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 Centre for Infections
 Evaluations and Standards Laboratory
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Have your say...

Have you got something to say about the activities of ESL?
 If so, please visit our customer feedback system at:
www.hpa-quality.org.uk/cfs

About the HPA

The Health Protection Agency (HPA) is an independent body that protects the health and well-being of the population. The Agency plays a critical role in protecting people from **infectious diseases** and in preventing harm when hazards

involving **chemicals, poisons or radiation** occur. We also prepare for new and emerging threats, such as a bio-terrorist attack or virulent new strain of disease.

About ESL

The Evaluations and Standards Laboratory (ESL) brings together expertise in five areas of quality related services:

- Development of National Standard Methods, developed over the last 12 years in partnership with professional organisations, experts and working microbiologists from throughout the UK
- Experience in evaluations and assessment of diagnostic devices and products related to microbiology for over 15 years
- The provision of Quality Control Reagents to enable labs to monitor the performance of such diagnostic devices day-to-day
- Development and Management of the quality system in the Centre for Infections
- Training courses in microbiology and public health open to health professionals world-wide.



ESL sits within the Centre for Infection of the Health Protection Agency. The Centre, employing over 800 staff, is renowned for its integrated microbiology and epidemiology services in responding to health alerts nationally and internationally. The Centre's remit covers specialist and reference microbiology, microbial epidemiology and infectious disease surveillance. Working with others the Centre co-ordinates the investigation and cause of national and uncommon outbreaks, advising the UK Government on the risks posed by infectious diseases.

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Need more information? Call or email us using the details above, visit our website www.evaluations-standards.org.uk, use our web-based feedback form www.hpa-quality.org.uk/cfs or complete the form below and fax to us on +44 (0)208 3276008, or post to:

Kim Morris
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I am interested in:

- Receiving the ESL Newsletter by email / post*
- Registering for the BSMT/HPA conference
- The QCRU Users Day
- 'Outbreak investigation: a practical course'
- 'Hitch Hikers Guide to Microbiology'
- Contributing to PoCT evaluations/NSMs/QCs
- Other (please give details)

*delete as appropriate

Name:

Dept/company:

Postal address:

.....

.....

Postcode:

Email address:

Telephone no:

Enquiry/comment:.....

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Evaluations and Standards Laboratory News

International Edition

February 2008

Issue 5



The 'Inter'-National Standard Methods

www.hpa-standardmethods.org.uk
 1,450 password holders world wide

National Standard Methods (NSMs) have been developed since 1996 to standardise microbiology methods within the UK. Over the years NSMs have been adopted as best practice by laboratories across the world. Recent baseline statistics show that we have password holders in 75 different countries.

Our international work includes liaising with the *Associazione Microbiologi Clinica Italiani* (AMCLI) - members were welcomed to working group meetings at the HPA and exchanged ideas for standardisation and syndromic algorithms. Our thanks go to Professor Antonio Goglio for initiating the collaboration, and to Dr Roberto Rescaldini and Dr Clementina Cocuzza for their excellent work on the translation of NSMs into Italian (available on the Itlabioforma website <http://fad.italbioforma.it/P5.asp>). Last year we were also pleased to welcome Professor Liz Dax to the HPA to give a presentation on the work of the Australian National Serology Reference Laboratory (NRL).

As a consequence of these collaborations, the Director of ESL Val Bevan was invited to present on quality-related subjects at the XXXVI AMCLI National Congress in Rimini and at the 24th NRL Workshop on Serology in Australia last year, and this led to invitations to participate in two important meetings in Europe this year: the ESCV (Lapland) and the WHO-CDC International Conference on Health Laboratory Quality Systems (Lyons).

Over the past few years we have been invited to advise on the development of systems for standardising clinical and public health microbiology methods in Romania, the Caribbean and in Cyprus and have also given presentations in Vienna, Athens, Singapore and China, and there are currently discussions about translating the methods into Mandarin.

HPA-MiDAS: Evaluations Unit

Evaluations Register

We are developing an online 'Evaluations Register' (available soon from our website). The Microbiological Diagnostics Assessment Service (HPA-MiDAS) improves the quality of diagnostic laboratory services by identifying tests and equipment that perform well (or not so well!). Gaps in evaluation information hamper the development of testing policies and procurement exercises and we have a key role in filling those gaps. So visit the ER, find expert advice and share your data with your peers.

New evaluation reports (available now/coming soon)

- ☞ CleanCatch® Midstream urine collection device
- ☞ **Roche HIV combi** (automated HIV Ag/Ab assay)
- ☞ Adaltis EIAGEN Syphilis
- ☞ **Abbott ARCHITECT / System:** HIV Ag/Ab, HCV, HBsAg, Rubella IgG, CMV IgG, Syphilis TP
- ☞ *Chlamydia trachomatis*: multicentre evaluation of chlamydia NAATs (nucleic acid amplification tests)
- ☞ **MRSA selective media:** four media assessed by six laboratories

And more.....keep checking our web pages for the latest updates



Quality Control Reagents Unit

New reagent

The second Total anti-HBc quality control reagent (QCRTHBcQC2) is now available (see page 2).

New batches

HIV1p24QC1, Anti-HBsQC1, HBsAgQC1, HBsAgQC2, and THBcQC1 are available now. New batches of Anti-SyphilisQC1, Anti-HIV1QC2, Anti-RubellaQC1, Anti-VZVQC1 are coming soon.

Annual QCRU User Day

At this well-attended meeting last November, delegates called for a workshop to discuss the use of IQC reagents and other laboratory related issues in future meetings, so the next User Day will host it's first Workshop on Internal Quality Control and Laboratory Quality.

2008-09 price list

The new price list effective 1st April 2008 is available. Please get in touch if you would like a copy sent to you.

quality.reagents@hpa.org.uk Tel: +44(0)208 327 6933; Fax: +44(0) 208 3276081 or return the form at the end of this Newsletter.

EVALUATION HIGHLIGHT:**Cytomegalovirus (CMV) antibody assays****What is CMV?**

CMV is a common (50-80% of adults) herpes virus which although often asymptomatic among the immunocompetent, can cause mild to severe disease, particularly in the immunocompromised, pregnant women or newborn babies.

What evaluations have we done recently

The National Blood Service commissioned a study of **six IgG/total antibody CMV assays**, and more recently the Abbott Architect CMV IgG assay. These reports will be available through our website in the first quarter of 2008.

... and what are we doing now?

An extended study funded by CEP* is currently underway to include a further **sixteen** assays (yes, sixteen!) so far, representing the vast majority of currently available IgG/total antibody CMV tests.

*NHS-PASA Centre for Evidence based Purchasing

Total Anti-Hepatitis B core QC

The second Total anti-HBc quality control reagent (QCRTHBcQC2) is now available with all the HPA reagent qualities you have come to rely on:

- made as similar to a true specimen as possible
- R&D scientifically led
- "CE" marked
- long shelf life
- competitively priced

Should I use QCRTHBcQC2 instead of QCRTHBcQC1?

QCRTHBcQC1 is suitable for test kits such as Biokit, Dade Behring Enzygnost, Abbott Architect, Siemens Healthcare Diagnostics ADVIA and BioMérieux VIDAS.

QCRTHBcQC2 will have a lower activity level than QCRTHBcQC1, and will be suitable for test kits such as Diasorin, Abbot Murex and AxSYM, Ortho Vitros, and Bio-Rad Monolisa.

For further information on Total HBc QCs, or kits not listed here that you wish us to include, contact us.

'Clostridium difficile – The Super Bug explained'

Over 200 UK and international delegates attended the popular symposium 'Clostridium difficile – The Super Bug Explained' organised by the Standards Unit and held on the 14th February 2008 at the HPA Centre for Infections (CfI).



The day, consisting of a series of talks and discussions regarding the accurate diagnosis of this infection and current guidelines, was well received by all. The scene was set for the day by Professor Brian Duerden, the UK Department of Health Inspector for Microbiology and Infection Control, who gave an overview of the current situation with regard to *Clostridium difficile* outbreaks and informed the delegates about the importance of outbreak reporting. This was followed by talks from Professor Mike Wren and Dr Jon Brazier, consultant scientists who specialise in anaerobic infections from London and Wales respectively, who spoke about the methods (and problems) involved in isolation and identification of *C. difficile*. Professor Wren also showed the delegates a useful algorithm for *C. difficile* testing. The day continued with talks on the evaluation of *C. difficile* kits and other available devices through presentations from Dr Keith Perry (ESL) and Stephen Lee (MHRA). In the afternoon session, Dr Bharat Patel (HPA) discussed current guidelines and Dr Andrew Pearson (CfI) spoke about current outbreaks and surveillance. The day concluded with talks from Professor Saheer Gharbia (CfI) on current developments in *C. difficile* genome profiling and molecular diagnostics and Professor Pete Borriello, Director of CfI, discussing key issues from the day.

Presentations from the day are available on our website, together with details of future events (www.hpa-standardmethods.org.uk).

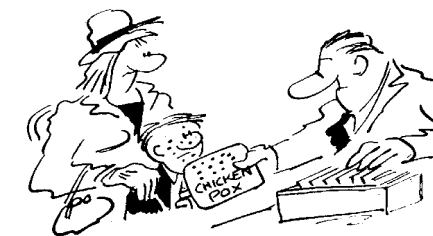
National Standard Methods Update**Available soon:**

- BSOP 42** - Investigation of bone
- BSOP 44** - Investigation of prosthetic joint infection samples
- QSOP 52** - Inoculation of culture media
- VSOP 4** - Hepatitis B diagnostic serology in the immunocompetent (including Hepatitis B in pregnancy)
- VSOP 10** - Blood borne virus testing in dialysis patients
- VSOP 26** - Epstein-Barr Virus serology
- VSOP 37** - Chlamydia infection – testing by nucleic acid amplification tests

Plus look out for... improved BSOP TPs (test procedures) with flow charts in the appendix providing easy access to the procedures.

Point of Care Tests: a call for caution

Point of Care Tests are undertaken outside central laboratory facilities, require no specialised equipment, and are easily read with rapid availability of results. The PoCT market is growing rapidly with devices available through primary care settings, pharmacies and the internet. A range of PoCTs are applicable to infectious disease detection e.g. for HIV, Influenza, *Chlamydia trachomatis*, Group A Streptococci, malaria, and biological agents. These are mostly based on serological lateral flow systems but there is potential for molecular PoCT developments.



professionals should be used to influence and form partnerships with primary care PoCT programmes. The same standards used for laboratory-based assays should be applied, and this includes application of accreditation schemes, standard operating procedures, assay validation, staff training, IQA and EQA schemes, safety aspects and full documentation*.

Access to self-test PoCTs via the internet is even more challenging. Devices may be sold without comprehensive validation and sometimes through suppliers of unknown repute. They are sold to a public unaware of the pitfalls of choosing the wrong device. More guidance needs to be made available for the general public.

Required standards
• Assay validation
• Standard operating procedures
• Application of accreditation schemes
• Staff training
• IQA and EQA schemes
• Safety
• Full documentation

The Evaluations and Standards Laboratory is in the process of developing a **National Standard Method** and is undertaking a performance evaluation of three HIV rapid tests.



Two quality controls (HIV1-QC1 and HIV2-QC2) have been validated for use on HIV rapid tests.

We would be interested in further discussion and feedback on improving PoCT practice. Please contact eslenquiries@hpa.org.uk.

*Some of the QC issues are addressed in: BS EN ISO 22870:2006 'Point-of-care testing (POCT). Requirements for quality and competence'.

TRAINING AND EVENTS

at HPA Colindale



BRITISH SOCIETY FOR MICROBIAL TECHNOLOGY
23rd ANNUAL SCIENTIFIC MEETING



16 May 2008

"Doing more for less – giving up on culture"

For provisional programme and application form please contact:
Janet Norcup – janet.norcup@hpa.org.uk

Outbreak investigation: a practical course

25 & 26 November 2008

Content to include:

- Outbreak detection: how and why (especially when not obvious)
- Outbreak investigation: when and why to undertake analytical studies
- Developing trawling questionnaires and generating hypotheses
- Practical exercises in questionnaire and study design
- Common statistical packages (Stata, EpiData Analysis) and hands-on analysis
- Legal framework for outbreak investigation

For further information and a registration form, contact Gloria Wilson on +44 (0)208 3277808, email: gloria.wilson@hpa.org.uk, or return the form on page 4.

The Hitch Hikers Guide to Microbiology: Microbiology for non-microbiologists

24 June 2008

Germes and their diseases explained in plain English, your questions answered and visit a laboratory. No previous knowledge required.

For further information and a registration form, contact Gloria Wilson on +44 (0)208 3277808, email: gloria.wilson@hpa.org.uk, or return the form on page 4.