

Central Quality Assurance Scheme Handbook

**A Series of trial packages which can be selected to provide an
EQA scheme for every Haematology laboratory**

**All of the scheme packages have been accredited by
CPA (EQA) UK**

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Introduction

This document is designed to be used as both a user manual for participant laboratories and an information prospectus for potential participants.

It outlines the philosophy under-pinning our EQA provision, the history and development of the Scheme, the management and organisational aspects, and gives details of how to interpret the results and how to seek advice may that be required. It also indicates the terms and conditions that the Scheme requires to be fulfilled by a participating centre.

Above all, we hope that the reader will recognise that the major ethos of the scheme is one of simplicity. Turnaround is quick, analysis is informative without being over-elaborate and advice is always available. The aim is to encourage excellence rather than to penalise poor performance.

The Scheme packages have all been accredited by CPA (EQA) and the inspectors were quick to recognise the excellent relationships and rapport that we have with our participants.

CQAS has a good working relationship with the National Quality Assurance Advisory Panel for Haematology and we are always keen to listen to the views of participants. The scheme's history is one of user self-direction and we feel this to be of great importance. If there are any areas about which you would like further information, then please do not hesitate to contact us.

John George
 Deputy Scheme Organiser

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What Should You Expect From An EQA Scheme?

The Central Quality Assurance Scheme (CQAS) is the only accredited scheme in the UK which offers EQA for general haematology, haemostasis, haemoglobinopathies and plasma viscosity. The scheme currently operates predominantly in the UK and Ireland but is developing pilot partnerships within the European Union and in South Africa.

It is important to get an understanding of the reasons why people participate in EQA schemes.

These include:

- As a means of “benchmarking” quality
- For the purposes of peer comparison with other laboratories
- To compare and contrast methodologies and reagents
- To use the scheme as a form of internal QC if results turnaround is sufficiently fast to allow this.
- To comply with external accreditation requirements
- As a means of increasing educational opportunity and improving laboratory service provision.

We should also be mindful of the factors which might have significant influence on this measurement of performance.

These include:

- Variation between individual laboratory scientists
- The source, stability and configuration of the EQA sample
- The instrumentation and measurement principles used
- The source, stability and sensitivity of the reagents
- Artefactual and physiological influences
- Reference and calibration procedures used
- The appropriateness of the reference ranges (ie have they been calculated “in-house” and do they reflect the local population?)
- The number of laboratories in the method group
- The mathematical manipulation of results in the laboratory
- The statistical analysis principles applied by the EQA scheme

All of these factors can have a varying influence on both singular and continuous EQA performance.

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The Responsibilities of the EQA Provider

The EQA provider must strive to produce a sample which is stable and produces consistent results from the time it is prepared to the time of testing. Allowance should also be made for the fact that sometimes, if results are out of consensus, a certain amount of repeat analysis may be required. The sample should be of a comparable matrix to that normally tested in the laboratory. For example, animal blood should not be used in an attempt to produce apparent abnormality in human testing scenarios.

The effects of fixation and lyophilisation should be minimised and, where possible, cellular integrity and functional characteristics should be maintained.

The results reporting and statistical analysis procedures are critical elements of the EQA process. Where possible, like methodology and reagents should be analysed within the same group. Small numbers of laboratories using a particular method can lead to that group being compared with an overall mean and their apparent performance being affected by larger-group bias. There should be as little as possible manipulation of results prior to, and after, submission but it must be accepted that errors could possibly occur. CQAS employs an electronic double-entry checking system to minimise input errors. We are moving towards online direct entry by participants.

The method of statistical analysis should be such that poor performance is based on methodological error or clinical relevance rather than statistical chance. Most importantly, the turnaround should be quick so that the results are relevant when the participant receives them.

Sample Preparation

Clearly, where samples need to be sent by overland post, air cargo or even transported locally, an element of stabilisation is required. For coagulation samples this invariably involve freeze-drying of plasma and care is taken throughout the lyophilisation process to use appropriate buffers and stabilisers to prevent the deterioration of coagulation factors.

The stabilisation or fixation of red blood cells alters their response to outside influences such as diluents, lysing agents and cytochemical dyes. The variation in response to these changes may be instrument-dependent, so the grouping of instruments for statistical analysis of performance is vitally important.

Even the gentle fixation process used by CQAS still has influences on red cell shape, size, deformability and resistance to lysis. For all cellular components one also has to consider changes in optical and biochemical characteristics. These will impact both on basic enumeration of cells and differentiation of white cell types in particular.

For haemoglobinopathy trials the sample should be such that sensitivity to varying, and clinically relevant, levels of abnormal haemoglobin subtypes is maintained. The aims of the trials should be to be able to separate trait from disease, to clearly separate and

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identify abnormal haemoglobins and to be able to provide a subjective assessment of the clinical situation.

In preparing the sample, the EQA provider must ensure that any small changes which take place during sample preparation do not impinge on the laboratories ability to be able to identify abnormality. (ie. the co-migration of abnormal haemoglobins in HPLC or electro-separation techniques as a result of pre-analytical manipulation).

How Does CQAS Meet its Responsibilities?

CQAS always tries to achieve as rapid turnaround as possible and to supply regular EQA material. Routine haematology and coagulation packages are distributed every two weeks and results are analysed and reported within hours of the final submission time. Laboratories can telephone, post, fax or e-mail results up to 11.00 on the analysis day. Online results submission is being developed. Presentation of results is simple, with minimal statistical manipulation and emphasis on simple, user-friendly key points.

Professional oversight of the scheme is carried out by the UK National Quality Assurance Advisory Panel (NQAAP) for Haematology, for whom a detailed annual report is produced. NQAAP may recommend the introduction of new trials or the modification of existing ones. They also approve and monitor the criteria for poor performance and ensure that the scheme is maintaining an appropriate balance between monitoring of performance and education and improvement.

The general strategies for the scheme are focused by the Steering Committee, a team of professionals (doctors and scientists), most of whom are drawn from participating laboratories. They work closely with the CQAS management team to direct issues such as:-

The range of trial surveys offered

The types of sample used and the frequency of distribution

The methods employed for statistical analysis

The means by which the statistical and performance data is presented

New investigation, research and development

The CQAS management team also have a close working relationship with participants, whose views are taken seriously and acted upon to improve the service offered.

The CQAS-participant interface can take a number of formats. The most simple is two-way phone, fax and e-mail contact, which most participants will use from time to time, even if just for simple enquiries. More formal arrangements, such as a participants forum and user questionnaires can both gain opinions and encourage debate. The scheme is inspected every two years by Clinical Pathology Accreditation (EQA) and part of the inspection involves a survey of user satisfaction. It is also vital that CQAS has a good working relationship with manufacturers. EQA is a team game which requires input from all of the players.

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The CQAS Philosophy

For CQAS to operate successfully, it must operate within a spirit of co-operation. Whilst confidentiality is obviously important participants must, and do, accept that there is a need for open discussion. All results are displayed, although user codes are confidential to the user and the Scheme. However, where a participant has a problem they will have initial access to similar method codes but can also be put in touch with those laboratories should CQAS gain the appropriate agreement. The main desire has to be to improve the provision of laboratory haematology by a process of education and co-operation rather than mandatory regulation. There are four key issues which are fundamental to the success of the scheme. These are:

Rapid turnaround of reports

An acceptable and appropriate sample

A user-friendly, approachable service

| The ability and desire to provide constructive, rather than destructive, advice if things go wrong.

Participants should want to be part of an EQA scheme, not feel that they are compelled to do so. CQAS has a follow-up service which offers encouragement and advice at all times. Key personnel can assist with problem solving and methodology review with the emphasis on education, explanation, liaison and joint investigation.

To foster this philosophy, good links with manufacturers of instruments and reagents are vital. This may include the evaluation of new products, agreement on the best statistical grouping for the product within the scheme, user-specific requirements for a particular instrument group and even the provision of custom made systems.

No information is ever disclosed by us to anyone who is not authorised to receive it. We wish to encourage laboratories to come forward if they have problems, and seek solutions either by communication with other labs or by using our advice service. That isn't to say that a spirit of friendly competition is unhealthy. We still have annual "Awards" for good performance and the gold and silver stars are coveted as unexpected, but pleasant, surprises at Christmas time.

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What is Expected of a CQAS Participant?

Terms & Conditions

CQAS registration is for the 12 months between April 1st and March 31st. Any number of packages may be selected as appropriate to the individual participants' requirements. The registration sum payable will be the total cost of all packages ordered.

Re-registration order forms are issued in February and payment should be made no later than 30th June. Reminders are issued in May to those centres from whom the Scheme has not received a new order. If there is no contact made by the laboratory with regard to continued registration, the dispatch of EQA material will cease at the end of June.

Laboratories wishing to register with the Scheme after April 1st, or those already registered who wish to take up participation in a new package, will be given a pro rata price to be paid at the start of participation.

Details for the participating centre must include a named member of staff, a contact telephone number plus, if possible, an email address.

Laboratories registering for any package must return results for at least 75% of trials during the 12 month period. (Non return is classed as a poor performance). Only those centres reporting at least 75% of results will be included in the December cumulative performance report.

Methodology questionnaires issued at the time of initial registration and, occasionally, to update records, should be completed and returned as soon as possible. CQAS should be notified of any changes in methodology or instrumentation as soon as possible and not on results return sheets.

Result return sheets should be legibly completed and always include the laboratory code. They should be signed by a member of staff that the Scheme can contact if there is a problem.

Results should be returned by the closing date or time of the trial. Results will not be accepted beyond the closing date or time.

Reports issued by CQAS remain the property of the Scheme and should not be reprinted or used in any published data without permission from the Scheme.

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CQAS Scheme History

The Central Quality Assurance Scheme started life in 1974 as a pilot scheme for blood counts operated from Good Hope Hospital, in Sutton Coldfield, for hospitals in the Birmingham area. Regional support quickly allowed expansion into Staffordshire, Herefordshire, Worcestershire, Warwickshire and Shropshire. The scheme was known as the West Midlands Quality Assurance Scheme at this time.

In 1977, the Queen Elizabeth Hospital joined forces with Good Hope and began to produce samples for monthly assessment of prothrombin time (PT) and activated partial thromboplastin time (APTT). Freeze drying techniques were quickly developed so that the repertoire could be expanded to include fibrinogen and Factor VIII (1982), von Willebrand Factor Antigen, capillary anticoagulation and haemoglobinopathy screening (all 1984), antithrombin assays (1986), protein C and protein S (1991) and plasma viscosity (1992).

Importantly, it is the opinions of participants which have figured mostly in constructing the repertoire of trial packages that we see today, as well as the timings of distribution and the combination of tests included in the packages.

1993 was perhaps one of the most critical year in the history of the scheme in that a decision was made to offer it on a national basis. There were already a number of "guests" from outside of the region but 1993 saw the beginning of a steady influx of new participants from around the UK and Ireland, which would give the scheme a much broader user base for statistical comparison but would not compromise the rapid turnaround of results. The scheme eventually changed its name to Central Quality Assurance Scheme, to better reflect its widening participation base.

1993 also saw the introduction of haemoglobinopathy interpretation exercises. Occasional blood films and additional factor assays were added in 1995. Reticulocytes (1996), white cell differentials (1997) and a revised near-patient testing package for capillary anticoagulation control (1999) and Ristocetin Co-factor in 2003 continued the repertoire expansion. The latest addition to the scheduled repertoire, following a successful pilot issue at the end of 2008, is D-dimer estimation.

Since 2000, lupus anticoagulant studies surveys have been introduced as extra surveys to those scheduled and participants take part only if relevant to their test repertoire. Blood films and reticulocyte counting have now become regular quarterly components of the routine haematology screening package.

In 2005 another milestone occurred in the scheme's history as the opportunity was taken to consolidate all services at the Queen Elizabeth Hospital in Birmingham. We shall be moving to new accommodation in a brand new build in 2011.

The scheme was already approved by the Joint Working Group for Quality Assurance but in 1999 it was formally accredited by CPA (EQA) and is now the only nationally accredited scheme to offer haematology, haemostasis, haemoglobinopathy and plasma viscosity packages.

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The aims are unchanged. The improvement and advancement of Laboratory Medicine in its service to the patient are fundamental. To assist this, the statistical analysis should be relevant, comprehensive and yet concise, to allow rapid dissemination of information.

Management Structure

The scheme is currently overseen by the Scheme Organiser, Dr. Jonathan Wilde, who is Consultant Haematologist in the University Hospital Birmingham (UHB) NHS Foundation Trust. The Deputy Scheme Organiser is Mr John George and the Scheme Manager is Susan Dennis, who are both based at UHB. The organisers and manager receive advice and direction on the overall operation of the Scheme from a Steering Committee (see below).

All trial packages are co-ordinated by Susan Dennis and trained CQAS staff. The Scheme Manager has support from other staff in their host departments who can be called upon to give advice to participants.

The Steering Committee, Organisers and Manager take advice on the strategy of the Scheme via the views of participants attending regular user meetings. The current structure of packages has been devised specifically at the request of participants.

The Steering Committee

The current Steering Committee is composed as follows:-

Dr Christine Wright MBChB, MRCP, MRCPath (Chairman)

Christine Wright is Consultant Haematologist at City Hospital in Birmingham where she specialises in Haemoglobin disorders and medical education. She is part of a national group working towards the development of a National Service Framework for Thalassaemia. Within the West Midlands she is a member of a regional group reviewing the transitional care of adolescents and young adults with haemoglobin disorders. Christine is a member of the British Society for Haematology, the UK Thalassaemia Group and the Birmingham Haemoglobinopathy Group.

Ms Mary Byrne

Mary Byrne is the Chief Medical Scientist in the Coagulation laboratory in St. James's Hospital in Dublin. This laboratory is the largest in the Republic of Ireland and is affiliated to the National Centre for Hereditary Coagulation Disorders. Mary has spent most of her career at St James's Hospital and was appointed to this position in 2000. She has broad experience in the diagnosis of patients with inherited and acquired bleeding and thrombophilia disorders and has co-authored a number of peer-reviewed papers in this field. Mary has a range of education commitments in coagulation. She is a fellow of the Academy of Medical Laboratory Science and is a member of The International Society on Thrombosis and Haemostasis.

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Mr. Simon Davidson, MRCPath, FIBMS

Simon Davidson is the Clinical Scientist in Haematology at the Royal Brompton Hospital in London. Simon joined the Steering Committee in 2002, replacing David Keeling. He is currently undertaking a PhD at the Imperial College of Medicine and has published over 30 papers in the field of haemostasis.

He has previously worked at the John Radcliffe Hospital in Oxford and the Freeman Hospital in Newcastle. Simon is a member of a number of professional bodies including The International Society of Thrombosis and Haemostasis, The British Society of Haemostasis and Thrombosis and the Institute of Biomedical Science.

Mr. A.J. George C.Biol., M.I. Biol., FIBMS.

John George is the Deputy Organiser of the scheme and is also a Director in the host UHB NHS Foundation Trust. He is a member of the British Societies for Haematology, Haemostasis and Thrombosis, and has represented the BSH on joint - society education working groups. He was a member of the Steering Committee for the UK NEQAS for Blood Coagulation from 1993-1995, has been an Inspector for CPA UK Ltd and chaired an International Working Party on pre-analytical variables.

He has around 50 publications in the field of haematology, haemostasis and quality control.

Dr. R.J. Luddington PhD., M.Phil

Roger Luddington is the Clinical Scientist in the Coagulation Department at Addenbrooke's Hospital, Cambridge and a member of the East Anglia Haematology Group. He has a wide experience of haemostasis and related topics, specialising in the thrombotic disorders. He also has regular teaching commitments in this area. Roger has published widely on the subject of haemostasis with over 30 scientific publications as main papers or abstracts. He is involved in calibration and evaluation exercises with both NIBSC and WHO. Roger has taken on the roll of Scheme secretary.

Mr Paul Murphy – FIBMS

Paul Murphy is Section Leader of the Coagulation/Haemophilia Unit for the Newcastle upon Tyne Hospitals NHS trust. He is involved in the standardisation of haemostatic investigations across three large hospital sites. He has had an interest in haemostasis for many years, and in particular the diagnosis of bleeding disorders and the further investigation of abnormal laboratory results. Paul has spoken on this topic many times at both regional and national symposia.

Dr. J.A. Murray MB, Ch.B, FRCP, FRC Path.

Dr. Jim Murray is Consultant Haematologist and Post Graduate Clinical Tutor in the UHB Trust and Honorary Senior Lecturer in The University of Birmingham. He was a member of the Steering Committee for UK NEQAS for Blood Coagulation up to 1996 and is an

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Inspector for CPA UK Ltd and is also Chairman of the Haematology Scientific Advisory Committee for CPA. He is an examiner for MRC and is also a member of the Haematology Committee of the Association of Clinical Pathologists.

Mr. R. Pearce BSc, FIBMS

Richard Pearce has been Head BMS for Haematology in Shropshire since 1990, having previously worked at Walsgrave Hospital, Coventry and in Hereford. He has a particular interest in the use of Information Technology in the laboratory beyond the core LIMS systems. In addition, as two of the three laboratories in Shropshire are multidisciplinary based, he is responsible for developing and maintaining links with Clinical Biochemistry in order to facilitate efficient working practices and minimising duplication of effort.

Dr Paul Revell BSc, MBBS, FRCP, FRCPath, FRCPCH

Dr Paul Revell is a Consultant Haematologist at Stafford General Hospital. He was nominated by the National Quality Assurance Advisory Panel (NQAPP) for Haematology to represent them on the committee.

Dr J van Veen MRCP, MRCPath, MD

Dr Joost van Veen is Consultant Haematologist at the Royal Hallamshire Hospital in Sheffield, with a particular interest in haemostasis. He joined the Steering Committee in May 2008.

Dr. J.T. Wilde MA, MB, Ch.B, MD, FRCP, FRC Path.

Dr. Jonathan Wilde is the scheme organiser. He is Consultant Haematologist in the UHB Trust and an Honorary Senior Lecturer in the University of Birmingham. He is also Director of the West Midlands Regional Adult Haemophilia Centre. Jonathan is a member of the British Societies for Haematology and for Haemostasis and Thrombosis. He has published numerous papers and abstracts, mainly in the field of haemostasis.

The constitution of the Steering Committee appears at the back of this prospectus. The terms of office are listed below:

Steering Committee re-election dates

Dr Christine Wright (Chairman) 2013

Mr Simon Davidson	2010	Dr Jim Murray	
Ms Mary Byrne	2009	Mr Richard Pearce	2010
Mr John George	Indefinite	Dr Jonathan Wilde	Indefinite
Dr Roger Luddington	2010	Dr Joost van Veen	2013
Mr Paul Murphy	2009	Dr Paul Revell	NQAAP representative

Funding of the Scheme

The scheme was originally supported by the West Midlands Regional Health Authority (WMRHA) and consequently, up to March 1991, participants in the Scheme came predominantly from within the region.

The WMRHA, through its Regional Specialities Agency, acted as both broker and purchaser for its 22 District Health Authorities. Most of its haematology laboratories are still members of the scheme. From 1st April 1994 WMRHA laboratories had funding devolved and the scheme is now totally self-sufficient. Funding is raised by direct invoicing in response to orders. We have a number of NHS customers around the country along with a growing number of private laboratories and commercial companies. Considerable interest is being shown by other countries and we have an increasing number of participants in the Republic of Ireland. Indeed less than 20% of participants are from the former West Midlands RHA area. Over 25% are from hospitals outside the UK

The service provided by the scheme is exempt from VAT. It is a non-profit making organisation and all funds are invested in the maintenance and improvement of the scheme. Current subscriptions are calculated by projecting the number of likely participants and relating this to the staff time and other costs involved in providing the scheme. Prices are unlikely to increase by more than the rate of inflation, but may have to do so in exceptional circumstances e.g. in response to national pay settlements, taxation changes, etc. We are confident that we have got our pricing strategy right and that we provide excellent value both in terms of the number of trials dispatched and the quality and speed of analysis provided.

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**Central Quality Assurance Scheme
 Trials Structure**

Participants have requested that the trial surveys offered are broken down into logical packages which allow the customer to purchase only those which are relevant to their area of interest.

QA1 Haematology Screening

This is a routine haematology/haemostasis screening package which offers Hb, RCC, MCV, WCC, platelets, reticulocytes, PT, APTT and fibrinogen as the analytes. Surveys are issued every two weeks and there are 24 trials per year. Samples are dispatched on Tuesday to be tested by 11.00am on Wednesday of the following week. For non-UK participants, samples are dispatched 4 days earlier to allow more time for delivery. The results are currently faxed or emailed to the Scheme office, allowing statistical analyses, production and posting of a report on the same day. Online reporting is being developed. Closing date and report issue – same day

Rolling twelve month cumulative performance graphs are issued every 6 trials for both blood count and routine coagulation.

Blood film analysis was introduced for occasional surveys in 1995/6 and is now provided on a quarterly basis. Occasional white cell differential are dispatched at no extra cost. In addition, separate INR dosage assessments and samples for investigation of coagulopathy are also dispatched intermittently, again, at no extra cost.

QA2A Coagulation Screening

This comprises PT, APTT and Fibrinogen estimations. It is an alternative to the full screen offered above but the distribution and reporting are identical. As with QA1, PT and APTT samples reflect a variety of commonly encountered clinical conditions and are also used to investigate anticoagulant control.

Report as for QA1

QA2A Blood Count

This is available if required, at the same fortnightly frequency as QA1 and QA2A.

Report as for QA1

QA3 Haemoglobinopathy

The haemoglobinopathy package consists of 8 surveys per year. These alternate on a 6 - weekly basis between quantitation and interpretation exercises. In the former, participants are asked to carry out two assays of HbA₂, two of HbF and one of HbS. The interpretation exercise involves screening an unknown sample, looking at a blood film or

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data (supplied) and utilizing this data along with clinical details to suggest the likely abnormality.

Report issued within 7 days of the closing date.

QA4 Factor Assays

This package consists of 8 surveys per year. Two samples for Factor VIII and one for Factor IX assay are dispatched on a six weekly basis. Assays for other coagulation factors (e.g. X, XII) are provided at less frequent intervals at no extra charge.

Within the cost of this package, participants may also register for von Willebrand Factor Antigen and, if performed in the laboratory, Ristocetin Co-Factor. Three samples for von Willebrand Factor Antigen and, if required, 3 for Ristocetin Co-Factor are dispatched every 12 weeks with a 4 week closing date to allow for batch testing.

Report issued within 7 days of closing date.

QA5 Capillary Anticoagulation Control (Near Patient Testing)

This package is designed for the users of a variety of near-patient testing systems such as CoaguChek S, Thrombotest and Manchester Capillary Reagent. One sample is distributed every month with suitable reconstitution fluids and test method dependent on instrument/reagent combinations. A rapid-turnaround of results is employed. Samples represent a variety of anticoagulation intensities and are provided as freeze-dried plasmas with instructions on how to standardize their usage in a "whole blood" procedure. These are instrument-specific. A number of GP practices take part in this package.

Report issued within 5 days of closing date.

QA6 Thrombosis Screen

Two samples for antithrombin estimations and one each for protein C and protein S are distributed four times per year. This package has a 4 week closing date to allow for batch testing. Analysis includes assessment of all method principles.

Report issued within 7 days of closing date.

QA7 Plasma Viscosity

Two samples are distributed every four weeks. Analysis includes assessment of the Coulter, Benson (BV200, BV1), Medirox, Visco Lite, and Schott-Gerate viscometers registered.

Report issued within 2 days of closing date.

Rolling twelve month cumulative performance graphs are issued every 3 trials.

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QA8 D-dimer

Two liquid samples to be distributed four times per year. This package has a 2 week closing date. Analysis includes assessment of all methodologies.

Report issued within 7 days of closing date.

Note this package is new for 2009 and CPA accreditation will be sort in due course

Multi Instrument Registration

Package QA1 Routine Haematology;Blood Count / Coagulation Screen

Package QA2a Coagulation Screen only

Package QA2b Blood Count only

Testing and analysis of results from more than one instrument is offered where the instrumentation is on a single site and testing may be undertaken with a single set of samples:-

1.0ml sample for PT, 1.0ml sample for PTT, 1.0ml sample Fibrinogen

3.0ml sample for blood count

Results analysis for multiple instruments but only one registration fee.

Please note, instrumentation within the same hospital group but on separate sites requires separate registration and fee

Preparation and Distribution of Samples

Samples for blood count are usually prepared from microbiologically screened, discard venesection bags. Samples are partially fixed and aliquoted in-house.

Samples for plasma viscosity are prepared from screened NBS plasma or voluntary donations and distributed in liquid form. Coagulation and haemoglobinopathy samples are all freeze-dried.

All samples purchased from commercial sources are microbiologically screened.

All material is sent by Royal Mail – Airmail where required.

Additional Surveys

Additional surveys are provided free of charge to participants during the year. These include Lupus Anticoagulant detection, MNPT and ISI validation, testing of new sample matrices, interpretation exercises etc. Evaluations of new products and special pilot exercises are undertaken, sometimes in conjunction with other associated organisations. These do not form part of the cumulative assessment.

These are at no extra cost to participants.

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**Central Quality Assurance Scheme
 Statistical Analysis**

The Steering Committee expects that statistical analysis should be relevant and easy to follow. Participants have echoed this view that simple analysis with, if appropriate, graphical display, are vital.

The majority of analyses are based on a deviation index from a mean or median value:

$$DI = \frac{\text{Result} - \text{Mean}}{\text{Standard Deviation}}$$

Participants are divided into method groups where there are sufficient numbers (n=>5), and thus receive both overall and group data.

The method group DI is used for continuous assessment of data unless the participant is using a method with too few users to establish a separate group. In this latter case, the DI from the overall mean is employed.

Assessment of Unsatisfactory Performance

In the vast majority of cases a DI limit of ±2.0 is set as the limit of acceptable performance within groups for each parameter. For haemoglobin, normal INR and APTT ratio, low white cell (<1.0x10⁹/l) and platelet counts (<10x10⁹/l) where results are very tight, we have a limit of ±3.0, which seems more appropriate. For all other parameters the DI limits are 2.0. On no occasion would the limit exceed 3.0.

Hazardous performance would be designated as any DI exceeding ± 4.0 (5.0 for normal PT, normal PTT/ratio & Haemoglobin) where this would affect clinical interpretation or therapeutic intervention. Where no underlying reason for hazardous performance can be identified (obvious reasons could be incorrect reconstitution or incorrect sample used for specific test in multiple sample dispatches) the participant is contacted ahead of a repeat sample or samples being dispatched. This enables investigation into hazardous performance to start as soon as possible.

In all other cases, participants are issued a repeat sample or samples either during the results return period when their return is out with consensus or at the time of reporting when a result has been truncated.

Unsatisfactory Performance – Action Criteria

Participants are contacted by mail or email following two unsatisfactory performances in a given parameter which could be within the same trial, example Factor VIII or in two trials of four, example, fibrinogen (intervention before a fifth trial and possible third unsatisfactory performance). Non return without explanation is assessed as an unsatisfactory performance.

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The Scheme, where possible, prompts investigation into likely problem areas and the centre is asked to report any corrective action(s) taken. Advice is given when a participant contacts the Scheme for assistance following an unsatisfactory performance.

A participant can request samples with consensus mean values to verify any corrective action taken and report results to the Scheme to review.

We would like to emphasize that participants are notified of unsatisfactory performances as soon as possible so that any problem may be swiftly addressed. In this way, we have found persistent unsatisfactory performance can be avoided.

Persistent Unsatisfactory Performance (PUP)

Three unsatisfactory performances in five trials or five issues of a particular parameter is judged as PUP. This can be any combination in 3 of unsatisfactory results or non returns without explanation. In multi-parameter analyses, each parameter is evaluated separately e.g. in FBC trials PUP could be 3 MCV results with DI values greater than 2.0. However, one RBC with $DI > 2.$, then one $MCV > 2.0$ and one $WBC > 2.0$ DI is not PUP.

PUP is judged on a roll-on basis and where no further action has been undertaken by the participant to investigate and amend unsatisfactory performance.

The participant is contacted by the Scheme Organiser who will re-state the details of the unsatisfactory performances and request what investigations or actions are being undertaken to resolve the unsatisfactory performances or an explanation of the cause if already known. A further offer of assistance will be made.

The participant must reply to the Scheme Organiser within 2 weeks stating what actions or on-going investigations are being taken to resolve the highlighted problem.

Where there is an analytical problem deemed, by the Scheme, to be a manufacturer issue, the participant will be asked to keep the Scheme updated on any intervention by the manufacturer and may, if requested, intervene on behalf of the participant.

The participant will also be informed that the Scheme will pass details of the PUP status on to the National Quality Assurance Advisory Panel (UK) including their identity.

National Quality Assurance Advisory Panel (NQAAP)

The process and criteria for unsatisfactory performance are determined and approved by the UK NQAAP for Haematology.

The Scheme is monitored via annual written and verbal reports to the NQAAP.

All PUP must be reported to NQAAP on a 3 monthly basis. NQAAP will then contact the participant. The Panel report to the Joint Working Group (JWG) for Quality Assurance

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which is accountable to the Royal College of Pathologists. Details of PUP are only escalated from NQAAP to JWG if not resolved.

Advice Service

The telephone / e-mail advice service is provided at no extra cost. We will attempt to answer participant problems whether or not they are directly related to the scheme. There have been a number of occasions, for example, where a laboratory has suspected a problem with a particular method. We have simply sent them known "consensus-mean" samples to verify the problem, analysed the results and indicated a possible solution whenever possible. We are able to build a data bank of similar queries so that we can contact other users of the same method to establish whether they have encountered similar problems.

Other examples have included visits, at participants' request, to centres with consistent problems. Often the cause was easily identified because someone from "outside" was able to see the problem from a different perspective. (We may ask for support for travelling expenses if the distances involved are excessive). We are also pleased to see participants who wish to visit us for informal discussions.

Participants may have questions related to methodology / instrumentation / reagents that are new to the centre or a giving cause for concern. The Scheme management team have both experience in, and information related to, many different methodologies and is always willing to discuss choices or problems. We do not recommend methods but we can help laboratories to feel confident in their own choice. Medical advice relating to quality control and interpretation of QC findings can also be provided when appropriate.

Participants are free to telephone if they need to discuss a problem. The numbers to call are as follows:

QUEEN ELIZABETH HOSPITAL

Dr. J.T. Wilde	Organiser and Consultant Haematologist	0121-472-1311 Ext.3141
John George	Deputy Scheme Organiser	0121 627 8143
Susan Dennis	Scheme Manager & Trials Co-ordinator	0121-627-2472 (and Fax)
Karen Morris	Quality Officer	0121-472-1311 Ext 3516

Members of the Steering Committee can also be contacted directly if required.

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Complaints Policy

It is hoped that you will never feel it necessary to make a formal complaint about the operation of the Scheme as we pride ourselves with our customer liaison record. In the first instance, most problems should be able to be solved by the manager/trials co-ordinator (see preceding pages for contact numbers). If however, you are still not satisfied that the complaint has been resolved you should write to either of the following:

Dr J. T. Wilde
 Scheme Organiser
 Haematology Department
 Queen Elizabeth Hospital
 Edgbaston
 Birmingham B15 2TH
 Email: Jonathan.Wilde@uhb.nhs.uk

or to

Mr A. J. George
 Deputy Scheme Organiser
 Haematology Department
 Queen Elizabeth Hospital
 Edgbaston
 Birmingham B15 2TH
 Email: john.george@uhb.nhs.uk

They will ensure that the complaint will be dealt with quickly. All complaints will be investigated and receive a full and positive response within 20 working days.

If, for any reason, you are not satisfied with the outcome, you can seek further clarification. As a next stage you can write to the Chairman of the Steering Committee or, as a last resort, to the Chairman of the National Quality Assurance Advisory Panel for Haematology (currently Dr P Carrington, Dept of Haematology, Trafford General Hospital)

We cannot envisage a circumstance where such drastic course of action would be necessary and pride ourselves on the ability to employ informal local resolution at the Scheme Manager or Scheme Organisers' level.

Quarterly Reports

A quarterly report – March, June, September & December - is dispatched which coincides with the call-off of cumulative performance graphs for the blood count, routine coagulation and plasma viscosity. The final report for the year includes performance figures for all packages and, as a little light heartedness, gold stars are awarded for the best performance in a particular test and silver stars to those with an average DI value of <0.5 (only centres that have returned at least 75% of results are included).

The report regularly includes a review of the blood count and coagulation trials since the last report plus an overview of the other trials dispatched and reported during this time.

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There may be some point of interest regarding an instrument / reagent / method / set of results which were raised in the report for a particular trial. This information can be made available to all participants through the quarterly report.

Details of any forthcoming special surveys would be included. Participants complete a fax back sheet to indicate they wish to take part with an indication of their current methodology.

The report is also a newsletter so details of the Haematology Update meeting would be included. It can act as a vehicle to ask opinion on suggested changes or on comments that participants may have made on any aspect of the Scheme provision. Again the fax-back sheet would be used. Replies would be discussed in the next report (or earlier if necessary).

Meetings

For over 30 years, Scheme participants have met to discuss problems, plan strategies, analyse their performance and just talk to one another at our annual meeting. This gives an opportunity to exchange views, to question the organisers, to listen to and comment on short presentations, and to get to know one's colleagues in other haematology laboratories. We aim to continue this arrangement. So far there have been five meetings specifically for participants in Ireland who may have difficulty attending meetings in the UK, the last one being in September 2008. We hope that these will now be held every 2 years. We also envisage coming to meet participants in their own laboratories on request. The educational element of the meetings is very important and we will continue to invite expert speakers to present up-to-date papers on a variety of relevant topics. The meetings are varied and cover practical, clinical, developmental and theoretical aspects.

CQAS Web Site

www.cqas.org.uk

The web site currently provides an electronic format of this User Manual. It includes information regarding the Scheme, details of the Steering Committee, EQA packages, poor performance criteria and contact names and numbers. The latest details of the annual Haematology Update Meeting are also posted there.

Our aim for results for packages QA1, QA2A and QA2B to be entered via the web site is still being worked on with emphasis on easy access to input results whilst ensuring proper security of results and laboratory identification. By early 2009, we hope to perform some pilot runs with laboratories where this facility is available. Each centre will have their own log-on code to bring up details of their current contact name and address, instrumentation

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and reagent details. Results will be entered via this page so it will be possible for the laboratory to check their registration details and update them when changes occur.

Continuing development of the web site is working towards:

Inclusion of specific return sheets for all other packages

The on-line “posting” of analysis reports

Introduction of a web-site advice update service

Real-time on-line external quality assurance will be a real possibility in the future.

Liaison with the Commercial World

Diagnostics and pharmaceutical companies participate in the scheme. It is also the practice of some companies to offer new products to the scheme for evaluation. Some companies may see this as free advertising on their part; others would see it as a risk since the product may not always perform well. We see it as a chance to look at the performance of a product in a variety of laboratory environments. We make no recommendations, we simply analyse the data and comment on the results. The final decision on whether to use a particular product can only be made by individual laboratories. It should also be noted that the Scheme does not, under any circumstances, give the names and/or addresses of participants to commercial companies. It is, however, intended to have a more formal liaison between diagnostics and instrumentation companies and the Executive members of the Steering Committee.

Results are confidential as is the identity of participant labs. However, those who wish to correspond with users of the same or similar instruments or reagents are encouraged to do so if this is mutually agreed.

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Central Quality Assurance Scheme and the UK NEQAS Schemes

We see no need for rivalry between CQAS and the two major UK NEQAS schemes. We do not currently have the capability to service the number of participants that the UK NEQAS schemes can. Indeed, it would be detrimental to our rapid turnaround if we tried to do this. We offer a different service which complements UK NEQAS rather than competes with it. This is reflected by the fact that the majority of our participants are also registered with the relevant UK NEQAS schemes.

There is room for complementary EQA schemes to work together without one being detrimental to another. There is liaison between the schemes at both organiser and manager level.

CQAS and the Future

The Scheme is always looking to improve the service it provides and is keen to listen to views of participants, who have a clear perception of some of the things that they want from an EQA scheme. Previous developments have included:

Specific surveys for “dosing” of warfarin.

Issues of “fresh” , unfixed samples for FBC and white cell differential.

Work on low platelets and white cell counts

Evaluations of new plasma viscometers

Developed closer liaison with suppliers

CQAS is keen to develop collaborative partners and participant bases within the European Union. As part of this development we would be keen to discuss the potential for pilot participation in any (or all) of our packages with a view to looking at the logistics of transporting samples over a long distance and maintaining the integrity of the sample. It would also give laboratories an opportunity to see whether the scheme would work for them before making any firm commitment.

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Our Commitments

1) To provide a rapid return of trial reports so that data are current.

NB if we receive a participant's results and they are clearly out of consensus with others, it is our policy to contact that participant to elucidate the problem and send material for repeat testing at the earliest opportunity.

2) To promote good laboratory practice by education and discussion

3) To listen to participants' views and questions, both informally by direct communication and formally at regular "user" meetings.

4) To improve quality control of laboratory testing by complementing the work of other EQA schemes.

5) To respond to the changing demands and expanding repertoires of our participants.

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Central Quality Assurance Scheme (CQAS) Steering Committee Constitution

Aims and Objectives

- 1) To advise the Scheme Organiser and CQAS co-ordinating staff on the overall operation of CQAS including :
 - a) tests to be included within EQA survey packages.
 - b) new survey packages to be introduced.
 - c) frequency of distribution of materials.
 - d) type of materials to be distributed and their safety.
 - e) methods of data analysis.
 - f) presentation of results.
 - g) opportunities for new business.

- 2) To assist the CQAS organisation to undertake research within the field of Quality Assessment and Quality Assurance in Haematology, Haemoglobinopathies and Haemostasis.

- 3) To promote educational aspects of Quality Assessment and Quality Assurance in these fields.

- 4) To work closely with the National Quality Assurance Advisory Panel (NQAAP) in Haematology and the Joint Working Group on Quality Assurance (JWGQA) as laid down in the letters of recognition of acceptance as an approved national scheme.

- 5) To assist the Scheme Organiser / Manager to register the scheme as required by the JWGQA and to comply with the requirements of any regulatory body which is set up to oversee the work of the scheme.

Membership

The committee will consist of:

- 1) Chairman
- 2) Secretary
- 3) Scheme Organiser

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- 4) Deputy Scheme Organiser
- 5) Scheme Manager
- 6) A representative of the Advisory Panel in Haematology
- 7) Six ordinary members

In addition, other key members of the CQAS team will be invited to be in attendance. Observers from outside organisations (e.g. DOH, CPA) may attend as required. Any person may be co-opted to be in attendance for the whole or part of the meeting.

The Officers

The Chairman, Secretary and Scheme Organiser will be elected by a simple majority of those members holding voting rights.

The Scheme manager (and additional staff) will be appointed by the Scheme Organiser

Terms of Office

The Chairman and Secretary will normally hold office for 6 years but may serve a further 3 year term by agreement with the Committee. After 9 years, the Chairman or Secretary must stand for a formal and full re-election process.

The terms of office of the Scheme Organisers and Scheme Manager shall not be limited. In the event of a change in Scheme Organiser or location of the Scheme, the Scheme Manager and permanent members of staff will be offered the opportunity to continue their employment.

Elected members will normally serve for 5 years but may serve for a further 2 year term by agreement with the Committee. After 7 years an elected member must either be elected as an officer or must stand for a formal re-election process.

Voting

Voting rights are held by members listed in 1) to 7) above.

Voting on policy matters will be by simple majority on a show of hands or, if necessary, by a secret ballot at the discretion of the Chairman.

Voting on the election of Officers and elected members will be by simple majority on a secret postal ballot, should such a ballot be necessary.

The Chairman has the right to cast an additional deciding vote in the event of a tied vote.

Quorum

A quorum shall be:

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The Chairman or the Secretary.

The Scheme Organiser or Deputy Scheme Organiser or Scheme Manager.

4 other members to include at least two ordinary members.

In the absence of the Chairman, the Chair will be taken by the Scheme

Organisers or Scheme Manager.

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Meetings

Formal meetings will be held at least once per year, but will generally aim to meet twice per year. One meeting must be a full Annual Management Review.

The Secretary will provide at least four weeks notice of each meeting by posting an Agenda and supporting papers prior to the meeting.

An Extra-ordinary Meeting may be called on receipt of a written request to the Secretary by any 5 voting members. Such an Extra-ordinary meeting will be arranged by the Secretary within 6 weeks of notification.

Change of Rules

These constitutional rules may only be changed by a two-thirds majority of voting members casting a vote in a secret ballot.

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