and simply had to make the time. Overall the process of applying for a CE Mark was a positive thing. There are a number of things that we have put in place before we could send our form in and overall we can see the benefit of what we have done. When problems arise in the assay we will potentially see these at an earlier stage, now that we have a higher level of vigilance and feedback in place.

Of course we will not know if the contents of our technical file meet the required level of stringency until one day in the future someone from MHRA knocks at the door. However, we have done our best and will of course be open to any positive comments, just as we are when the CPA inspector calleth!

Perhaps the biggest thing we had to get over in this work was the somewhat artificial separation between the “manufacturing” side of an in-house assay and the “operation”. It was in trying to distinguish between these areas that we struggled at the outset.

We certainly feel that the approach to our other assays will be easier. However, as they have been established for some years whether we have the evidence for the technical file is another matter. For example, if you keep standards aliquoted in a freezer but do not have data on a stability experiment of such storage then I guess there is new experimental work to do before you can sign a conformity letter and send in form RG3. So, for us at least, new properly worked up assays appear easier to CE mark than those that have been established for years. CE marking our first in-house assay has to be a “win-win” as it has both improved our procedures and potentially makes it more marketable. Whatever any further guidance from the MHRA says it is our intention to CE mark all relevant assays in coming months. ■

WELL, DID YOU LEAVE ENOUGH TIME AT THE END OF THE EXAM TO CHECK YOUR ANSWERS?

YES, ABOUT TWO AND A HALF HOURS!



Website of the Month: Online Medelian Inheritance in Man (OMIM)

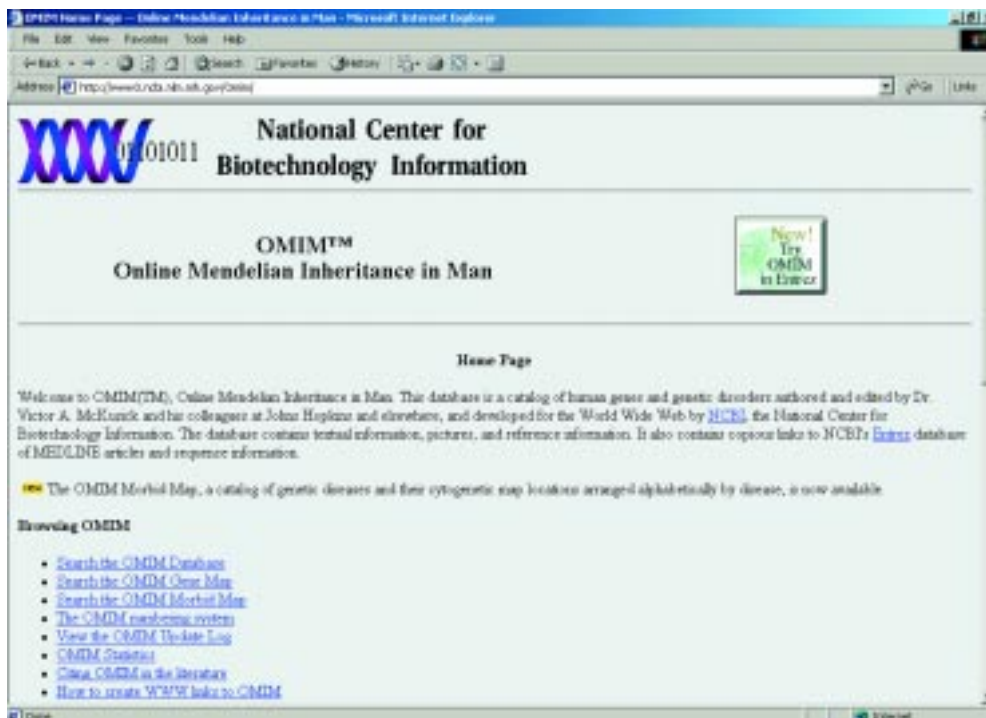
By Dr Tim Lang, Oxford

<http://www3.ncbi.nlm.nih.gov/Omim>

This is easily searchable database of genetic disorders, which is run similarly to PubMed. It has similar search options with links to many other related sites. Once you have found the condition you are looking for it allocates it's a unique number, its MIM number. Following this link provides the user with a vast amount of information ranging from clinical features and pathogenesis to genetics and variability.

A particularly useful tool of the site is the clinical synopsis, this summarises all the important clinical and laboratory features on one page. There is a bias to the genetics of the disease but I found that it is an ideal starting point for researching information on a particular condition. It is a useful tool for the laboratory supporting a paediatric service in a non-specialist hospital.

- Don't forget links to all past and present 'Websites of the Month' are available from the ACB website (www.acb.org.uk). If you wish to suggest a site for the 'Website of the Month', please submit a short review (150-200 words) to Ian Godber at Wishaw General Hospital (webmaster@acb.org.uk). ■



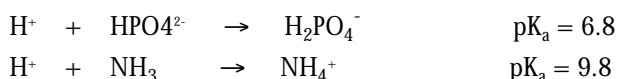
Deacon's Challenge

No. 31 Answer

The normal pH of plasma is 7.40: the minimum pH of urine is 4.5. Assuming an average urine volume of 1.5L/24h, estimate the limit of titratable acidity of the urine, **indicating what assumptions you make.**

MRCPATH, May 1999

Acid in urine exists as free hydrogen ions and hydrogen ions bound to salts (i.e. buffered). The two principal buffers in urine are phosphate and ammonia:



By convention, titratable acidity of urine is defined as the amount of acid consumed when urine is titrated with alkali to the pH of the glomerular filtrate (the same as plasma pH i.e. 7.40).

Since the pK_a of the ammonium ion is at least 2 pH units above the plasma pH, it exists almost entirely as NH₄⁺ and there is virtually no free ammonia available for buffering secreted acid. Therefore, ammonium ions do not contribute significantly to titratable acidity. Similarly, at pH 4.5 bicarbonate (pK_a 6.1) is virtually completely consumed. By contrast, the pK_a of phosphate is close to blood pH and is present in sufficient amount to act as the primary urinary buffer.

The amount of phosphate available for buffering, i.e. the amount of HPO₄²⁻, can be calculated from the Henderson Hasselbach equation, the plasma pH and the urinary total phosphate:

$$\begin{aligned} \text{pH} &= \text{pK}_a + \log_{10} \frac{[\text{HPO}_4^{2-}]}{[\text{H}_2\text{PO}_4^-]} \\ 7.40 &= 6.8 + \log_{10} \frac{[\text{HPO}_4^{2-}]}{[\text{H}_2\text{PO}_4^-]} \\ \frac{[\text{HPO}_4^{2-}]}{[\text{H}_2\text{PO}_4^-]} &= \text{antilog}_{10} (7.4 - 6.8) = \text{antilog}_{10} 0.6 = 3.98 \end{aligned}$$

If the total amount of urinary phosphate is known, then the amount of each species of phosphate can be calculated:

$$\begin{aligned} [\text{Total phosphate}] &= [\text{H}_2\text{PO}_4^-] + [\text{HPO}_4^{2-}] \\ [\text{H}_2\text{PO}_4^-] &= [\text{Total phosphate}] - [\text{HPO}_4^{2-}] \\ \frac{[\text{HPO}_4^{2-}]}{[\text{Total phosphate}] - [\text{HPO}_4^{2-}]} &= 3.98 \end{aligned}$$

Rearranging and solving for $[\text{HPO}_4^{2-}]$:

$$\begin{aligned} [\text{HPO}_4^{2-}] &= 3.98 [\text{Total phosphate}] - 3.98 [\text{HPO}_4^{2-}] \\ [\text{HPO}_4^{2-}] + 3.98 [\text{HPO}_4^{2-}] &= 3.98 [\text{total phosphate}] \\ 4.98 [\text{HPO}_4^{2-}] &= 3.98 [\text{Total phosphate}] \\ [\text{HPO}_4^{2-}] &= \frac{3.98 [\text{Total phosphate}]}{4.98} = 0.80 [\text{Total phosphate}] \end{aligned}$$

The total phosphate concentration is not given. The daily excretion of phosphate is extremely variable and reflects dietary intake. One quoted range is 16-48 mmol/24 h. Therefore it would be reasonable to assume a value of 50 mmol/24 h as an estimate of the maximum daily excretion likely to be encountered. Therefore:

$$\text{Amount of } \text{HPO}_4^{2-} \text{ in 24 h urine} = 0.80 \times 50 = 40 \text{ mmol}$$

N.B. no use is made of the 24 h urinary volume.

At a urine pH of 4.5, (at least 2 pH units below the pKa of phosphate), essentially all HPO_4^{2-} is consumed by buffering H^+ , and the component of titratable acidity due to phosphate is therefore approximately 40 mmol.

At a pH of 4.5 the free hydrogen ion concentration can be calculated as follows:

$$\begin{aligned} \text{pH} &= \log_{10} \frac{1}{[\text{H}^+]} \quad \text{and} \quad [\text{H}^+] = \frac{1}{\text{antilog}_{10} \text{pH}} \\ [\text{H}^+] &= \frac{1}{\text{antilog}_{10} 4.5} = \frac{1}{31623} = 0.000032 \text{ mol/L} = 0.032 \text{ mmol/L} \end{aligned}$$

which is small enough to be ignored.

Therefore the limit of titratable acidity can be estimated as approximately **40 mmol/24 h** if the following assumptions are made:

1. Free hydrogen and bicarbonate ions and ammonia do not contribute significantly.
2. Phosphate is the major urinary buffer.
3. Other forms of phosphate (H_3PO_4 and PO_4^{3-}) are insignificant.
4. The maximum likely phosphate excretion is 50 mmol/24 h.

Question No. 32

A laboratory performs sweat tests by collecting sweat for 20 min using 5.5 cm filter paper disks. In order to comply with the proposed Sweat Test Guidelines that the sweat secretion rate should exceed 1 g/m²/min what is the minimum weight of sweat that should be collected?

MRCPath Success Tips Part 2

By Dr William Marshall, King's College, London

The Written Papers

In the previous article in this series, I described the scope and content of the Part 1 written papers: in this, I will indicate how you might prepare for them, and how to tackle the questions themselves.

The key to success in the examination overall, and in its individual parts, can be summarised as PPP – planning, preparation and practice. You would not undertake any other major endeavour without considering these. The examinations are a major endeavour and becoming a Member of the College will greatly facilitate (and in practice, often be a requirement for) obtaining a career grade senior post in clinical biochemistry.

Planning and Preparation

In addition to finding out about the nature and scope of the examinations, your planning should encompass a detailed work plan, including personal study and attendance at local, regional and national courses. I suggest that it is useful to make a (realistic) timetable, so that you are able to coordinate attendance at courses with personal study, and arrange to cover the whole curriculum in sufficient time before the examination to leave time to return to topics that you have found particularly challenging.

How Much Time to Prepare?

It is difficult to advise on how long you may need to be working intensively for the examination: many candidates will have an MSc in Clinical Biochemistry, and this can be invaluable in introducing you to the subject as a whole, and in ensuring that you cover topics that you may find intrinsically less attractive or have little or no exposure to in your own work. The College prescribes a minimum period of training (though exceptions can be made for exceptional students) but I would suggest that, as a rough guide, candidates who have an MSc should plan to spend a year of fairly intensive work preparing for the written papers, during that time spending perhaps two evenings and one day at weekends studying. More or less may be required, according to a candidate's own ability, personal circumstances, and, critically, the availability of protected time to study within the normal working day.

Sources of information

Your sources of written information will be largely textbooks and review articles. In my view, it is not necessary to source from original literature, except perhaps in the case of recent important developments.

Books

You will require your own copy of a standard textbook of clinical biochemistry. A textbook of general biochemistry is probably less important than one of human physiology. Clinical scientist candidates may find it helpful to have a simple textbook of general medicine, to provide background material. There are many suitable books in each category. Browse in a

bookshop with a good collection of biological science and medical books before you buy. Go for content, not just appearance, and avoid books that were published more than 4-5 years ago: they may well be out of date and/or about to be superseded by a new edition. And don't forget the ACB's own Venture Publications series.

Reviews

You should read the regular review articles that appear in *Annals of Clinical Biochemistry* and *Clinical Chemistry*. The *British Medical Journal*, *Lancet* and *New England Journal of Medicine* (all published weekly) carry frequent review articles and leaders on topics of relevance to clinical biochemistry and are a must. *Medicine*, the monthly part-text that over a three year period generates a textbook of general medicine, has whole issues or sets of issues devoted to relevant topics such as diabetes, nutrition, endocrinology, toxicology, etc. It should be available in all postgraduate libraries but why not persuade your department to take up a subscription? The *Medical Clinics of North America* series includes issues on metabolic and endocrine topics, while *Clinics in Endocrinology and Metabolism* covers these subjects exclusively.

Browsing and Networking

In addition to reading these sources systematically, be prepared to browse, and to exchange information with colleagues. Studying for any examination can be a lonely business – working with someone else, even if you only meet occasionally and mostly communicate by telephone or email, can provide additional stimulation, and help you realise that you are not alone.

Meetings and Courses

Attend departmental and local meetings: local clinical meetings are especially important, in my view, particularly for clinical scientists, so that you can see how laboratory data are used in diagnosis and management in clinical medicine, and how their contribution relates to that provided by other investigative techniques, for example, imaging. Attendance at ward rounds and clinics may provide similar opportunities but can be daunting for relatively junior members of staff and are primarily concerned with the delivery of health care, not teaching.

Local and national training courses and meetings also provide good educational opportunities. These can be enhanced by doing some preparatory work on the topic(s) beforehand, by being prepared to be an active learner and not just a passive listener, and by doing some additional reading afterwards. It is all too easy to think that you are learning something just by being present in a lecture theatre but deep learning requires an effort on the part of the listener.

Practice

Knowledge is the key to success in the written papers, and should encompass not just knowledge of the subject, but knowledge of what is required of you and of your own strengths and weaknesses. Think hard about the latter, perhaps with a trusted friend, so that you are able to build (and perhaps share) your strengths, and strengthen your weaknesses. It is satisfying to read a topic and realise that you know it well, but if you already knew that, it only provides a superficial boost to the ego. Better to work hard at a topic that you find difficult and master it: that will provide you with justifiable satisfaction that will stimulate you to further effort. If you can write a well-structured essay but find it difficult to write legibly at speed, concentrate on your handwriting, not on essay structure, or consider whether you are trying to write too much.

Submitting your work to be read and criticised by someone else can be difficult, but is a very important aspect of preparation. Try and find someone to do this who has experience of

the exams, and knows what is required. Don't be afraid to ask even senior members of the profession to do this. We've all done it in the past, we've all benefited from the input of our seniors in our time, and if someone hasn't the time to do this for you (within reason) their opinion probably isn't worth much, anyway.

Planning an Essay

Essays should have three parts: introduction, body and conclusion. By the time you come to sit the papers, you will probably know more about some topics than you can possibly write in the 40 or so minutes that you have. Read the question carefully and decide what the examiners want. If they ask you to give a critical account of the methods available for the measurement of glycated haemoglobin, do so: only briefly mention what it is and why it is measured. If, on the other hand, you are asked to describe it, its formation and importance in the management of diabetes, do that, and mention measurement only briefly. The introduction may include a definition or a pithy statement, followed by two or three key facts. Imagine that you are reading a newspaper article: if you couldn't find out what the article was about in the first two sentences, you'd abandon it and go on to something else. Journalists are told that the first sentence is the most important: so it should be in your essays. Get the examiners on your side by showing them at the outset that you know what you are writing about and are going to make their job easy for them.

In the body of your essay, imagine that you are taking them by the hand and showing them round an exhibition of your knowledge. You would take them to the most important things first: do that in your essay. Hold their attention. If you have a lot of relevant information that you won't be able to include in detail, make reference to it so that they know that you know more is in front of them: to pursue my analogy, give them a peep through the door labelled 'rare but interesting' but keep them focused on 'common and important'. Prioritise; discuss frequent conditions/standard methods or techniques before rare/novel ones; stay focused; draw on your own experience; keep asking yourself, 'Am I answering the question?' and so on. Use diagrams and flow charts if they can usefully illustrate your text: they can also save time, but don't waste it by duplicating their content in your essay.

Aim to write a concluding paragraph of three or four sentences, summarising what you have written. Read the question (again). If you have been asked to come to a conclusion, do so. Finish with a clear, positive statement. Leave the examiner wanting to give you a high mark.

In the Examination

You should have furnished yourself with a pen or pens that you are comfortable using and that write legibly and without producing blobs and smudges. Do not use correction fluid: if you make an error, cross it through. Correction fluid takes ages to dry and if you try to write over it wet, it will gum up your pen and you'll waste precious time attempting to declog it.

When you are writing practice questions, you may have chosen them yourself (but they are only worth doing if you write them under examination conditions) or have been given an idea of the general area that the question will cover. Whether you try to 'spot' questions (I don't recommend it) or not, you will not have that advantage when you come to the examination. Help yourself by following a few simple rules. First, read the whole paper through. Sit on your hands, do what you will, but do not start writing immediately. Second, decide on which questions you are going to answer. You may be able only to select two or three easily: that's enough at this stage. Which one will you find easiest? Do that one first – but still plan it. You may be able to save a few minutes if it's a familiar topic that you have practised, and while you are writing it, your subconscious mind will be doing some preliminary work on the other questions. Third, keep an eye on the clock: do not run over time. Fourth, ignore the

other candidates. The examination is not competitive so they are irrelevant to you: whether they appear to be writing reams without pause while you are stopping frequently for a few seconds' thought doesn't matter.

Try to finish a few minutes before the end so that you can look over what you've written: the vital fact that remained tantalizingly on the tip of your pen (as it were) in an earlier question may now slip effortlessly on to the page.

Leave when you're told that you can go, first checking that you have included your candidate number on the answer books. Examination post mortems are rarely encouraging, but rarely avoidable: if you can manage not to agonise over what you have written (or not written) with other candidates, you may sleep better. It's out of your hands now. You've done your best and it's down to the examiners. If you've passed, your next hurdle will be the Part 1 Practical and Oral, which I'll discuss in the next article. Also, because I don't want to taint this one with any negative sentiment, I'll also discuss how to cope if your number does not appear on the pass list.

- Thanks Trevor Gray and Beverley Harris for their comments on early drafts of these articles.

Coming soon

The Practicals and Oral

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Euromedlab Barcelona 2003

Reported by

The congress brought together delegates from all over Europe, and beyond, for what was an excellent scientific congress, and a fantastic display of Spanish hospitality.

During the opening ceremony two opening lectures were given. The first lecture entitled 'Modernism': a dazzling style' was delivered by Professor Daniel Giratt-Miracle, an art critic and historian. He described how Catalonia after a long period of decline began a period of renewal in the 19th century with an aim to restore its national identity lost in 1714. Dr Mariano Barbacid, Director of the Spanish National Cancer Centre, gave the second lecture entitled 'Preclinical models in cancer'.

Human Tower and Obesity

The welcome party was held at the 'Poble Espanyol' (Spanish village), an area of 116 houses illustrating building styles from all over Spain, originally laid out for the 1929 International Exhibition. Here delegates walked around the village accompanied by a never-ending stream of tapas, served with local beers and wines. The final destination on our walk around the village was the square, where the main entertainment was held. A traditional Catalan human tower was followed by a performance to music that involved stilt performers, masked entertainers and dancers. This was visually stunning with lighting, fireworks, and smoke effects included. The evening was completed with a stop-off at Barcelona's magnificent fountain, which performs half hourly shows to orchestral accompaniment each night.

The scientific programme included plenary lectures on 'Obesity' (Prof Casaneuva, Spain) and 'Genetics of Alzheimers Disease (Prof Van Duijn, The Netherlands). The parallel sessions covered topics including 'Controversies in the diagnosis of growth hormone deficiency', 'Diabetes mellitus: the global challenge', 'Pharmacogenomics and pharmacogenetics', 'New applications on tumour markers', 'Trace elements in chronic disease', 'Obesity and cardiovascular diseases in the Mediterranean region' and 'Doping by enhancement of oxygen delivery to muscles' (don't ask!!).

A number of extremely popular industry-sponsored workshops were organised, these ran throughout the day, and included the 'Direct impact of Troponin I testing on the early diagnosis of AMI' chaired by our very own Graham Beastall. These were accompanied by parallel sessions, talking a wide range of subjects. A particularly interesting session looked at minimising risk, all the way from accurate sample identification to interferences in immunoassay.

Euromedlab 2003 was host to Europe's largest exhibition of laboratory products. There was almost too much to see in the exhibition,

*Euromedlab 2003,
the 15th
IFCC-FESCC
European
Congress of
Clinical Chemistry
and Laboratory
Medicine,
Barcelona,
June 2003*



although being held on two floors there was plenty of room to walk around each exhibit and to examine the newest analysers. It wasn't until I made my way to Booth 6 in the foyer that I realised why it was so quiet in the exhibition, and why I was able to walk freely around each stand: It seemed as though most of those attending the conference had also made their way to Booth 6. And why? Booth 6 was home to the ACB and the site of promotion for EUROMEDLAB 2005 in Glasgow. Everyone had rushed there to grab the very nice freebies (and for a chance to see Steven McCann in his kilt). Undoubtedly the highlight of the conference!

British Delivered Science, Glasgow and Whisky!

The ACB contingent divided their time at Barcelona between publicising the Association and the latest Venture Publications, and promoting the Glasgow congress in 2005. Roy Sherwood delivered the latest publication on Neonatology and Laboratory Medicine, straight off the press to the stand. The promotion for Glasgow was coordinated by Ian Godber, Steven McCann, and Vicki Grant, from the Glasgow based conference organisers, 'Meeting Makers'. This was a great success, with over 1000 forms requesting further information brought back to the UK. In return 1000 miniatures of whisky were generously given out to delegates, along with hundreds of other items and 3000 first announcements. Everywhere you turned within a mile radius of the congress centre, a 'Glasgow 2005' paper carrier bag could be seen.

During the closing ceremony, Graham Beastall invited delegates to Glasgow in 2005, and after a video illustrating the great welcome which will be extended to visitors to this conference, the delegates were piped out of the hall by Bill Richmond, to a Scottish reception of shortbread and Irn Bru, a fine way to round off an excellent week. ■





West Midlands ACB Region hosts

National Clinical Audit Meeting

Queen Elizabeth Postgraduate Centre
University Hospital, Edgbaston, Birmingham
27th November 2003

Morning Session

Chairman: Dr Jonathan Berg, Chairman ACB West Midlands Region

Paediatric Session

10.00-10.30 Sweat tests: from evidence to guidelines

Dr Anne Green

10.30-11.00 Audit of sweat testing protocols

Mr Paul Griffiths

11.00-11.10 Sweat tests: the NEQAS perspective

Mr Findlay Mackenzie

11.15-12.00 **In-house assays, the IVD directive and CE marking** Sue Spencer

12.00-12.15 Discussion on the impact of IVD on in-house assays

Lunch

12.15-13.15

Afternoon Session

Chairman: Dr Julian Barth, Chairman, ACB National Audit Committee

Plenary Lecture

13.15-13.45 Thyroid function tests

TSH is inadequate as a front line test

Dr Geoff Beckett

Clinical Validation Session

13.45-14.00 Critical limits

Dr Janet Tillman

14.00-14.20 Interpretative comments scheme

Mr Findlay Mackenzie

14.20-14.40 Clinical authorisation

Dr Peter Prinsloo

14.40-15.00 Do interpretative comments influence outcome?

Dr Eric Kilpatrick

15.00-15.30 Tea

GI Function Test Session


15.30-16.05 Overview of GI function tests

Dr Peter Hill

16.05-16.30 Audit of GI function tests

Dr Andy Duncan

16.30 Meeting closes/depart



The registration fee is £60 (£30 to Grade A trainees) to include coffee, lunch and afternoon tea. Demand is expected to be high so please register early to avoid disappointment, sending a cheque payable to "ACB West Midlands Region" to Dr David Kennedy, ACB West Midlands Meetings' Secretary, Clinical Biochemistry Department, Good Hope Hospital, Sutton Coldfield, West Midlands.

Further information, registration and abstract submission forms can be obtained the ACB West Midlands website or email David Kennedy at Meetings@ACBwm.org.uk



www.acbwm.org.uk



Letters

Readers speak out

Measurement of Recovery

I was very concerned to learn that a major immunoassay kit supplier has used an inappropriate procedure to calculate analytical recovery (Recovery calculations are over-optimistic; Sept 2003, ACB News).

The recovery of a method is the proportion (usually expressed as a percentage) of the concentration of the analyte which is measured by the assay. This is usually achieved by adding a known amount of analyte (the "spike") to a specimen in order to simulate the matrix encountered in routine use, then measuring the analyte using the analytical method in question. Since analyte-free specimen is rarely available the analyte concentration in the basal specimen is also measured and subtracted from the spiked value to give the measured value for the spike. In the approach used by DPC the result for the spiked specimen is divided by the sum of spike added and the measured basal concentration. For this recovery to be valid, the concentration of analyte in the basal specimen must be accurately known. This procedure is fundamentally flawed since they have used the measured value which is subject to the same under-recovery as that of the spike, with the result that recovery is seriously overestimated. The degree of overestimation will depend on the relative magnitudes of the basal and spike values.

It is also important to appreciate that recovery should never be estimated from a single pair of measurements. In the example quoted by Mike McConway, if we assume that the CV of this assay is 5%, then the SD at the value of 560pg/mL measured in the basal sample will be $5 \times 560/100 = 28$

pg/mL which gives 95% confidence limits of 504 to 616 pg/mL. These limits cover a span of 112 pg/mL, which is larger than the spike added (86 pg/mL), with the result that almost any recovery value could be obtained. I suggest that where possible basal and spike values of similar magnitude should be used and the mean recovery calculated from a large number of replicate measurements.

Dr Allan Deacon

Department of Chemical Pathology
Bedford Hospital
Bedford
MK42 3DJ

Dextropropoxyphene Headache Solution

The published solution to Deacon's Challenge No 30 is perhaps unnecessarily long, and the complexity of the approach leads to a rounding error in the calculation, though affecting only the fourth significant figure. Surely it should be enough to write as follows?

The required standard contains 100 mg per litre, that is 10 mg per 100 mL. 10mg dextro-propoxyphene is contained in $10 \times 565.7 / 339.5 = 16.66$ mg of the napsylate

Professor Tom Boyde

33 Oswin Street
London
SE11 4TF



Behind you for infectious disease diagnosis.

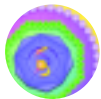
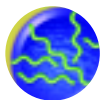
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Beaumont Hospital

Beaumont Hospital is a major teaching hospital, linked with the Royal College of Surgeons in Ireland covering North Dublin – City and County. It provides Accident & Emergency – Trauma services, together with national speciality services, including Neurosurgery, Renal and Pancreatic Transplantation, National Cochlear Programme and Regional Specialities. The hospital employs approximately 3,000 staff and has a complement of 630 beds.

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- demonstrated specialised knowledge and expertise in the area of endocrinology/toxicology/therapeutic drug monitoring.
- possess a high standard of professional attainment
- have excellent interpersonal and communication skills and a high capacity for responsibility and individual initiative
- demonstrate adaptability to the rapid changes taking place in the laboratory services within the health service

Closing date for receipt of application for this post is **Friday, 31st October, 2003.**

If you are interested in any of the above posts please forward a curriculum vitae (4 copies) outlining qualifications and experience to date, together with the names and addresses of two referees, one of whom should refer to a current employer, to the:

Recruitment Section, Human Resources Department, Beaumont Hospital, Beaumont Road, Dublin 9.

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Department of Clinical Biochemistry and Immunology

**Grade B Clinical Scientist
(11-16)**

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Applications are invited from state-registered Clinical Scientists. You will be employed at Heartlands Hospital, Birmingham.

You will have successfully completed a Grade 'A' training scheme or equivalent. As well as contributing to the service commitment of the department, you will be involved in development and research, clinical liaison, teaching and audit.

You will have a broad general background with, preferably, a research interest/experience and a track record of being a team player. There are teaching opportunities associated with the University of Birmingham and the University may offer honorary academic status where appropriate.

You will play a key role in the service provision and development of the laboratory. The department has research interests in hypertension, lipids and diabetes.

The department offers a comprehensive service to a population of approx. 500,000 and carries out 2.5 million tests per year. We have recently taken delivery of a major laboratory analytical system and the directorate was the recent recipient of a million pounds from the Government's pathology modernisation programme.

This post is an opportunity to further develop your career within a dynamic and supportive Teaching Hospital environment. The departmental team has close links with the hospital and actively carries out collaborative research, audit and service development.

For a job description and further information, or to arrange a visit, please contact Mr. E.F. Legg or Dr. A.F. Jones, Department Clinical Biochemistry and Immunology, Heartlands Hospital, Birmingham on 0121 424 3228 (Direct Line) or 0121 424 0199.

Alternatively E-mail:

Edward.Legg@heartsol.wmids.nhs.uk

Closing date: 29th October 2003.



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Consultant Clinical Scientist

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We provide services for routine biochemistry, inherited metabolic disorders, enzyme analysis and neonatal screening. You will be expected to participate in audit, scientific and clinical aspects of the service. You must be a registered clinical scientist, have MRCPATH and possess the skills, experience and motivation to contribute to our service provision for a wide range of clinical specialities.

For an informal discussion/visit, please contact Dr Ying Foo on 020 7813 8321.

For an application form and a job description, please contact our 24 hour recruitment line on 020 7813 8407, fax 020 7813 8227 or visit our website www.gosh.healthjobsuk.com
Please quote reference SP257.

Closing date: 3rd November 2003.

The Trust will apply for Enhanced Disclosure with the successful candidate, and confirmation of this will be required before the post may be taken up. For information on Disclosure please visit the CRB website at www.disclosure.gov.uk

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You will be a State Registered Clinical Scientist with MRCPATH or equivalent and willing to participate with us in providing leadership and motivation to ensure effective service delivery.

This is a whole time post, but part time appointments may be considered.

Requests for flexible working will be seriously considered.

For an informal visit/enquiry please contact Dr C Heyningen, Consultant Chemical Pathology on 0151 529 3907 or Dr I Watson, Consultant Biochemist on 0151 529 3575.

Applications form and job description available from Human Resources Department on 0151 529 3905, (24 recruitment line). Minicom users only, call 0151 529 5030. Please quote reference number A343.

Recruit@aht.nwest.nhs.uk

Closing Date: 28 November 2003.

Royal Free Hampstead

NHS Trust

Department of Clinical Biochemistry

The department has a particular interest in the area of cardiovascular disease and biochemical consequences of HIV disease. We have recently undergone a major refurbishment programme, and completed the implementation of a fully automated robotic core laboratory for pre-analytical sample processing, classical chemistry and immunodiagnosics and are fully CPA-accredited. We are recognised for the training of medical, clinical scientist and biomedical scientist trainees and participate in the teaching of medical students. We encourage all staff in the pursuit of further educational achievements and CPD for which funding is usually available.

Clinical Biochemist

Grade B (Scale Points 17-19)

We require an enthusiastic individual to join us in providing a comprehensive clinical biochemistry service at this major London teaching centre.

You will be a state registered clinical scientist, possessing at least DipRCPath or its equivalent and possibly a higher degree. You will have a broad range of experience as a Clinical Biochemist as you will participate in the clinical authorisation of routine tests on a rotational basis.

You will be required to take a lead for a particular area of the departments' service and a specialist interest in endocrinology and molecular techniques would be an advantage. You will act as the department co-ordinator for research, development and clinical trials, sharing some aspects of departmental management with other staff and may be required to participate out-of-hours responsibilities. You will be self-motivating, innovative, forward thinking, have excellent interpersonal and communication skills and be a good team player.

For further information/informal visits, please contact Dr Michael Thomas, Head of Department and Consultant Clinical Biochemist on 020 7830 2991.

Application packs are available from the Human Resources Department, Lower Ground Floor, Royal Free Hampstead NHS Trust, Pond Street, London NW3 2QG. Tel: 020 7830 2064, quoting ref: GICB020 or email: hr@royalfree.nhs.uk (quoting the reference number in the subject box).

Closing date: 3 November 2003.

For further information about the Trust and other vacancies available visit our website.

www.royalfree.nhs.uk

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East Kent Hospitals

NHS Trust

Department of Clinical Biochemistry, Directorate of Pathology

Clinical Scientist

Grade B (principal) scale points 16-20 £29,355 - £34,342 p.a.

Ref: WKE3586

Applications are invited from state registered clinical scientists for this newly created post within the East Kent Hospitals NHS Trust. The Trust has 1800 beds and serves a population of approximately 620,000, making it one of the largest Trusts in the UK. It is part of a joint Kent Cancer Centre (with Maidstone Hospital) and has a large renal replacement therapy service supporting most of Kent. The laboratory service is based on the Trusts three acute sites at Ashford (William Harvey Hospital), Canterbury (Kent and Canterbury Hospital) and Margate (Queen Elizabeth the Queen Mother Hospital), reflecting the major urban conurbation's in the area, but a large rural population is also served. There are excellent relationships between the Department and its clinical users.

The Department operates as a 'mini-network' with common IT support and equipment (including Roche Integra 800, Bayer Centaur, Roche Elecsys, Biomen HAB140, Nicholl's Advantage, Beckman Immage and Pharmacia Unicap). The clinical staffing includes three consultant and one principal grade scientists and one chemical pathologist. The Department has an active R&D programme focusing on biochemical markers and management of kidney disease. There are collaborations with other medical departments in the Trust (including the departments of renal medicine, nuclear medicine, gastroenterology and health care of the older person). You will be expected to undertake clinical research and an interest/experience in research relating to kidney disease would be particularly encouraged. Links with the University of Kent are being developed in line with the anticipated expansion of the medical school in Kent. You will be involved in all aspects of service delivery including teaching, audit and clinical validation. In addition, you will be expected to be part of the senior management team of the department.

Responsible to the head of department, this post will be based predominantly at the Canterbury site where you will, after appropriate training, assume responsibility for quality management and clinical services. You will also have weekly sessions (including 'duty biochemist') at Ashford. The area offers a variety of beautiful country and seaside locations and is well placed for access to both London and France.

You must be enthusiastic and self-motivated. You should hold an appropriate postgraduate qualification such as MSc/PhD and/or DipRCPath/MRCPath and will be expected to participate in CPD.

For further information or to arrange an informal visit, please contact Dr Edmund Lamb, Head of Department on 01227 766877 ext. 74736 or Mrs Ruth Lapworth, Clinical Director of Pathology on 01233 616025.

For an information pack and application form, please contact our 24 hour Recruitment Line on 0800 085 1807, quoting the above reference number or write to The Recruitment Team, Human Resources Directorate, Kent & Canterbury Hospital, Ethelbert Road, Canterbury, Kent CT1 3NG. Email: Recruitment.team@ekht.nhs.uk

Closing date: 21 November 2003.

For other job opportunities within East Kent Hospitals NHS Trust go to our website www.ekht.nhs.uk and click on vacancies.

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To find out how the UniCel DxI 800 can streamline your immunoassay testing, visit us at www.beckmancoulter.com/uniceldxi or email beckmancoulter_uk@beckman.com. Your patients can't afford to wait, so why should you?



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SIMPLIFY • AUTOMATE • INNOVATE

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