



**U.K. National External Quality Assessment
Scheme for Blood Coagulation**

**PARTICIPANTS' MANUAL
& GENERAL INFORMATION
2012-2013**

Revised: 07/03/2012

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BACKGROUND

UK NEQAS for Blood Coagulation was originally founded in 1967, with recognition as a UK NEQAS in 1975. Professor F E Preston was appointed Director in 1992, and organisation of the programme was transferred in November 1993 from the Royal Free Hospital, London, to the Royal Hallamshire Hospital, Sheffield Teaching Hospitals NHS Foundation Hospital Trust. Professor I D Walker was appointed Director from 1st February 2005, on the retirement of Professor Preston.

The purpose of UK NEQAS for Blood Coagulation (BC) is to provide external quality assessment (EQA) for tests of blood coagulation, and other tests of haemostasis, and so promote high standards of performance and practice. EQA, together with internal quality control (IQC) procedures, are seen as vital components of overall laboratory quality assurance. In addition, UK NEQAS provides a repeat testing and advisory service to participants, and educational activities including scientific meetings and peer reviewed publications.

PARTICIPATION

Although primarily intended to meet the needs of clinical laboratories, participation by industrial and other laboratories is welcomed. Most participating laboratories are sited within the UK, but registration is open to laboratories in all countries, whether government supported, private or commercial. UK NEQAS BC is operated on a not for profit basis, under the auspices of UK National External Quality Assessment Service and professional bodies.

Samples for over 30 different tests of blood coagulation are distributed to more than 1,000 participating laboratories in the laboratory based Level 1 & Level 2 programme; in addition there are over 3,000 participants in the Point of Care Testing / Near Patient Testing (POCT/NPT) programme.

UK NEQAS for Blood Coagulation ensures the protection of participants' confidential information.

PERSONNEL

Directed by Professor I D Walker, the Manager and Deputy Director of UK NEQAS BC is Mr T A L Woods, based at 3rd Floor Pegasus House, 463A Glossop Road, Sheffield S10 2QD.

| | | |
|---------------------------|--------------------|--|
| Members of staff include: | Dr I Jennings | Scientific Progm./ Deputy Scheme Manager |
| | Dr S Kitchen | Scientific Director |
| | Mrs D P Kitchen | Specialist Scientific Lead for Point of Care |
| | Mrs S Munroe-Peart | Biomedical Scientist & Quality Manager |
| | Mr P Brown | Computing Systems |
| | Mrs S L Rowbotham | PA to Scheme Director |
| | Miss J Chandler | PA to Scheme Managers |
| | Mr S Asif | Medical Laboratory Assistant |
| | Ms R Leigh | Clerical Officer |
| | Mrs J Ogden | Assistant Clerical Officer |

| | |
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| Web site: | www.ukneqasbc.org |

The organisation receives advice from a Steering Committee. The current members of the Steering Committee are as follows:

| | |
|------------------------------|---|
| Dr P Bolton-Maggs | Haematology Dept., Manchester Royal Infirmary, Manchester |
| Dr D Perry (Chairman) | Department of Haematology, Addenbrookes Hospital, Cambridge |
| Dr J Pattinson | Bucks Health care |
| Dr E Gray | Department of Haematology, National Institute for Biological Standards & Control, South Mimms, Herts. |
| Dr I Jennings (Secretary) | UK NEQAS for Blood Coagulation, 3 rd Floor Pegasus House, 463A, Glossop Road, Sheffield |
| Dr D Keeling | Oxford Haemophilia Centre & Thrombosis Unit, Churchill Hospital, Oxford |
| Mrs D P Kitchen | UK NEQAS for Blood Coagulation, 3 rd Floor Pegasus House, 463A, Glossop Road, Sheffield |
| Dr S Kitchen | Coagulation Laboratory, Sheffield Teaching Hospitals, Royal Hallamshire Hospital, Sheffield. |
| Professor M Laffan | Department of Haematology, Imperial College School of Medicine, Hammersmith Hospital, London |

| | |
|--|--|
| Dr I Mackie | Haemostasis Research Unit, Dept. of haematology, University College Medical School, London |
| Dr D Harrington | Department of Haemostasis & Thrombosis, St Thomas' Hospital, London |
| Professor I D Walker (Director) | UK NEQAS for Blood Coagulation, 3 rd Floor Pegasus House, 463A Glossop Road, Sheffield |
| Mr T A L Woods (Manager & Deputy Director) | UK NEQAS for Blood Coagulation, 3 rd Floor Pegasus House, 463A Glossop Road, Sheffield |
| Professor F R Rosendaal Statistical Advisor | Department of Clinical Epidemiology, University Hospital, Leiden, The Netherlands |

EQA PROGRAMMES

All EQA Programmes listed here currently have full accreditation status with CPA (UK) Ltd.

BLOOD COAGULATION PROGRAMME:

1. Tests covered in this programme:

Level 1 (Screening tests):

- Prothrombin Time (PT)/INR (Quick and/or capillary methods)
- PT (diagnostic)
- Activated Partial Thromboplastin Time (APTT)
- Heparin Dosage Assessment (HDA)
- Heparin Assay (HA)
- Thrombin Time (TT)
- Fibrinogen evaluation
- D-Dimer
- Lupus anticoagulant

Level 2 (Assays):

| | |
|-----------------------------|--|
| Factor II assay | Von Willebrand factor antigen assay |
| Factor V assay | VWF:RiCof (activity) assay |
| Factor VII assay | Antithrombin antigen assay |
| Factor VIII:C assay | Antithrombin activity assay |
| Factor IX:C assay | Protein C antigen assay |
| Factor X assay | Protein C activity assay |
| Factor XI assay | Protein S total and free antigen assay |
| Factor XII assay | Protein S activity assay |
| Factor XIII screen | Plasminogen assay |
| Quantitative VIII inhibitor | Activated Protein C resistance assay |

2. Registration

The nominated participant, normally the person with overall responsibility for the laboratory, is requested to register for all tests included in UK NEQAS BC, which their laboratory offers as a service. As part of registration, participants in the UK are requested to formally agree to adhere to the Joint Working Group's Conditions of Participation in UK EQA Schemes. With the few exceptions indicated in these Conditions, the Director is obliged to observe strict confidentiality regarding individual performance. All participant details are held in strict confidence and are not shared with any third party. Use of the participant number will assist in maintaining confidentiality in survey correspondence.

The UK NEQAS website www.ukneqasbc.org provides a range of information about the organisation, programmes and surveys and forthcoming events. Participants can also enter their results on the web, download survey reports, certificates of registration and certificates of performance.

Registered Participants (Level 1 & Level 2 including additional registrations at one centre): as at 16th February 2012

| | |
|---------------------------------------|-------------|
| Total number of registrations: | 1089 |
| UK (NHS & Private/Commercial): | 657 |
| Republic of Ireland: | 77 |
| Other European Union: | 238 |
| Rest of the World: | 117 |

3. Surveys

Six exercises are distributed each financial year. Four of these surveys include both screening tests and factor assays and there are 4 distributions each of thrombophilia screening exercise. Details of tests to be included in each survey are indicated in individual reports three months prior to survey distribution. All samples are of lyophilised plasma, from donors screened for hepatitis B surface antigen (HBsAg) and for antibodies to hepatitis C virus and human immunodeficiency virus types 1 and 2 (anti HIV-1+2). In the majority of cases, samples are from single donations. In addition to six main scheme distributions, relevant supplementary exercises are distributed on an ad-hoc basis to address current issues in haemostasis.

Survey dates in 2012/2013

Level 1 & Level 2:

| | | |
|---|-----------------|-------------------|
| Distribution dates for the financial year; (1 st April 2012 to 31 st March 2013) | Survey 193 | 3 April 2012 |
| | Survey 194/1194 | 22 May 2012 |
| | Survey 195 | 24 July 2012 |
| | Survey 196/1196 | 18 September 2012 |
| | Survey 197/1197 | 13 November 2012 |
| | Survey 198/1198 | 15 January 2013 |

4. Reports

Individual reports for each survey are sent two weeks after the closing date for the respective survey to the first, and (if registered), second named participants. For centres registered for online data entry, reports are made available as online pdf documents. Additionally, some weeks after the individual results, an overall exercise report is made available to registered participants for electronic download from the website (www.ukneqasbc.org). This report includes comprehensive analysis of test results by methodology, together with graphically presented data analysis for each test specimen.

5. Performance Analysis

Performance is determined by comparison of individual laboratory results with the target value for each test. Median values determined from participants' results are used as consensus or "target" values against which individual laboratory performance can be assessed. Use of the median avoids the effect of outlying results and the need to perform 'truncation' of data. Where consistent reagent or method-related differences have been identified, participants' results are assessed against their 'peer-groups' provided the number in that group is sufficient to be statistically valid.

Screening Tests

For PT/INR, PT for diagnosis, and APTT the percentage deviation of each individual laboratory's results from the reagent and overall medians are calculated, and the following criteria for performance are applied:

Performance is considered “*within consensus*” if the deviation is <15% from:

the **reagent median** if the number of users of that reagent is equal to or greater than 10 *or*

the **overall median** if the number of users of the reagent is less than 10.

Results >15% deviation from the median are considered “*outwith consensus.*”

For Heparin Dosage Assessment (HDA), and Fibrinogen assay, modified criteria apply. For HDA results >20% deviation from reagent medians for majority groups is considered *outwith consensus*. Marked differences in the heparin sensitivity of APTT reagents have led to the conclusion that it is inappropriate to assess minority reagent users against the overall median.

No performance analysis is applied to minority groups, although % deviation from reagent and overall medians are recorded on individual reports.

For Fibrinogen assay, Clauss method results are assessed against the overall Clauss method median, with results >15% from this median considered outwith consensus. Multifibrin U users are assessed separately.

Factor Assays

For factor assays, UK NEQAS BC distributes samples with factor concentrations covering the wide range encountered in clinical practice. For this reason, the percentage deviation from the median cannot be used as a means of defining performance. A ranked grading analysis to evaluate performance was devised by Professor S Thomson, Department of Medical Statistics & Evaluation, Royal Postgraduate Medical School, London.

The overall consensus median is taken as the central reference point or “target value”. Individual results are ranked into 5 unequal quantiles above and below the median, each quantile being designated by a letter depending on ranked distance from the median:

Group A: The nearest 25% of results above (A) and below (a) the median (i.e. 50% of results);

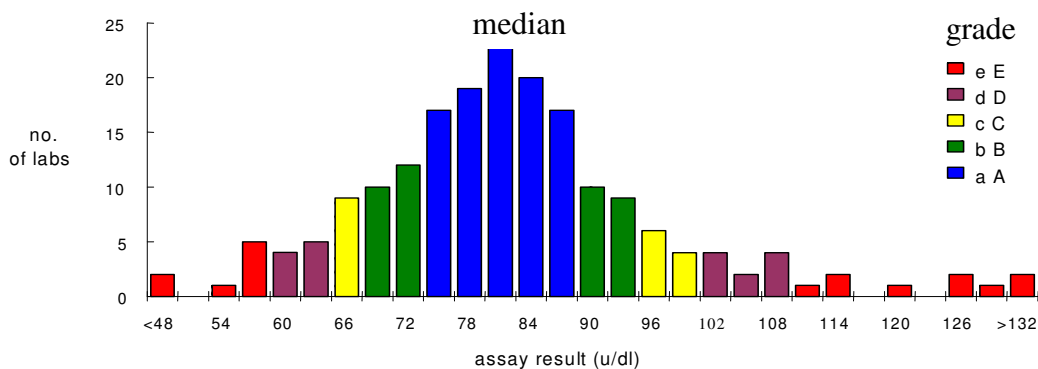
Group B: The next 10% of results above (B) and below (b) the median (i.e. 20% of results);

Group C: The next 5% of results above (C) and below (c) the median (i.e. 10% of results);

Group D: The next 5% of results above (D) and below (d) the median (i.e. 10% of results);

Group E: The 5% of results furthest from the median, above (E) and below (e) (i.e. 10% of results).

This is illustrated below:



Grades below the median are shown in lower case, and above the median in upper case, to aid in assessment of bias.

Performance is based on grades obtained in **two consecutive exercises** for any particular test. **Performance "outwith consensus"** is defined as a combination of a C (or 'c') grade together with an E (or 'e') grade, or any combination of D (or 'd') and E (or 'e') grades (e.g. cE, ec, Dd, de, ED and EE in consecutive distributions of that particular assay).

Persistent "outwith consensus" performance is defined as two consecutive **"outwith consensus"** performances. This will arise from three consecutive performances with the following combinations of grades (upper case only shown):

DDD, DED, ECE, EEC, DDE, DEE, EDD, EED, CEE, EDE, EEE

A **non-return** for a registered test will be graded as 'F' and taken as equivalent to an E grading. Thus, designations which include 'F' grades are based on performance over 2 or 3 exercises, respectively.

In some cases, significant differences have been noted between different methodologies. Where this occurs on a consistent basis, separate analysis of the groups is carried out, using medians specific to each method group. However, the system is only effective if the number of participants is greater than 20; consequently, grading analysis is not applied to groups of results from fewer than 20 centres.

At present, the following groups are analysed separately (groupings are regularly reviewed):

| | |
|--------------------------------|--|
| D-Dimers Assays | (kit-specific and FEU/non-FEU groups) |
| Factor VIII:C assay | (1-stage, 2-stage & chromogenic assays) |
| Antithrombin antigen | (results expressed in u/dl and mg/dl) |
| Antithrombin activity | (bovine thrombin, human thrombin, factor Xa substrate) |
| Protein C activity | (clotting and chromogenic assays) |
| Activated Protein C resistance | (Kit specific groups) |
| VWF RiCof (activity) | (ELISA, Aggregometry, Latex assay) |

If results of screening tests are outwith consensus on three consecutive occasions (including failure to return results), or results from factor assays are persistently outwith consensus, a letter of concern with an offer of assistance is sent to the head of department by the Scheme Director. Should persistent outwith consensus performance continue in any test for which a participant is registered, this will be referred to the National Quality Assurance Advisory Panel (NQAAP) for Haematology, with a letter being sent from the Haematology Advisory Panel Chairman on an anonymised basis initially through UK NEQAS BC. If performance issues are not subsequently resolved, further direct contact may be made from the Haematology Advisory Panel to the participant.

POINT OF CARE / NEAR PATIENT TESTING (POCT) EQA PROGRAMMES

Separate programmes are offered to provide external quality assessment for tests of blood coagulation carried out on systems designed for Point of Care or 'Near Patient' Testing (POCT/NPT) with over 3,000 registered participants. Programmes are offered for INR and ACT measurement.

DEVICES CURRENTLY INCLUDED IN UK NEQAS BC POCT EQA PROGRAMMES:

| | |
|-------------------|--|
| CoaguChek XS | CoaguChek XS Pro |
| CoaguChek XS Plus | Hemochron Jr Signature – citrate & non citrate |

Registration

Registration with the programme is made by completion of the registration form, available by contacting UK NEQAS BC by phone: 0114 267 3300, Fax: 0114 267 3309 or email: neqas@coageqa.org.uk Registration forms can also be downloaded from the website www.ukneqasbc.org It is important that the device in use is recorded on the form, as different samples are required for different devices.

Participant details are held in strict confidence and are not shared with any third party.

The annual registration fee covers survey material, full analysis and repeat samples, together with help and advice as required.

If you have more than one device

It is recommended that each device is registered in an EQA programme to individually test and check that reliable results are produced. Each device may be cross-referenced with a registration number in the POCT programme enabling a cumulative record to be maintained in the programme.

Registered Participants in the INR POCT programme as at 16.02.12

| | |
|--------------------------------------|-------------|
| Total number of participants: | 3219 |
| UK: | 3167 |
| Non-UK: | 52 |

| | |
|--|------|
| CoaguChek XS, XS Plus & XS Pro users : | 3185 |
| Hemochron Jr Signature users: | 34 |

Registered Participants in the ACT POCT programme as at 16.02.12

| | |
|--------------------------------------|-----------|
| Total number of participants: | 44 |
| UK: | 39 |
| Non-UK: | 5 |

Surveys for INR Testing

In the UK NEQAS BC POCT programme 4 surveys (testing sets) are scheduled for distribution per year – one survey set every 3 months. Each centre receives (normally by post) a package of the EQA material with full instructions. The tests are simple to perform but require about 20 minutes dedicated time to complete. Results are returned by post, fax or through our secure website using a participant specific password.

Surveys for ACT+ Testing

As above, but only 3 surveys per year.

Survey dates in 2012/2013:

POCT/NPT EQA Surveys for CoaguChek XS/XS Plus/XS Pro:

(1st April 2012 to 31st March 2013)

| | |
|-------------|-----------------|
| Survey XS21 | 1 May 2012 |
| Survey XS22 | 17 July 2012 |
| Survey XS23 | 16 October 2012 |
| Survey XS24 | 29 January 2013 |

POCT/NPT EQA Surveys for Hemochron Jr/Signature citrate and non citrate methods:

(1st April 2012 to 31st March 2013)

| | |
|--------------|------------------|
| Survey HJS21 | 29 May 2012 |
| Survey HJS22 | 28 August 2012 |
| Survey HJS23 | 27 November 2012 |
| Survey HJS24 | 29 January 2013 |

POCT/NPT EQA Surveys for Hemochron ACT+ Testing:

(1st April 2012 to 31st March 2013)

| | |
|-----------|-------------------|
| Survey 21 | 29 May 2012 |
| Survey 22 | 25 September 2012 |
| Survey 23 | 22 January 2013 |

REPORTS:

Data are analysed as detailed below. Individual reports are sent to participants within 2 weeks of the survey closing date. In addition, reports are posted securely to the website for download through participant specific login. An annual report is prepared on each programme.

Performance Analysis of INR Testing

The results are analysed and a median (target) value determined. A target range of 15% around the median is calculated. This is the acceptable limit for our samples. If INR results on the EQA samples are inside the limits, they are considered “*within consensus*”. If results are outside these limits, they are considered “*outwith consensus*”. In this way your results are compared to all others users of the same device using the same samples. Participants’ results and performance details are kept in confidence between UK NEQAS BC and the named individuals identified by the participant. If your results are outwith consensus in 3 consecutive surveys you will receive a letter from the Scheme Director bringing this to your attention and offering assistance.

If your centre does not return results for a survey this will be treated in the same manner as an outwith consensus performance. Centres not returning results in 3 consecutive surveys will receive a letter from the Scheme Director indicating performance ‘persistently outwith consensus’. UK NEQAS BC acknowledges that staffing problems in a centre may impact on the testing of survey samples, but dates for subsequent surveys are stated on the preceding survey report, allowing forward planning. Survey dates are also displayed on the website under the menu heading ‘Forthcoming Surveys’ and sub-heading ‘Distribution dates’.

Performance Analysis of ACT Testing

As above but using a target range of 20% around the median.

FVL / MOLECULAR GENETICS OF THROMBOPHILIA TESTING EQA:

This programme was established in 1996, to provide EQA for centres performing molecular genetic testing for FV Leiden and the Prothrombin 20210A mutation.

Registration

The participant registered should be the centre responsible for performing the tests. Data from participants will be treated with strict confidentiality. Registered participants will be given a unique participation number, which should be quoted in all correspondence. Use of this number will assist in maintaining confidentiality in survey correspondence.

Participating centres will be sent three surveys per year; each survey includes three whole blood samples for FV Leiden screening and P20210A mutation screening. Results are invited to be returned from either or both of these tests for the three samples in each survey and for the three surveys in a participation year. (Please see Annual Subscription Fees; Distribution Schedule.)

Samples are obtained from donors who have previously been screened for hepatitis B surface antigen (HBsAg), and for antibodies to hepatitis C virus and human immunodeficiency virus types 1 and 2 (anti-HIV-1+2).

Participants are requested to provide method details, together with a diagnosis for each of the samples. A closing date for return of results will be given, normally six weeks after the date of survey distribution. Individual reports based on the analysis of returned results will be sent to participants as soon as possible after the survey closing date.

Registered Participants in FVL / Molecular Genetics Of Thrombophilia programme as at 16.02.12

| | |
|--------------------------------------|------------|
| Total number of participants: | 122 |
| UK: | 69 |
| Non-UK: | 53 |

Surveys

Three surveys are sent each year, comprising 2-3 samples from donors with and without the FVL and Prothrombin mutations. Samples are usually citrated whole blood, but lyophilised DNA material is used on occasion.

Survey dates in 2012/2013

| | | |
|---|-----------|-------------------|
| FVL EQA Survey distributions (dates to be confirmed): | Survey 42 | 29 May 2012 |
| (1 st April 2012 to 31 st March 2013) | Survey 43 | 25 September 2012 |
| | Survey 44 | 22 January 2013 |

Performance Analysis

Participants are requested to return reports indicating the genotype of each sample. One occurrence of incorrect diagnosis within a survey is considered 'unsatisfactory'. Two incorrect occurrences in any three consecutive surveys are considered 'persistently unsatisfactory performance', and the Head of Laboratory will receive a letter offering assistance from the Scheme Director.

HOMOCYSTEINE ASSAY EQA:

Registration

The participant registered should be the centre responsible for performing the tests. All information from participants will be treated with strict confidentiality.

Participation fees include both the provision of any required duplicate post-exercise samples, subject to availability, and access to the advisory service. A small postal surcharge will be made for participants outside member countries of the EU. Subscription charges for UK NEQAS are payable in advance, and invoices will be raised at the start of the financial year. Participants may change their levels of test registration at any time by writing to the Scheme Director, or suitably amending the registration documents provided with each exercise.

Registered Participants in Homocysteine programme as at 16.02.12

Total number of participants: 28

Surveys

Following approval at the UK NEQAS for Blood Coagulation Steering Committee meeting of 16th January 2003, registered centres will be sent four surveys per year, each survey comprising one lyophilised plasma sample for homocysteine assay.

Samples are obtained from donors who have previously been screened for hepatitis B surface antigen (HBsAg), and for antibodies to hepatitis C virus and human immunodeficiency virus types 1 and 2 (anti-HIV-1+2).

Participants are asked to provide method details together with results for the sample distributed. A closing date for return of results will be given, normally approximately five weeks after the date of survey distribution. Results will be analysed and individual reports sent to participants as soon as possible after the survey closing date.

Survey dates in 2012/2013

| | | |
|---|-----------|-----------------|
| Homocysteine EQA Survey distributions: (1 st April 2012 to 31 st March 2013) | Survey 45 | 1 May 2012 |
| | Survey 46 | 31 July 2012 |
| | Survey 47 | 6 November 2012 |
| | Survey 48 | 5 February 2013 |

Performance Analysis

Following approval at the UK NEQAS for Blood Coagulation Steering Committee meeting, results from participants are assessed by the ranked grading analysis, as detailed on page 8 of this document. Combinations of grades resulting in performance “persistently outwith consensus” will generate a letter from the Scheme Director offering assistance in resolving performance issues.

COMPLAINTS

Any complaint about UK NEQAS BC will be treated as serious, and will be dealt with as soon as possible by the Director or Manager. If the outcome is not to the satisfaction of the participant, referral may be made initially to the President, UK NEQAS Executive Committee and subsequently to the Chairman of the National Quality Assurance Advisory Panel for Haematology.

Address for complaints:

UK NEQAS for Blood Coagulation

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EDUCATIONAL ACTIVITIES

In addition to an advisory role for individual laboratories, UK NEQAS BC also publishes and presents data through a variety of leading journals and meetings.

The well established Annual Scientific Meeting (ASM) includes presentations from nationally and internationally renowned speakers, in addition to data from survey distributions and open debate on EQA issues. More than 400 delegates attended over two days of the ASM on 6th and 7th September 2011 at Sheffield Hallam University Conference Centre, Sheffield UK. A further meeting is scheduled for 4th & 5th September 2012 at the Sheffield Hallam University Conference Centre.

Programmes and registration forms for the 2012 ASM will be distributed to registered participants in due course. Further information on this meeting will be available on the UK NEQAS BC website (www.ukneqasbc.org), including downloads for programmes and registration forms.

A meeting on Point of Care Testing for Monitoring Oral Anticoagulant Control took place on 15th June 2011 at the Royal College of Physicians of Edinburgh, 9 Queen Street, Edinburgh UK. A further Point of Care Testing meeting is planned for 2013.

Supplementary Exercises

Supplementary exercises are carried out to address topical issues in haemostasis testing. Recent exercises have included post factor-concentrate assays, and a diagnostic challenge to investigate prolonged APTTs. Reports are circulated to participating centres and data are presented at national and international meetings.

Questionnaires

Questionnaires are distributed to participants on a regular basis, to gain feedback on issues of general interest in haemostasis and thrombosis, in addition to specific aspects relating to UK NEQAS BC.

Publications

Selected Publications

Dianne P Kitchen, Steve Kitchen, Ian Jennings, Tim Woods, Isobel Walker. Quality assurance and quality control of thrombelastography and rotational thromboelastometry: The UK NEQAS for Blood Coagulation Experience. *Sem Thromb Haem* 2010; 36(7) 757-63.

David J Perry, David A Fitzmaurice, Steve Kitchen, Ian J Mackie, Sue Mallett. Point of Care Testing in Haemostasis. *B. J. Haem.* 2010; 150(5) 501-14.

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Kitchen S, Kitchen DP, Jennings I, Woods TAL, Walker ID. Quality assessment of CoaguChek point of care INR monitors: A note of caution. *Clin Chem* 2007 53; 1555-1556.

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Adcock DM, Brien WF, Duff SL, Johnston M, Kitchen S, Marlar R, Ng VL, Van den Besselaar A, Woodhams B. Procedures for the Validation of INR and Local Calibration of PT/INR. *Approved Guidelines. CLSI H54-A* 2005-20-07.

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Fitzmaurice DA, Gardiner C, Kitchen S, Mackie I, Murray ET, Machin SJ. An evidence-based review and guidelines for patient self-testing and management of oral anticoagulation. *British Society of Haematology*, 2005 Oct; 131, 156-165.

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Data are regularly presented at national and international scientific meetings, including British Society for Haematology, British Society for Haemostasis and Thrombosis, ISTH Scientific Sub-Committee meetings, World Federation of Haemophilia Congress.