

ACB News

The Association of Clinical Biochemists • Issue 485 • 20th September 2003



**CE Mark
Debate
Explained**

**Brewery
Tour with a
Difference**

**The IVD
Directive
Explained**



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The monthly magazine for Clinical Science

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

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Printed by Piggott Printers Ltd, Cambridge
ISSN 1461 0337

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Front cover:

Three delegates from Poland at the ISOBM make friends with James Watt.

focus2004
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The Association of Clinical
Biochemists National Meeting
ICC, Birmingham

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CE Marking of “In-House

Jonathan Berg, Editor

The Medical and Healthcare Products Regulatory Agency (MHRA) issued a guidance letter in July to NHS Chief Executives interpreting the legislation on in vitro diagnostic devices. It impacts on laboratories producing clinical results on in-house systems. The guidance has now been updated but after 7th December 2005 you will no longer be able to analyse samples from other Trusts on in-house devices without a CE mark.

Unless the guidance is retracted or changed significantly, you have two options:

1. Comply with the new law.
2. Ensure that you can apply the exemption to CE marking for in-house methods and only analyse samples from your Trust.

This issue of ACB News provides practical help. We have commissioned an article from a CE marking consultant who has written advice on how to proceed. Professor Ian Young is also looking into all this as Chairman of the Scientific Committee.

Important Assays are Affected

It is my personal belief that the MHRA had no idea of the substantial number of assays that are affected by the July guidance. In-house methods often have no commercial alternative. Taking a common example, if you are using an HPLC system to produce clinical results, using a column of your choice and making up your own mobile phase, then you are using an in-house method. If you are only analysing your own Trust's samples, then you can carry on by applying the exemption, but samples from other hospitals require the method to have CE status. Modified guidance issued on Friday 29th August now extends the period you have to comply to 7th December 2005 for in-house assays that are already in place. It is not clear what the position is regarding any new in-house assays introduced after 7th December 2003 and the MHRA have declined to offer a view until they have consulted with their solicitor again!

PKU screening is specifically mentioned in the act and requires a higher level of attainment. It is amazing that no one appears to have contacted the relatively few regional laboratories that offer PKU screening and made sure they are up-to-speed.

A Practical Way Forward

In my Trust the Clinical Governance Lead has organised an audit of in-house methods in our twelve departments across two hospitals. In clinical chemistry we have presently identified seven affected assays. Five of them (three vitamin assays, an enzyme assay and an assay using a commercial CE marked reagent in an unconventional way) are associated with significant income generation and we will need to register these for a CE mark. Our regional laboratory has over 140 such assays!

CPA accredited laboratories should be able to approach CE marking as long as their in-house assays have the proper documentation and work-up to support

“In-house” Assays

them. A technical file is required and the most difficult aspect is a medical device risk analysis. University departments and specialist research departments in the hospital environment will need to become aware of their situation and address CE marking from a different perspective.

Laboratories that have joined together in a network need to look carefully at their situation. If a network has been set up as a single “legal entity”, then sample sharing across the network could mean that such assays can still claim an exemption.

What a Debacle!

The MHRA guidance has apparently been the result of considered legal opinion and until issued it was not clear how NHS laboratories were affected by the IVD Directive. Unless retracted or substantially altered, new in-house assays still appear to require a CE mark after midnight on the 6th December 2003 for you to analyse work from another trust and established assays from 7th December 2005.

The impact of this interpretation of the IVD directive into law puts at risk 1,000s of in-house assays. This includes many in the area of gene analysis for which there are no commercial alternatives and a very large number of assays at regional laboratories. No one could have expected such laboratories to have applied CE marking in such a short time-frame.

The MHRA are in a real mess with this and once the “big guns” of the Royal College are brought out one can expect to see a period of reflection followed by yet more guidance. A positive way forward would be for professional representation round the MHRA table to balance the legal opinions they are receiving. In the meantime ACB News is putting a test CE mark in-house assay into the system to see just how much work this all is and we will report this in the October ACB News.

Jonathan Berg

Jonathan Berg
Editor

*If you have
in-house assays
that produce
results for other
laboratories then
read on . . .
Jonathan Berg
introduces the
recent guidance
on the IVD
Directive for NHS
laboratories*

IVD and In House Manufacture . . . MHRA Guidance No. 1

The following guidance went to Chief Executives in the NHS from Dr David Jeffreys, the head of the Medicines and Healthcare Products Regulatory Agency. This guidance is likely to impact significantly on many NHS laboratories and we have reproduced the guidance in full. There is also an editorial as well as a substantial article giving practical information on what to do next.

Chief Executive of Statagic Health Authorities
 Chief Executives of Acute NHS Trusts

Dear Chief Executive,

In Vitro Diagnostic Medical Devices (IVD) Directive: In House Manufacture

As you probably know the In Vitro Diagnostic Medical Devices Directive (IVDD) came into force on 7 December 2000 (provisions to be applied from 7 June 2000), with a transition period which ends on 7 December this year in respect of new devices being placed on the market. The IVDD requires manufacturers and other institutions that place IVD kits on the community market or put them into service to meet certain requirements relating to their safety, quality and performance. Failure to comply with these requirements may constitute a criminal offence. The IVDD has been transposed into UK in the Medical Devices Regulations 2002 (SI 2002 No.618).

Over the past few months the MHRA has been working hard to ensure that those likely to be affected by these Regulations are fully aware of their possible impact. Thus for example we have held a series of Study Days for NHS Laboratory Staff and others and made various presentations at conferences etc. This work will continue. Nevertheless, we have recently received a number of requests for information relating to the applicability of the Regulations to IVD test kits that are manufactured and used within the same healthcare institution. The purpose of this letter is to outline how we see the Regulations working in this context. In general, the IVDD and the transposing Regulations, apply to all manufacturers placing IVDs on the market, or putting them into service. "Putting into service" includes the use of a device in a professional context for the purpose of medical analysis, even if the device is not marketed. However, there is an exemption that applies to health institutions set out in Article 1.5 of the IVDD. This says that the IVDD does not apply to devices that are "manufactured and used only within the same health institution and on the premises of their manufacture or used on premises in the immediate vicinity without having been transferred to another legal entity". The IVDD does not define "health institution" but we interpret it to include an NHS Trust. Bearing this in mind, we have identified four basic scenarios that may apply to your Trust. These are set out below, with our interpretation of how the IVDD and Regulations apply.

Scenario 1: A health institution manufactures an IVD in-house and uses that IVD in-house, to test samples provided by patients within that healthcare institution, either on the premises of manufacture of the IVD or on nearby premises.

We believe this scenario falls squarely within the exemption allowed for by Article 1.5 of the IVDD and therefore the IVDD and Regulations do not apply.

Scenario 2: A health institution manufactures an IVD in-house and uses that IVD in-house, to test samples provided by patients within that healthcare institution, but not on the premises of manufacture of the IVD or nearby premises.

Because the IVD is not used on the premises of its manufacture or on nearby premises the exemption does not kick in and the IVDD and Regulations will apply.

Scenario 3: Health Institution A manufactures and uses an IVD to test patient samples provided by another legal entity.

In this case the device is not being used "within" the same health institution because it is being used for the provision of services to a third party (ie the testing of third party samples). Our view is therefore that the IVDD and Regulations apply and Health Institution A will need to comply with the relevant requirements. This remains our view regardless of whether or not it is providing this testing service as part of a commercial transaction.

Scenario 4: A health institution manufactures an IVD and transfers it for use to another legal entity, either free or in return for payment.

In this case, it is our view that the IVDD and Regulations apply, since the IVD is effectively being placed on the market by its transferral to another legal entity.

We have also been asked how the IVDD applies to an organisation, which is not an health institution, but which manufactures and uses an IVD without actually placing the device on the market. An example would be a commercial testing centre which provides pregnancy testing services direct to the public.

This situation is outside the scope of the exemption for health institutes referred to in Article 1.5 of the IVDD and therefore the organisation would have to comply with the provisions of the IVDD and Regulations.

I hope this clarifies the situation. Inevitably the scenarios set out above are in general terms only and I appreciate that there may be more specific instances unique to your own Trust on which you would appreciate further elaboration. If such is the case we will be happy to respond to any requests, subject to the caveat that our advice cannot be taken to be a definitive statement of the law. That can only be given by the courts. Where appropriate therefore you should normally consult with your own professional advisers.

Finally, you may wish to note that it is my intention to arrange for the above advice to be posted on the MHRA's web page and updated with additional scenarios as we come across them.

Yours sincerely,
 Dr David Jeffreys, Head of the MHRA's Device Sector
 2nd July 2003 ■

MHRA . . . Guidance No. 2

Dear Chief Executive,

As you know I recently wrote to you outlining our views on how the IVD Directive would apply to those institution that make and use IVDs within the same institution. A copy of this letter was placed on our web site and resulted in several letters questioning the rationale behind our interpretation. In addition some institutions, while accepting the interpretation, nevertheless felt that there was inadequate time left to comply with the Directive's requirements before it comes fully into force on 7th December 2003.

In consequence we have again consulted our legal advisors. They have confirmed that the interpretation given in my original letter was correct. However it may be useful if I explain a little the rationale behind that interpretation.

Before I do that, however, it is important to clarify the effect of a second transition period within the Directive. In effect this means that the Directive's provisions come fully into force on 7th December 2003 only for those devices that are placed on the market. Where devices are put into service without having been placed on the market, we believe that the manufacturer (i.e the health institution) has until 7th December 2005 to comply. This means that where a health institution makes and uses a device to test patient samples provided by another institution, in the context of providing a service (scenario 3 in my original letter), they have until December 2005 to comply with the Directive (although we would obviously advise such institutions to comply earlier rather than later).

I will now explain the rationale behind our interpretation of when the Directive will apply to health institutions. As my earlier letter made clear, we believe that where a health institution makes and uses an IVD on samples provided by the same health institution the Directive does not apply, because the in-house exemption set out in article 1.5 will apply. However, where the device is made and used in the same health institution, but on samples provided by a third party, in the context of providing a service, the exemption will not apply. The rationale for this is described below.

Subject to the in-house exemption in article 1.5, the requirements of the Directive and our implementing domestic legislation (the Medical Devices Regulations 2002) apply where an in vitro diagnostic device is (i) placed on the market; or (ii) put into service.

With regard to "placing on the market", so far as in-house activities are concerned, we have taken the view (as outlined in our guidance document Bulletin 18) that where a health institution manufactures a device for use on or by the patients of that

establishment, there is no placing on the market. On the other hand, where there is a transfer between legal entities, this will generally constitute a placing on the market, even if the transfer is free of charge.

As to the meaning of "putting into service" this is set out in article 1 of the Directive, read in the light of the 11th recital and article 9.13. Article 9.13 makes it clear that a person who manufactures devices and without placing them on the market, puts them into service and uses them in the context of his professional activity, must follow the appropriate conformity assessment procedure. The definition of "putting into service" in our domestic regulations (see regulation 2), which takes all of the above into account, reads as follows: "the first making available of the device in the Community to a final user, including where a device is used in a professional context for the purposes of medical analysis without being marketed." It is thus clear that there can be a putting into service even if a device has not been transferred to a third party.

I come now to the exemption clause in the Directive. This is set out in article 1.5 of the Directive and referred to in the 10th recital. (Recitals are not themselves binding but are a useful guide to interpreting the main provisions of the Directive).

Essentially, we have been advised that the wording of the Directive and recitals, makes clear that the intention behind the Directive is to exempt the non-trading use of a device made and used wholly within a health institution. The use of the word "within" in Article 1.5 makes it clear that the exemption applies to in house activities only and not to activities which involve the provision of services to third parties e.g. the testing of external samples. Where a device is used to provide services to third parties, although the device is used in the health institution, it is not used exclusively within it. This interpretation is consistent with the 10th Recital in that in-house transactions will by their very nature be non-commercial. Thus, the fact that a health institution tests samples provided by a third party – whether or not a fee is charged – means that the activity cannot truly be considered to be in-house and therefore exempt under Article 1.5.

Finally, as you know, the MHRA has already produced general guidance on the IVD Directive. This is available on our website. You may also wish to know that we are in the process of adding to this additional guidance specifically geared to health institutions. We plan to put this on our website very shortly.

I hope that this letter is useful to you.

Dr David Jefferys
29 August 2003 ■

ISOBM Meeting

Congratulations to Cathie Sturgeon and her team who organised an excellent meeting of the International Society of Oncodevelopmental Biology and Medicine at Heriot-Watt University in Edinburgh. The meeting had some excellent discussion on topics of considerable interest and ACB News will be reporting several of the sessions in forthcoming issues.

One sad aspect of the meeting was that Cathie's husband, Robert Sturgeon, died just two days before the meeting. Robert was a member of the organising committee for ISOBM and will be known to many readers as he has helped Cathie organise EQAS meetings over the years. The courage of Cathie and her children, who all worked unstintingly to ensure the success of the meeting, will be a lasting testament to Dr Robert Sturgeon. ■



James Watt with ISOBM delegates from Poland, Magdalena Chechlinska, Barbara Slesak and Antonina Harlozinska-Szmyrka.

CPA Close to Being a Compulsory Requirement . . .

For those departments who still think they can ignore accreditation here is a preview of some news spotted on the DoH website dated 22nd July 2003.

Compulsory Registration in Accreditation Schemes for NHS Pathology Laboratories

Currently registration for accreditation of pathology laboratories is voluntary, except for cervical cytology laboratories. It is for the most part overseen by CPA, developed by the Royal College of Pathologists and other professional bodies (including the Independent Healthcare Association), with support from the Department of Health. CPA is independent from the Department and other government departments. CPA standards are compatible with international standards (ISO).

Pathology services are key to timely access to services and to providing high quality patient care. Accreditation is a key underpinning of clinical governance and quality improvement. Therefore, to improve clinical governance, raise quality standards and improve openness and transparency for patients, all National Health Service pathology laboratories in England should enrol with an appropriate accreditation scheme as soon as practicably possible.

Further information will be contained in our document on modernising pathology services, which will be published in the early Autumn. This will also give further details about funding for pathology service modernisation." ■

Bennett Awarded Distinguished Scientist Award

Dr Mike Bennett who trained in Sheffield and has been an ACB member for 28 years was recently awarded the prestigious Distinguished Scientist Award for Outstanding Research Advances in the field of clinical biochemistry by the National Academy for Clinical Biochemistry in the USA. The award was presented at the AACC National Meeting in Philadelphia in July, and recognises "individuals who have demonstrated significant research accomplishments in the field of clinical biochemistry. Award recipients have made noteworthy contributions to the understanding of the biochemistry of disease, the application of the principles of clinical biochemistry,

or the important use of laboratory techniques."

Mike is internationally recognized for his research activities, which have focused on inborn errors of metabolism, especially disorders of fatty acid oxidation and lysosomal storage diseases. He has published 160 original investigative reports and numerous book chapters in these areas and is a member of the editorial boards of several influential journals, including *Clinical Chemistry*, *Annals of Clinical Biochemistry*, and *Molecular Genetics and Metabolism*. Mike lectured on sudden infant deaths at the recent Focus 2003 meeting in Manchester, and was subsequently interviewed by the BBC's *Newsnight* programme in a feature on cot deaths. ■

NPSA To Include Clinical Scientists

The National Patient Safety Agency (NPSA) will widen its focus to encompass healthcare scientists (HCS's) and allied health professionals (AHP's) following the appointment of a project manager to look specifically at these professions. Linda Thompson has joined the NPSA to promote patient safety amongst these professions and include them in the development of solutions when risks to patient safety are identified.

Part of Linda's remit will be to promote the role of the NPSA and the patient safety agenda amongst HCS's and AHP's and give the professions a voice within the agency. She will also look at reporting of patient safety amongst these professions, and work with these staff groups to develop solutions to identified patient safety issues.

One of the functions of the NPSA is to improve the safety of NHS patient care in England and Wales by creating and managing the National Reporting and Learning System (NRLS) for patient safety incidents. This will in time enable NHS Staff in England and Wales to report incidents to the NPSA that they are involved in or witness. By collecting and analysing this valuable source of anonymous data, the NPSA will be able to identify trends and patterns of avoidable incidents, provide feedback to organisations to enable them to

change practice, help develop models of best practice and systems solutions at national level, and support ongoing education and learning.

Matching Patients with Aspects of Care

The NPSA is researching issues relating to patient identification, such as bar coding in relation to medication, blood, procedure lists, dietetics and pathology specimens. The NPSA will work with the NHS Information Authority, the Department of Health and the Welsh Assembly Government among others to take this work forward. This research will be UK and internationally based. During 2003/4 the NPSA will work with SHOT to identify the root causes of patient and blood mismatching in transfusion settings.

The NPSA are committed to finding out more about the specific patient safety issues facing Healthcare Scientists. A patient safety incident is defined as: any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS funded healthcare.

For further information, please visit the following website: www.npsa.nhs.uk or contact: Linda Thompson, Project Manager on Tel: 020-7927-9516. Email: linda.thompson@npsa.nhs.uk ■

Royal Society of Medicine Clinical Cases Meeting

Tuesday 7th October 2003

North Hall, The Royal Society of Medicine, 1 Wimpole Street, London W1G 0AE

14.00	Registration	
14.30	A case of poisoning	<i>Dr Cathryn Corns, Southend</i>
14.45	Pituitary problem	<i>Dr Abubaker Elfatih, Wolverhampton</i>
15.00	A MADDening problem with Statins	<i>Dr Trevor Gray, Sheffield</i>
15.15	Tea	
15.30	A case from Great Ormond Street	<i>Dr Steve Krywawych, London</i>
15.45	Collapsed with hypoglycaemia	<i>Dr Pandina Kwong, London</i>
16.00	TPMT genotyping in South Africa	<i>Dr Rasaq Olufadi, Cardiff</i>
16.15	Close of meeting	

To book please contact: Claire Bowen, Academic Department, Royal Society of Medicine, 1 Wimpole Street, London W1G 0AE

Tel: 020-7290-3859 Fax: 020-7290-2989 Email: pathology@rsm.ac.uk

Book on-line at: www.rsm.ac.uk/pathology

National Screening Committee Down Syndrome Screening Programme

National Laboratory Conference

Delivering a Quality National Programme

Friday 26th September 2003 – Cost £25

National Motorcycle Museum, Coventry Road, Bickenhill, Solihull, West Midlands B92 0EJ

10.00-10.30	Registration and coffee	
10.30-10.40	Welcome and introduction	<i>Prof Chris Price</i>
10.40-11.00	The national survey of screening practice	<i>Mrs Pat Ward</i>
11.00-11.30	Data from the NEQAS surveys	<i>Mr Andy Ellis</i>
11.30-12.00	Using software tools to improve screening quality	<i>Dr Rick Jones</i>
12.00-12.30	'Licensing' of reagents and software	<i>Dr David Worthington</i>
12.30-13.30	Lunch	
13.30-14.00	National policy on Down's syndrome screening	<i>Dr Muir Gray</i>
14.00-14.30	Results and conclusions from SURUSS	<i>Dr David Worthington</i>
14.30-15.00	Providing first trimester laboratory services	<i>Dr David Aitken</i>
15.00-15.30	Tea	
15.30-16.00	Quality management of screening	
	Breast and Cervical screening programmes	<i>Dr Julia Verne</i>
16.00-16.30	Discussion	
16.30	Close	

Further details from: *Mrs Pat Ward, 1c Headlands, Kettering, Northants, NN15 7ER*
Tel: 01536 481902 . Email: paward@nscdoh.fsnet.co.uk

South Thames Quality Assurance Group

Annual Meeting

Friday 21st November 2003

Postgraduate Centre, Kent & Sussex Hospital, Tunbridge Wells, Kent TN4 8AT

	Registration and coffee	
10.45	Cardiac markers audit in Thames areas	<i>David Housley</i>
	Current issues in the application of measurement uncertainty and traceability to clinical laboratory analysis	<i>Mike Sargent</i>
	Ultrasensitive micro-array based ligand assays; the coming revolution in clinical chemistry	<i>Roger Ekins</i>
	Lunch	
14.00	Creatinine audit in Thames areas	<i>Cathryn Corns</i>
14.45	Serum (haemolytic) index tests	<i>Phil White/Steve Frost</i>
	Urine preservatives used in laboratories in Thames areas	<i>Graham Lawson</i>
	Discussion	
16.00	Tea and depart	

To register for the meeting, please send £10 to Graham Lawson, Department of Clinical Chemistry at the Kent & Sussex Hospital.
The meeting is free of charge to trainees.
Telephone 01892-526111 X2368. E-mail: Graham.lawson@mtw-tr.nhs.uk

Joint ACB Wales and South West & Wessex Regions Autumn Scientific Meeting

**Thursday 13th and Friday 14th November 2003
The Angel Hotel, Cardiff**

Provisional Programme

Thursday 13th November

Opening Address

Dr Owen Crawley, Chief Scientific Advisor to the Welsh Assembly Government

Session 1:

Paediatrics and the laboratory
Inherited Metabolic Diseases and Pregnancy
HRT in Pregnancy

*Dr Graham Shortland, Cardiff
Dr Anne Green, Birmingham
To be confirmed*

Session 2:

Abnormal LFTs in the asymptomatic patient
Folate, Homocysteine, endothelial function and
CVD – what is the link?
Homocysteine and neurological Disease

*Dr Roy Sherwood, London
Dr Ian McDowell, Cardiff
Dr Andrew McCaddon, Wrexham*

Session 3:

Members Papers and the Bayer Award

Thursday Evening

Course dinner at the Angel Hotel, Cardiff

Friday 14th November

Session 4:

The Biochemical consequences of Polypharmacy
Chemical Incident Investigation

*Dr Graham Mould, Guildford
Prof Philip Routledge, Cardiff*

Session 5:

Monitoring of Immunosuppressive drugs
The provision of an acute toxicology service

*Dr David Holt, London
Dr Ian Watson, Liverpool*

Session 6:

All Wales Clinical Biochemistry Audit Group Meeting
South West and Wessex Region Audit Presentation

Registration Fees: Full delegate (registration Thursday and Friday, Course Dinner and 1 nights accommodation) £195, day delegate (Thursday) £55, day delegate (Friday) £40, Course dinner £25

*There is no charge for attendance at the Audit session
which is open to all interested healthcare professionals.*

Registration closes 6th October 2003.

For more details contact:

*Catherine Davies, Department of Clinical Biochemistry, Royal Gwent Hospital,
Newport, Gwent NP20 2UB or email Catherine.Davies@gwent.wales.nhs.uk*

Research Practice in Laboratories & Evidence Based Medicine

**Royal College of Pathologists
London, 5th December 2003**



**The Association of
Clinical Biochemists**



10.45 Registration and coffee

Chair: *Ms Janet Smith, Chair of ACB, University Hospital Birmingham*

11.00 Establishing a new diagnostic test

Prof Chris Price, Bayer Diagnostics UK

11.30 Minimising analytical factors in clinical trials

Dr Julian Barth, Leeds General Infirmary

12.00 Clinical decision making based on laboratory results:

problems of uniformity in a multi-centre project such as HAPO

Prof Liz Trimble CBE, Queens University, Belfast

12.30 Monitoring glycaemic exposure over 25 years in the UKPDS

Dr Susan Manley, University Hospital Birmingham

13.00 Lunch

Chair: *Dr Graham Beastall, Vice President Royal College of Pathologists, Glasgow Royal Infirmary*

13.45 From evidence to guidelines – management of patients with diabetes

Dr David Sacks, Harvard Medical School, US

14.30 Consulting a statistician before you start

Mrs Irene Stratton, University of Oxford

14.45 Asking the right questions as a clinician

Professor Desmond Johnston, Imperial College, London

15.00 Introducing the UK Biobanks research program

Prof Bill Ollier, University of Manchester

15.20 Identifying the role of the clinical laboratory in research

Dr Richard Sullivan, Cancer Research UK

15.40-16.15 Discussion with panel of invited speakers

Chair: *Professor William Fraser, Royal Liverpool University Hospital*

Sponsored by the Royal College of Pathologists and the Association of Clinical Biochemists

4 CPD credits available. Email: susan.manley@uhb.nhs.uk for registration by 31st October 2003

ACB, North West Region

Regional Audit Meeting

**Postgraduate Centre, Trafford General Hospital, Moorside Road, Davyhulme
30th September 2003**

15.00 Audit of lipid reporting in the North West

Dr A M Hassan, Manchester Royal Infirmary

15.15 Lipid reporting, consumer aspects

Dr A Hutchesson, Bolton Royal Infirmary

15.30 National audit of information supplied with GP requests

Ms K Smith, Glasgow Royal Infirmary

15.45 An audit of dyskalaemia

Dr C Vanheynigen, Aintree Hospitals

16.00 Tea

16.30 Audit of service provision for the poisoned patient

Mr E L Robinson, Wythenshawe Hospital

16.45 Troponins revisited

Dr A W Stott, Royal Liverpool Hospital

17.00 Re-audit, postoperative fluid balance in an orthopaedic setting

Dr I Watson, Aintree Hospitals

17.15 Audit of incident reporting

Miss C Humphries, Manchester Royal Infirmary

17.30 Improving patient care through audit

Dr G Ayers, Manchester Royal Infirmary

17.45 Concluding remarks

18.00 Dinner and Exhibition

To register please email: ian.laing@cmmc.nhs.uk or telephone 0161 276 6318



"This cocaine addict must have been as high as a kite mark!"

CE Marking and the IVD Directive

By Sue Spencer, Director, Cascade Consulting

What is the IVD Directive?

The IVD Directive is the latest in the family of medical device directives and applies to all devices which meet the following definition;

‘in vitro diagnostic medical device’ means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological state, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures.

The European legislation was originally written to promote free trade and prevent countries applying technical requirements to diagnostics, which favoured the home market. In order to facilitate free trade throughout Europe the products have to be safe and meet a set of minimum safety criteria called the Essential Requirements. The visual outward sign that a product meets the Directive is a CE mark applied to the labelling and instructions for use.

From the 7th December 2003 all products which meet the definition of an IVD must meet all the requirements of the Directive to be legally provided. Manufacturers of products which do not are committing a criminal offence under the Consumer Protection Act and can be found in UK in the Medical Devices Regulations 2002 (SI 2002 No.618). It is important to note that the legislation applies to product which is sold or given away.

Does CE Marking Apply to Me?

The Directive includes two important phrases:

- (10) Whereas, having regard to the principle of subsidiarity, reagents which are produced within health-institution laboratories for use in that (1) OJ C 136, 4.6.1985, p. 1. (2) OJ L 189, 20.7.1990, p. 17. Directive as last amended by Directive 93/68/EEC (OJ L 220, 30.8.1993, p. 1). (3) OJ L 169, 12.7.1993, p. 1. environment and are not subject to commercial transactions are not covered by this Directive;
- (11) Whereas, however, devices that are manufactured and intended to be used in a professional and commercial context for purposes of medical analysis without being marketed are subject to this Directive;



Practical advice by Sue Spencer for anyone who analyses samples for other “legal entities” using “in-house” reagents or equipment and wants to carry on after 7th December

This article was written before the additional 29th August guidance from MHRA, which gives existing in-house assays an extension to 7th December 2005

Article 1 (5) This Directive shall not apply to devices manufactured and used only within the same health institution and on the premises of their manufacture or used on premises in the immediate vicinity without having been transferred to another legal entity. This does not affect the right of Member State to subject such activities to appropriate protection requirements.

The question has always been what constitutes a health care institution and what constitutes professional and commercial service and does it apply to the NHS?

On 2nd July 2003 MHRA sent a letter to Chief Executives of hospital trusts which states:

The IVDD does not define “health institution” but we interpret it to include an NHS Trust. Bearing this in mind, we have identified four basic scenarios that may apply to your Trust. These are set out below, with our interpretation of how the IVDD and Regulations apply.

Scenario 1

A health institution manufactures an IVD in-house and uses that IVD in-house, to test samples provided by patients within that healthcare institution, either on the premises of manufacture of the IVD or on nearby premises.

We believe this scenario falls squarely within the exemption allowed for by Article 1.5 of the IVDD and therefore the IVDD and Regulations do not apply.

Scenario 2

A health institution manufactures an IVD in-house and uses that IVD in-house, to test samples provided by patients within that healthcare institution, but not on the premises of manufacture of the IVD or nearby premises.

Because the IVD is not used on the premises of its manufacture or on nearby premises the exemption does not kick in and the IVDD and Regulations will apply.

Scenario 3

Health Institution A manufactures and uses an IVD to test patient samples provided by another legal entity.

In this case the device is not being used “within” the same health institution because it is being used for the provision of services to a third party (i.e. the testing of third party samples). Our view is therefore that the IVDD and Regulations apply and Health Institution A will need to comply with the relevant requirements. This remains our view regardless of whether or not it is providing this testing service as part of a commercial transaction.

Scenario 4

A health institution manufactures an IVD and transfers it for use to another legal entity, either free or in return for payment.

In this case, it is our view that the IVDD and Regulations apply, since the IVD is effectively being placed on the market by its transferral to another legal entity. We have also been asked how the IVDD applies to an organisation, which is not a health institution, but which manufactures and uses an IVD without actually placing the device on the market. An example would be a commercial testing centre which provides pregnancy testing services direct to the public.

This situation is outside the scope of the exemption for health institutes referred to in Article 1.5 of the IVDD and therefore the organisation would have to comply with the provisions of the IVDD and Regulations.

First . . . Audit Your In-House Methods

MHRA have taken sometime to come to their opinion and have sought legal advice so the position is unlikely to change. Although the Directive was originally written to promote free trade it also seeks to introduce a level playing field of public safety as it relates to diagnostic products which is very much part of MHRA's role.

NHS trusts need to look at how they are operating their diagnostic services and perform an audit to determine if they have any "home brew" assays, which may fall under this Directive. They then need to determine, using the scenarios above, if they must meet the Directive.

CE Marking . . . What You Need to Do?

Once you have determined you have an IVD needing a CE mark this is what to do. Firstly you must classify it to determine the perceived risk of a device and in Annex II there is a classification system. Annex II List A contains the highest risk devices and list B contains the moderate risk devices. There are additional rules for self test devices – which may be the main category for a clinical laboratory.

Annex II List A

- Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups: ABO system, rhesus (C, c, D, E, e) anti-Kell.
- Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of HIV infection (HIV 1 and 2), HTLV I and II, and hepatitis B, C and D.

Annex II List B

- Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups: anti-Duffy and anti-Kidd.
- Reagents and reagent products, including related calibrators and control materials, for determining irregular anti-erythrocytic antibodies.
- Reagents and reagent products, including related calibrators and control materials, for the detection and quantification in human samples of the following congenital infections: rubella, toxoplasmosis.
- Reagents and reagent products, including related calibrators and control materials, for diagnosing the following hereditary disease: phenylketonuria.
- Reagents and reagent products, including related calibrators and control materials, for determining the following human infections: cytomegalovirus, chlamydia.
- Reagents and reagent products, including related calibrators and control materials, for determining the following HLA tissue groups: DR, A, B.
- Reagents and reagent products, including related calibrators and control materials, for determining the following tumor marker: PSA.
- Reagents and reagent products, including related calibrators, control materials and software, designed specifically for evaluating the risk of trisomy 21.
- The following device for self-diagnosis, including its related calibrators and control materials: device for the measurement of blood sugar.

Note that only analytes specifically listed are included in a class, so for example PSA is the only cancer marker in Annex II List B.

Most In-House Assays are Self-Certification

The vast majority of IVD's are not listed in Annex II and are sometimes described as "self certification" products. All devices require technical documentation to be compiled as described in Annex III to prove that the device meets the Essential Requirements described in Annex I of the Directive. The Essential Requirements are a list of minimum safety requirements, which must be met and include both technical and labelling requirements; the volume of technical documentation required is proportionate to the risk of the device.

Essential Requirements Checklist

All IVD's have to meet the minimum set of safety requirements of the Directive and there needs to be documentary evidence that these have been met. Companies normally prove compliance with the Directive by preparing an Essential Requirements checklist. This is a matrix which lists the Essential Requirements and then describes the standards the manufacturer has applied and details the technical documentation the manufacturer considers prove compliance with the Directive; alternatively the manufacturer may cite a reference to a location where supporting technical documentation or data can be found.

All products have to be designed manufactured and labelled under a quality system. The "harmonised standard" for quality systems is ISO 13485, but unless products are classified as high risk this does not have to be approved by an external organisation or Notified Body. **CPA accredited labs are operating to a quality system**; however, they would need to introduce procedures for vigilance and post market surveillance and review complaint handling and corrective and preventive actions to meet the Directive.

The first five essential requirements all talk about risk and **a risk analysis is one of the key exercises** which need to be completed to meet the requirements. There is a standard ISO 14971 to help guide you; however, risk analysis is a new technique and many people need additional guidance or training to get started.

For each class of device there are a number of different routes which a manufacturer may select to prove compliance with the Directive. The higher risk devices require a review by an external agency, called a Notified Body. Self certification products i.e. those not listed in Annex II list A or B or self tests do not require a notified body; companies have to pay the Notified Body to conduct the audit.

The associated cost for CE marking each class of device is summarised below;

Classification of Product

Costs and resources to be considered:

Annex II List A

- Time to compile risk analysis and technical documentation plus addition procedures such as vigilance and post market surveillance.
- Any addition lab testing to meet the CTS or essential requirements.
- Design dossier review and quality audit by a notified body approx £400/day.
- Batch release by notified body of each Lot approx £1500/batch.
- Registration with MHRA £70 per application one form can list multiple products.

Annex II List B

- Time to compile risk analysis and technical documentation plus addition procedures such as vigilance and post market surveillance.
- Any addition lab testing to meet the essential requirements.
- Review of technical file and quality audit by a notified body approx £400/day.
- Registration with MHRA £70 per application one form can list multiple products.

Other “Self Certification” Devices

- Time to compile risk analysis and technical documentation plus addition procedures such as vigilance and post market surveillance.
- Any addition lab testing to meet the essential requirements.
- Registration with MHRA £70 per application one form can list multiple products.

Conclusion

If laboratories currently have all the data to meet the essential requirements CE marking will involve:

- An administrative exercise to gather the information into a technical file to prove compliance.
- A risk analysis exercise.
- Modification of the laboratory quality system to deal with the new vigilance reporting requirements.
- Registration with the MHRA and a Notified Body audit for high risk devices.

This article is designed to set the scene so that you can get a feel for what the IVDD entails and enable you to determine what the regulations are and if they affect you. It is not possible to give an exhaustive guide to the Directive so a reference section is provided which gives sources of other information and where to look for further help and guidance.

Laboratories are advised to determine if the legislation affects them. Regardless of the decision made it is advised that this decision and associated rationale should be documented and reviewed when ever the service is changed.

References

Copy of the IVD Directive	http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31998L0079&model=guichett
MHRA introduction to the IVD Directive	http://www.medical-devices.gov.uk/mda/mdawebsitev2.nsf/webvwIndex/0B61F6FE70183A5900256AC3003AB40E?OPEN
MHRA Guidance on Registration	http://www.medical-devices.gov.uk/mda/mdawebsitev2.nsf/webvwIndex/3BCE74099FA5A8A200256B550075BC5A?OPEN
MHRA list of UK Notified Bodies	http://www.medical-devices.gov.uk/mda/mdawebsitev2.nsf/webvwSearchResults/830D7830D7042368A257A00256A8F00364E1D?OPEN
BIVDA website	http://www.bivda.co.uk
EDMA	http://www.edma-ivd.be/
IVD Technology Article on how to CE mark	http://www.devicelink.com/ivdt/archive/03/04/008.html
Cascade Consulting website	http://www.cascade-consulting.com

Thanks to Sue Spencer who wrote this for ACB News at very short notice. For those of you who need professional help, Sue’s email is: sue@cascade-consulting.com ■

Express delivery from Beckman Coulter

Beckman Coulter is about to launch the world's fastest Immunodiagnostic System. Take a break at the Beckman Coulter Express Coffee Bar and see it first at the Biomedical Science Congress, Stand 701. 29th September - 1st October 2003



Deacon's Challenge

No. 30 Answer

A standard has to be made up containing 100 mg dextropropoxyphene (Mol. Weight 339.5) per litre. How much dextropropoxyphene napsylate (Mol Weight 565.7) must be weighed out to make 100 mL of standard solution?

MRCPath, May 2003

First calculate the millimolar concentration of dextropropoxyphene in the standard:

$$\text{Concentration (mmol/L)} = \frac{\text{Concentration (mg/L)}}{\text{MW dextropropoxyphene}} = \frac{100}{339.5} = 0.295 \text{ mmol/L}$$

The millimolar concentration of dextropropoxyphene and dextropropoxyphene napsylate will be the same. To calculate how much dextropropoxyphene napsylate must be weighed out (in mg) multiply the millimolar concentration by the molecular weight of dextropropoxyphene napsylate:

$$\begin{aligned} \text{Concentration (mg/L)} &= \text{Concentration (mmol/L)} \times \text{MW dextropropoxyphene napsylate} \\ &= 0.295 \times 565.7 = 166.9 \text{ mg/L} \end{aligned}$$

$$\text{To prepare 100 mL of standard, weight required} = \frac{166.9}{10} = \mathbf{16.7 \text{ mg}} \text{ (to 3 sig figs)}$$

Question No. 31

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

Brewery Tour With a Difference

Reported by Alan Rumley, Glasgow

Focus social events are the most enjoyable part of the annual meeting (hope my boss doesn't read this) with the chance to meet old friends in a convivial atmosphere. There is usually an event which is centred on beer drinking (preferably real ale) and this year was no exception. So I booked for the above tour on the registration form but was disappointed not to receive a ticket in my registration pack. However, I will be eternally grateful to Nikki and the girls on the registration desk who obligingly slipped me a ticket surreptitiously when they saw how distressed I was.

So on Tuesday evening we set off from the Manchester International Conference Centre on the bus at 1830hrs with eager anticipation and a thirst (for knowledge as well as beer) and shortly arrived at a large brewery which resembled an industrial chemical complex rather than an historic brewery with a sign at the entrance saying "Scottish Courage Brewery". Not a prepossessing site for real ale drinkers. Worse still there appeared to have been a major incident under way involving fire engines, police, paramedics, many others in fluorescent jackets and no way were they letting us in! After much disgruntled muttering from the disappointed boozers about the wrong brewery the bus driver confirmed by phoning his depot that we were at the correct brewery. The Focus organiser on the bus then confirmed with the man on the gate that this was not the correct brewery and they were definitely not expecting a bus load of thirsty biochemists on a tour so p*** off!

Mohican's in Manchester

A further phone call by the organiser elicited the address of Hyde's Brewery thankfully not far away and after a short drive we were deposited outside the correct premises. We had waited in the cold for about 20 minutes when a lady appeared who introduced herself as the HR manager, explained that the tour guide had not turned up yet and took us to the hospitality suite and served us some very welcome beer while we waited.

A thin, six foot six inch tall Mohican in leather jacket and jeans appeared - our tour guide. Knowing that we were biochemists he asked if anybody could tell him how starch is converted into sugar because he had always wanted to know that and he warned us not to ask any difficult questions. The tour commenced and after learning a lot about his philosophy of life and next to nothing about brewing and the brewery by

"Take a tour of Hyde's historic brewery and learn about the art of brewing. Sample some of the ales and then finish off the evening with a curry at Sangam's Indian restaurant"

common consent we agreed with his proposal to cut the tour short and return to the bar for more beer. We were able to sample all of the various excellent brews made on the premises, five different ones I think (its all a bit hazy now). The humour of the group had improved considerably after more beer was consumed and a pint pulling competition was held. The winner was yours truly thanks to some expert coaching by the barmaid and the prize was ten bottles of Hyde's beer with four for the runner up.

Unlimited free beer was now available but unfortunately we had to tear ourselves away to be bussed to the Indian restaurant where we met up with a group of sober people who had preferred an evening at the Velodrome (well it takes all sorts I suppose). We were served lots of very good Indian food and more beer and were taken back to our hotels inebriated, full of curry and contented and some even managed to go to the hotel bar for more drink!

A splendid time was had by all. So, many thanks to the Focus organisers and although in the early part of the evening before things picked up it was said a few times, they avoided the ultimate judgment of incompetence that "they couldn't organise a piss up in a brewery". ■



Relaxing with lager and curry after the very different brewery tour

Emphasis on the Regions

Reported by Gwyn McCreanor, Assistant Secretary

There is a need to establish objectives for all standing committees. The timescale will be to submit plans to the Chair of the Association before the next Council meeting on 2nd October 2003. The plans will be implemented in a January to December cycle to coincide with the Annual Report. Publications Committee have been doing this for several years and agreed it was useful, especially the financial aspects.

Review of Regional Activities and Involvement in Strategy

A range of innovative activities are going on at regional level and it was agreed that these experiences should be shared with Council, in order to raise awareness and share with other Regions. All Regional representatives were asked to report to the next Council meeting the issues they are proud of and those areas where they are experiencing problems.

Regional websites were discussed and the possibilities of having regional areas on the ACB website or having links on the ACB website to the regional sites. It was decided that there is a requirement for a corporate style and a view from the Association Executive on how websites should develop.

Establishment of a Government Officer

The Association Chair is drawing up a job description for a Government officer whose roles will include scanning DOH website, maintaining a list of members who have the expertise and are prepared to comment on issues, and will liaise with BIVDA. This is important in the area of NICE and NSF initiatives and research grant opportunities. The Scientific Committee is currently carrying out some of these roles e.g. registering the Association for involvement in relevant NICE guidelines.

National Occupational Standards

Dr McCreanor gave a brief update of progress with the Occupational Standards project.

Function maps have been drawn up for generic, common and specialist standards. These have been field tested at a range of different hospitals and the standards have been re-written to take account of comments. Assessment guidance is being developed and the standards will be piloted in September 2003.

Regional Boundaries

The Association Secretary has revised the rules and moved Northamptonshire into Trent and Southampton into South West & Wessex.

Report of the Association Council held on Thursday 12th June 2003

Pathology Modernisation

The final draft of the document is circulating among the implementation guidance group and should be published in July. Some money will be available over the next 3 years, distributed to Strategic Health Authorities, to help set up diagnostic strategies, including imaging and therapies.

Diagnostic and Treatment Centres (DTCs) were discussed. Concerns were raised about centres being set up without Pathology involvement. Dr Freedman reported that she is the RCPATH representative on the CHI steering group for standards for DTCs. Communication with PCTs needs improving and the Regional ACB and College committees should work together to achieve this.

State Registration

State registration rules have gone to the Privy Council and the Register will open on 9th July using the new rules. ACS assessments are ongoing and the standards are exceptionally high.

Medical Input into the Association

Several names of individuals who could provide medical input into the association have been put forward and a meeting will be held at the end of June.

A suggestion was received from the SAC of RCPATH that ACB Executive should meet with the College to discuss joint working on areas such as workforce planning, education & training and liaison with professional bodies. Discussion continued about Medical Consultants who are not ACB members, and Regions were asked to consider how many such individuals are in their region.

Review of Working Relationship with Corporate Members

Task forces are to be set up to discuss the future of Focus after Euromedlab 2005 and explore the development of promotional strategy and the value of laboratory medicine.

Screening

The National Screening Committee review of screening includes Downs Screening. Prof Chris Price chairs the Laboratory Group and Dave Worthington is the Officer for the Laboratory Group. Prof Price will ask Dave Worthington to write an article for ACB News.

Report from AGM

Honorary Members for 2003 are Dr CG Fraser and Dr LJ Kricka.

Emeritus Member for 2003 is Mr BL Smith.

Mr C Weinkove, Dr HT Delves and Dr J Seth were accepted as Fellows of the ACB.

Award Lectures for Focus 2004

Council was asked to approve the Focus 2004 awards:

Roche award – Dr Jeremy Squire (Canada) – Microarrays in cancer diagnostics

Konelab Award – Dr Patrick Garner – Bone markers

ACB Foundation Award – Dr Mike Wheeler – Androgens/sport

AACC Transatlantic Lecture – Dr Robert Christenson – Natriuretic peptides.

Education Committee

Education Committee has reviewed and updated its Grade A and Grade B documentation.

A training day on Informatics and Point of Care Testing has been arranged for the autumn.

Focus 2004 topics are:

- Metabolic Bone Disease
- Screening

Training Day Topics at Focus 2004 are:

- Porphyria
- BNP and Heart Failure
- Hypertension and Obesity
- Metabolic Screening

Publications Committee

Stephen Halloran announced that he will be stepping down as editor-in-chief of the Annals of Clinical Biochemistry in 12 months time, a replacement is yet to be appointed. Council approved new Annals appointments of Ed Lamb and Mike Badminton.

Scientific Committee

An advert for scientific scholarships was placed in the June edition of ACB News.

Liaison with other organisations is ongoing and Dr R Hill is responsible for reviewing NICE website and passing documents to the appropriate persons within the ACB for comment.

Trainees Committee

Paediatric training and opportunities for future posts were discussed.

Workforce Advisory Committee

WAC met on 7th May and minutes were not available. A detailed report will be sent to ACB News.

HCS Awareness week is 17-22 November 2003. It will be a locally-driven initiative so regions need to ensure local awareness. Mike Hallworth has written to chairmen of ACB regions to suggest they give this a high level of publicity.

Paediatric secondment for Grade A trainees in London was raised as a problem as there is only one training centre which cannot cope with the increasing numbers of trainees.

Royal College of Pathologists

Training posts were discussed and although extra posts have been introduced there was dismay that these have been allocated on a weighted capitation basis. There were also concerns that NTN's were being placed in departments without medical consultants.

The paper concerning the delivery of abnormal results to GPs has been sent to RCGP for comment.

MRCPath is regulated by the Blue book and this is to be re-written and put on the website. Council were asked to submit comments to Dr Gray by the end of June. ■

Letters

Readers speak out

England . . . Not Wales OK!

In the article on Improving Working Lives, Anthony Walsh goes on happily about 'all NHS organisations' and 'Every manager' without making it clear that on this the Department of Health is speaking only for England. At least, my Director of Human Resources here in Cardiff assures me that in Wales the IWL targets are merely aspirational [trans: we would like to but we don't have the money] and that the Welsh Assembly have not signed up to them. I understand that the same is true for Scotland and Northern Ireland. I know Whitehall has a problem in taking on board that they don't speak for the rest of the world so it behoves us, or rather you, to make it clear what applies to England and what applies to the rest of us. In particular, because it is quite confusing, and we look at the Focus briefings to get it right.

Graham Read

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levels, require dose alteration to ensure optimal treatment while minimising side effects. Red blood cell lysate TPMT activity can be used to identify these patients and ensure appropriate treatment.

If you would like to participate in this scheme, please contact Jane French at TPMT@ukneqas.org.uk to receive further details. It is anticipated that the first sample distribution will occur in January 2004, followed by distributions every two months.

Loretta Ford

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Birmingham B15 2UE
TPMT@ukneqas.org.uk

Joint Organisers, TPMT International EQA Pilot

Pilot EQA Scheme for TPMT Phenotyping

A Pilot UK NEQAS for TPMT Phenotyping is being established jointly by UK NEQAS Birmingham and the TPMT service at the Clinical Chemistry Department, City Hospital Birmingham.

At present there is no EQA scheme for TPMT activity assays anywhere on the world stage. Since the number of analysing laboratories in any one country is likely to remain small, we are setting up a pilot scheme open to international participation to address this growing and important area.

Red blood cell activity of thiopurine S-methyl transferase (TPMT) is used to assess patients prior to commencing treatment with drugs such as azathioprine. TPMT metabolises thiopurines to inactive metabolites. The enzyme displays genetic variation and patients who lack TPMT activity, or have reduced

Recovery Calculations are Over-Optimistic

I was very interested in the recent worked example describing recovery calculations in immunoassay (Deacons Challenge, Question 27, June 2003 ACB News) because it reminded me of concerns I have about a different calculation method to be found in the literature accompanying some commercially available immunoassay kits. An example will illustrate my point:

A sample, whose intact PTH concentration is 516 pg/mL, is 'spiked' 1 to 19 with a 1720 pg/mL solution of intact PTH; after assaying the mixed sample, the new concentration was found to be 560 pg/mL. What is the recovery of PTH? (data from DPC Immulite 2000 intact PTH kit insert, dated June 8, 2000).

Newcastle upon Tyne Hospitals



NHS Trust

TRUST WIDE

DEPARTMENT OF CLINICAL BIOCHEMISTRY

Principal Clinical Biochemist*Grade B, £33,021 - £40,174 pa, Starting point in the range of 19-24 depending on qualifications and experience, 37 hpw**Ref: RVI/2003/608*

An opportunity to join a team providing comprehensive Clinical Biochemistry services at local, regional and national levels is available to an enthusiastic, ambitious, team orientated Clinical Scientist. A major programme of staff re-structuring, equipment updating and refurbishment of all three laboratory sites in the Trust is nearing completion and provides the basis for exciting and challenging service development. An individual with abilities to organise, lead and motivate while being open-minded and receptive to new ideas will be ideally suited to this vacancy.

The post is open to a State Registered Clinical Scientist possessing MRCPath or equivalent and possibly a higher degree. Active participation in CPD is essential and will be strongly supported. The laboratories are CPA accredited.

An application form and job description are available from the Job Shop, Royal Victoria Infirmary, Queen Victoria Road, Newcastle upon Tyne NE1 4LP on (0191) 282 4114.

Closing date: 16th October 2003.

This Trust operates a "No Smoking" policy all vacancies are open to job share unless otherwise stated.
www.sector1.net for more vacancies within this organisation

You will be expected to have a broad range of experience as a Clinical Biochemist. An ability to provide effective interpretative and problem oriented scientific research and development input will be necessary. Initially you will be closely involved in a dynamic, evolving General Biochemistry Service, Diabetes support services, Acute Coronary Syndrome investigate service development and POCT. Additional areas of special expertise/interest will be an advantage.

For further information and/or an informal visit please contact Dr Dermot Neely, Head of Department and Consultant Chemical Pathologist, on (0191) 282 4554, Mr Ian Gibb, Consultant Clinical Biochemist, on (0191) 282 4585 or Dr Arnott Fleetwood, Consultant Clinical Biochemist, on (0191) 282 4361.



Euro/DPC is the European manufacturing and distribution organisation of the Los Angeles based Diagnostic Products Corporation, the world-wide independent manufacturer of immunodiagnostic kits and instruments for hospitals and veterinary laboratories. Euro/DPC is an ISO 9002 registered company.

Scientific Affairs Manager

Due to the significant growth in DPC UK business, a new role of Scientific Affairs Manager has evolved. Reporting to the UK General Manager the main aspects of this role encompass the management of all external and internal scientific affairs providing support for our DPC UK customers and staff. Traveling is an integral part of this role, but some of the time will be routinely based at our company headquarters in North Wales.

It is anticipated that the successful applicant will have passed the MRC Path examination with a specific interest in the immunoassay arena. The ideal candidate will be a high achiever, of outgoing personality and willing to be an integral part of the UK's most successful independent immunodiagnostic company.

The successful applicant will enjoy excellent company benefits, including a competitive salary, a quality company car, a non-contributory pension scheme and other rewards.

Closing date: 3rd October 2003

If you would like to be considered for the above position, please contact the Human Resources Department for an application form.

Euro/DPC Limited, Glyn Rhonwy,
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NHS Trust

Department of Chemical Pathology
CLINICAL BIOCHEMIST GRADE B

Starting point in the range 8-13 depending on experience

£21,451 - £26,097

Applications are invited for the post of Senior Biochemist in the Department of Chemical Pathology at this busy DGH. This 580-bed hospital has a wide range of clinical services including A&E, ITU, HDU, CCU and Regional NICU and has recently been awarded 3 star status. The Department is fully CPA accredited and provides a comprehensive service for the population of South Bedfordshire. Relationships between the laboratory and clinical teams are excellent and allow ample opportunity for input at the clinical interface, as well as participation in audit, teaching, research and development.

The recently refurbished and extended laboratory is well equipped with modern analysers and there will be significant advances in IT provision in the coming year, which will affect the way we work with the acute and primary health care sectors. The post will extend across the whole of the work performed but a special interest in Point-of-Care Testing will be encouraged.

You will have undertaken formal training in clinical biochemistry in a Grade A scheme and will be supported in working towards gaining the MRCPath qualification.

Full training for the completion of MRCPath will be provided, including case discussion and attendance at clinics. You will be encouraged to attend regional and national meetings and funding is available to allow this. The opportunity to work with Dr Danielle Freedman is an excellent opportunity to extend Grade A training to State Registration in a challenging and stimulating environment.

Luton is only an hour from London by road or rail and the hospital is very conveniently placed adjacent to the M1 motorway at Junction 11. London Luton Airport is nearby allowing for easy access to other parts of the UK and abroad. Property prices are very reasonable.

Informal enquiries and visits should be arranged through Dr Danielle Freedman, Consultant Chemical Pathologist on 01582 497212 or Mrs Pauline Ridgwell, Consultant Clinical Biochemist on 01582 497969.

For further information on this and other roles, and to apply online please log onto www.jobswithlutonanddunstablehospital.co.uk or Tel: 01582 497284 (24hr answerphone) for an application pack. If you are hard of hearing please use our minicom 01582 497405.

Please quote reference number ACB/TP0023.

Closing date: 17 October 2003.

At the Luton and Dunstable Hospital we have an excellent range of benefits and development opportunities, and are committed to improving the quality of working lives for all our staff.

Committed to equality.



accredited by the
Health Quality Service

University Hospital Birmingham NHS Trust
Department Of Clinical Biochemistry

Clinical Scientist Grade B

8-13 (depending on qualifications and experience)

Job Ref: 3G0351

We invite applications for this new post, which would be ideally suited to a clinical biochemist wishing to build on Grade A training to proceed towards the MRC Path examination.

The Trust encompasses the Queen Elizabeth and Selly Oak Hospitals. A new hospital development is scheduled for completion in 2008. It is the major teaching Trust in the West Midlands Region. As well as providing clinical biochemistry services to the Trust, other hospital Trusts in Birmingham and over 100 GP practices, the Department provides Regional and Supra Regional endocrine services and specialist support for tertiary referral centres within the Trust. These include transplantation, oncology, cardiac surgery, burns, trauma, renal medicine and liver services.

Senior staff of the Department are committed to training and involved in undergraduate and postgraduate education both regionally and nationally.

We can provide the opportunity to gain experience of a variety of analytical techniques and to be actively involved in the biochemical aspects of the diagnosis and treatment of patients with a wide range of disorders.

There are strong links with academic and clinical specialties in the University of Birmingham Medical School and the Trust and there are excellent opportunities for research and development. The successful applicant will be encouraged to develop a specialist interest.

We are looking for a highly motivated clinical biochemist who works well as part of a team and is prepared for a challenging but rewarding role in a busy teaching hospital environment.

For further information, or to arrange an informal visit, please contact Janet Smith on 0121 627 8449, Peter Gosling on 07771 647586 or Penny Clark on 0121 627 1627 ext: 52297.

Application forms and job descriptions are available from the Recruitment Centre, 1st Floor, J Block, Selly Oak Hospital, Raddlebarn Road, Selly Oak Birmingham B29 6JD, tel: 0121 627 8255, email recruitment.centre@uhb.nhs.uk Please quote reference number 3G0351

Closing date: 10th October 2003.

All posts within University Hospital Birmingham NHS Trust working in clinical areas, or with direct patient contact, will be subject to a disclosure check through the Criminal Records Bureau.

The Trust is an Equal Opportunities Employer and positively encourages applications from all sections of the community. All posts within the Trust are open to Job Sharing unless stated. The Trust operates a No Smoking Policy.

University Hospital Birmingham 
NHS Trust



One Trust, Endless Opportunities

Royal Wolverhampton Hospitals 

NHS Trust

Department of Clinical Chemistry

Clinical Biochemist Grade B 17-19

£29,576 - £31,989 p.a. (Pay award pending)

37 Hours per week

Our well-equipped busy CPA accredited Department of Clinical Chemistry provides a comprehensive service to New Cross Hospital (a 900 bedded Teaching Hospital), Wolverhampton Eye Infirmary, West Park Community Hospital and Primary Care Trusts within the area. A research laboratory and excellent IT facilities support our established research interests in cardiovascular risk, parathyroid hormone, renal disease and informatics. We are committed to training and education and have strong links with the Universities of Birmingham and Wolverhampton.

Applications for this new post are invited from enthusiastic state registered Clinical Scientists, possessing at least DipRCPPath. The appointee will be expected to be working towards the MRCPPath and develop research interests within the existing departmental R & D infrastructure. The appointee will be involved in all aspects of laboratory work. HPLC experience would be advantageous but not essential.

For further information or to arrange an informal visit please contact Dr R Gama, Consultant Chemical Pathologist and Head of Department on (01902) 643056 or Dr M Holland, Consultant Clinical Biochemist on (01902) 643054.

For an application form and job description please email Alain Rolli at Alain.Rolli@rwh-tr.nhs.uk or contact the Departmental Secretaries on (01902) 643018, Department of Clinical Chemistry, New Cross Hospital, Wolverhampton WV10 0QP. Please quote reference number: SC69.

Closing date: 20th October 2003.

This post is subject to Criminal Records Bureau checks.

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No smoking environment



University College London Hospitals 
NHS Trust

**NATIONAL HOSPITAL FOR NEUROLOGY AND NEUROSURGERY
DEPARTMENT OF NEUROIMMUNOLOGY**

Clinical Scientist

Scale Points 16 - 22, depending on qualifications/experience

Grade B: £32,031 - £39,818 p.a. inc.

Ref: CS/401/GC

Applications are invited for this post which is based in the Department of Neuroimmunology at the Institute of Neurology, National Hospital for Neurology & Neurosurgery. The Department is an NHS laboratory, which is part of Biochemical Medicine at UCLH Trust. The laboratory has an international reputation for the analysis of cerebrospinal fluid and is a reference centre for investigation of oligoclonal IgG.

There are strong links with the Institute of Child Health, with which it collaborates in the study of carbohydrate deficient glycoprotein syndromes, a group of inborn errors affecting protein glycosylation. Other major areas of interest include anti-neuronal antibodies in paraneoplastic and autoimmune neurological syndromes and the diagnosis of specific inflammatory diseases of the CNS, including multiple sclerosis.

The Department is undertaking a major new initiative investigating the role of CSF analysis in dementia and you will be encouraged to develop an interest in this area. Commensurate with these interests, a range of protein analytical techniques, including gel electrophoresis, immunoblotting, and isoelectric focusing, as well as various immunoassays are routinely in use. The laboratory has an established history of research and development within its area of specialisation and staff members are encouraged to contribute to the continuation of this process.

Responsible to the Head of Department (Prof. E. J. Thompson) you will, after appropriate training, assume responsibility for the provision of designated services within the laboratory. These will include analytical, validation, reporting and service development activities. You must be registered with the Health Professions Council and should hold an appropriate postgraduate professional qualification, such as MSc/PhD and/or DipRCPPath./MRCPath. Ideally, you will have evidence of involvement in research and development, possibly marked by peer review publications. You will be encouraged to undertake postgraduate research and will be supported to obtain higher qualifications where appropriate.

For further information or to arrange an informal visit, please contact either Dr. G. Keir or Prof. E. J. Thompson on 020 7837 3611 ext. 3814.

HOW TO APPLY:


- Print an application pack from www.uclh.org/jobs or
- Telephone 0870 442 4529 weekdays 8am-7pm or Saturdays 9am-2pm quoting the reference number.
- All our vacancies can be viewed on our website at www.uclh.org/jobs

Closing date: 17 October 2003

UCLH is an employer committed to equal opportunities and improving working life for all our staff. All our jobs are open to job share, with or without a partner.



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Royal Devon & Exeter Healthcare 
 NHS Trust

Consultant Clinical Scientist

£37,421 - £51,215 p.a. 40 hours p.w.

Ref: 438

This replacement position represents one of a series of anticipated senior retirements from the Department of Clinical Chemistry over the next year and therefore provides good opportunity for you to stamp your own character on the continued scientific development of the laboratory.

The Royal Devon and Exeter has historically been a busy District General Hospital providing a comprehensive range of services to the 350,000 patient population in its healthcare area encompassing Mid and East Devon. As from September 2002 it also constitutes part of the new Peninsula Medical School providing additional teaching and research opportunities.

You should have membership of the Royal College of Pathologists and will be Deputy Head of Department for the provision of Clinical Chemistry services. You will be expected to participate in equal share in the Duty Biochemist duties for result validation and interpretation and be a member of the Pathology Consultants Committee.

For further information or to arrange an informal visit, please contact Dr. Maurice Salzmann, Consultant Clinical Chemist on 01392 402933.


Application form and job description may be obtained via our website www.nedevonhealth.nhs.uk, or by telephoning our Personnel Department on 01392 402380. Please quote the reference number when applying.

Closing date: 30 September 2003.

Certain posts within this Trust involve access to children and/or vulnerable adults and in line with Trust policy, postholders will be required to undertake a disclosure check.



We are committed to Equal Opportunity for all and encourage flexible working arrangements including job sharing.

University Hospital of North Staffordshire 
NHS Trust

CLINICAL SUPPORT SERVICES DIVISION

DEPARTMENT OF CLINICAL BIOCHEMISTRY, CENTRAL PATHOLOGY LABORATORY

Clinical Biochemist

GRADE B £22,307 - £24,128 (POINT 9-11)

University Hospital of North Staffordshire NHS Trust is a progressive, ambitious organisation that is constantly evolving to improve active health care services to support the needs of over 3 million people across Staffordshire, Shropshire and South Cheshire.

Employing 7,100 staff on 3 main and two smaller sites, there is currently a £270 million scheme in place to modernise the Trust and improve health care provision in the area, which includes moving the majority of acute facilities onto a single site hospital by 2007. In conjunction with Manchester and Keele Universities, the on-site Undergraduate Medical School opened in September 2002.

Committed to improving the working lives of its staff, the Trust has a flexible approach to working hours and operates an employee friendly policy which includes part time and term time hours, maternity and paternity leave and also offers the opportunity for career breaks. Job sharing will be considered. The Trust is dedicated to the personal development of its staff.

The Clinical Biochemistry Department in the University Hospital of North Staffordshire is one of the largest in Britain. It provides local and region-wide services, including Endocrine, Genetic and Protein/Immunology Services for a population of up to 2 million people. The department occupies the purpose built Central Pathology Laboratory that also houses the other Pathology services. The Clinical Biochemistry Department has full CPA accreditation.

This post results from the retirement of the previous post-holder. You will be expected to contribute to routine service provision and help expand the

molecular genetic and other services of the department. There are excellent opportunities for training towards the MRC Path.

Members of the department, including the Head, Professor Richard Strange, have academic appointments in Keele University Medical School, and the person appointed would have an opportunity to participate in the department's research activities. These comprise of externally grant-funded studies that focus on the role of genetic polymorphism in determining disease risk.

You should have a good honours degree in a relevant subject and ideally a PhD. Applications are welcomed from those who have undergone Grade A training, as well as from enthusiastic scientists who have a strong Biochemical background and an interest in a career in Clinical Biochemistry, but no experience in a routine service provision. Appropriate training will be given to such applicants.

To discuss the post, or to arrange a visit to the department, contact Professor Strange on 01782 554667, Dr Neary on 01782 554669, or Dr Fryer on 01782 555175.

Please visit our website www.nsht.nhs.uk for a full job description and application form. Alternatively, contact Mr B Davis, Head BMS, Biochemistry Department, Central Pathology Laboratory, Hartshill, Stoke-on-Trent, Staffordshire ST4 7PA.

Closing date: 10th October 2003.

University Hospital of North Staffordshire treat all applications equally and all appointments are made purely on merit. We operate a No Smoking Policy.



For further information
on the Trust visit our website:
www.nsht.nhs.uk

To advertise your vacancy contact:

ACB Administrative Office, 130-132 Tooley Street, London SE1 2TU
Tel: 0207-403-8001 Fax: 0207-403-8006 Email: ACBNewsAdverts@ACB.org.uk
Deadline: 26th of the month prior to the month of publication

Training Posts: When applying for such posts you should ensure that appropriate supervision and training support will be available to enable you to proceed towards state registration and the MRCPath examinations. For advice, contact your Regional Tutor.

The editor reserves the right to amend or reject advertisements deemed unacceptable to the Association.

Advertising rates are available on request



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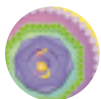
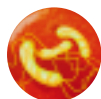
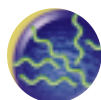
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