UK NEQAS Haematology
Participants’ Manual

Version 7.3, issued January 2017

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<tr>
<td>7.0</td>
<td>April 2016 Online and in hard copy</td>
<td></td>
<td>Original document replacing all previous versions.</td>
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<td>7.1</td>
<td>October 2016 Online</td>
<td>16 42</td>
<td>Staff list updated Complaints and Appeals section re-instated. Omitted in error from version 7.0.</td>
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<tr>
<td>7.2</td>
<td>November 2016 Online</td>
<td>48</td>
<td>Addition of multiplier for calculation of Plasma Viscosity analytical performance score</td>
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<tr>
<td>7.3</td>
<td>January 2017 Online</td>
<td></td>
<td>ESR Scheme now accredited to ISO 17043</td>
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UK NEQAS controlled document H54
QUICK REFERENCE

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WD18 0FJ
UK
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Fax: + 44 (0)1923 217879
Email: haem@ukneqas.org.uk
Web: www.ukneqash.org

How do I register?
Contact the Scheme Office (see above) and request a registration pack.

How do I re-register?
Between January and March of each year, participants are contacted and asked to confirm their re-registration details for the following financial year online.

What is the cost of participation?
Please contact the Scheme Office for our current subscription fees or for a quotation.

What is my PRN?
This is your Participant Reference Number. It is a 5 digit, unique reference number or identifier and should be quoted in all communications with the Scheme.

Where do I find the Scheme’s Terms and Conditions?
These are available to download from the documents section of the Scheme website (www.ukneqash.org)

Where do I find the JWG Conditions of Participation?
A link to the Joint Working Group on Quality Assessment in Pathology (JWG) Conditions of Participation can be found on the UK NEQAS Haematology website (www.ukneqash.org).

When will my specimen package arrive?
Specimen packages should be received within 2 days of dispatch for participants in the UK. Outside the UK, courier delivery usually takes up to 4 – 5 days.

What do I do if my specimen package doesn’t arrive?
Please contact the Scheme Office and request a replacement specimen pack.

How do I obtain repeat specimens?
Where practicable, repeat specimens are available throughout the survey period to replace specimens received in an unsatisfactory condition (i.e. broken, leaking, unlabelled, haemolysed or clotted) and to replace those accidentally damaged or misplaced in the laboratory, depending on the demand for services and the batch of material distributed.
Specimens may be unavailable or unsuitable for analysis after the survey has closed. Please contact the Scheme office for availability of repeat specimens.

What do I do if I can’t return my results in time?
If you are unable to return your results by the closing date, you may submit them late subject to certain conditions. If the website has closed for online entry, you should download a blank results form from the data entry website or contact the Scheme office. Remember to include your participant reference number (PRN) on the results form.

The first report you receive will not show your results if the report is generated before we have entered them, but a second ‘late’ report, showing your results, will be generated before the next survey is processed. Unless we have agreed to accept your results late without penalty, you will receive a non-participation score (see the section on Performance Scoring).

Where can I find the web-entry instructions?
A PDF copy of the web-entry instructions is available for download from the Documents section of the website (www.ukneqash.org).

I have made an error when entering my results online.
If you realise you have made an error in your online submission or you submit an incomplete set of results, contact us directly. We are able to reset your web entry page until the closing date, allowing you to resubmit your results.

How do I change registered method or instrument details?
Alterations to your registered instrument or method details, should be sent to us in writing, either by letter, fax or email and signed or sent by one of the named contacts, the head of the laboratory or laboratory manager. Changes must be received at least 3 weeks before the scheduled distribution date to be effective for that distribution.

I have forgotten my web-entry log in details / Can I change my web-entry log in details? / Can I change my registered details online?
We are in the process of allowing you to retrieve forgotten PRN / Identities, reset forgotten passwords and amend contact details through our website. These facilities will be available later in 2016 and you should visit the FAQ in the Haematology section of our website (www.ukneqash.org) for the most up-to-date information.
Otherwise, please contact the Scheme office.

Why are my results missing from my report?
This usually occurs because data has been submitted late or not at all, or has not been received. If you know you have returned your results in time, contact the Scheme office immediately.

Why do I get a different answer when I calculate my own statistics?
Results are generally loge transformed before calculating the survey statistics, including the calculation of DI value; hence you will not be able to replicate the survey statistics exactly unless you process the data in the same way. Even then, small differences will arise as a result of variation in the number of decimal places used, rounding of figures etc.
How do I register for Digital Morphology?

Laboratory managers can register a group of staff for Digital Morphology when registering or re-registering for other UK NEQAS Haematology services. Individual practitioners should register via www.ukneqash.org, following the links from the Training and CPD section or the on the front page of the website to the Digital Morphology home page.

Why can’t I see the current Digital Morphology case?

Only participants with a current, active licence can access open cases. Ensure you have activated your licence. If not, see your lab manager to obtain the activation key.

Why haven’t I received email notifications about the Digital Morphology cases?

Contact the UK NEQAS Haematology Scheme office to verify your email address is on the database.

I have forgotten my Digital Morphology log in details.

Contact the UK NEQAS Haematology Scheme office or click on the ‘forgotten password’ link from the Digital Morphology home page.

How do I register my staff on the UK NEQAS Parasitology Teaching Day?

You can register staff for the Parasitology Teaching Day at re-registration. Contact the UK NEQAS Haematology Scheme office if you wish to register at other times or you wish to register additional staff. Registration at times other than at re-registration is subject to availability of places.
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UK NEQAS HAEMATOLOGY

UK NEQAS Haematology is the expert centre within the UK National External Quality Assessment Service (UK NEQAS) for all aspects of Haematology diagnostic testing external quality assessment (EQA), with almost 5,000 UK and international registrations and a further 3,000 individual practitioners in our educational morphology programme.

UK NEQAS Haematology provides a wide range of EQA services for automated cell counting, blood morphology, haemoglobinopathies and other inherited red cell disorders. Participants may select the combination that fits their laboratory profile, making the Scheme flexible and adaptable to participants’ needs.

All UK NEQAS Haematology services comply with the UK NEQAS Charity’s Code of Practice and are offered on a not-for-profit basis.

UK NEQAS Haematology, on behalf of the World Health Organization (WHO), also organises an International EQA Scheme, which is available free of charge to WHO nominated laboratories and by subscription to laboratories in regions where delivery times may be prolonged.

This Manual contains the information you will need to participate effectively in UK NEQAS Haematology. It should be kept in the laboratory and be readily accessible to all laboratory staff. The latest version of this Manual is available to download from the Documents section of the UK NEQAS Haematology website (www.ukneqash.org).

The UK NEQAS website provides detailed and up to date information on the operation of UK NEQAS Haematology and Transfusion. As well as the route for data entry and retrieval, you will find service updates, closing date reminders and links to other related organisations or sources of information.

You can also keep up to date with some of our services via Facebook and Twitter; further details are available in the relevant sections of the Manual or from the website.
THE UK NEQAS CHARITY

UK NEQAS facilitates optimal patient care by providing a comprehensive external quality assessment service in laboratory medicine. Through education and the promotion of best practice, it helps ensure that the results of investigations are reliable and comparable wherever they are produced.

The UK NEQAS Charity is led by an elected President and an Executive Board of Trustees, with representation from UK NEQAS Schemes in the main disciplines of laboratory medicine. The Board of Trustees is served by the UK NEQAS Charity office, located at the Northern General Hospital in Sheffield.

UK NEQAS Charity Central Office
President: Dr Bill Egner
Company Secretary: Mrs Julie Gelder

UK NEQAS Office
PO Box 401, Sheffield, S5 7YZ, UK
Telephone: +44 (0)114 261 1689
FAX: +44 (0)114 261 1049
Email: office@ukneqas.org.uk
Web: www.ukneqas.org.uk

UK NEQAS Haematology is a member of the UK NEQAS Charity and operates in accordance with the UK NEQAS Codes of Practice (available from the UK NEQAS Charity website, www.ukneqas.org.uk).

Related UK NEQAS services are UK NEQAS for Blood Transfusion Laboratory Practice, UK NEQAS for Leucocyte Immunophenotyping and UK NEQAS for Blood Coagulation. Further details of these and all other UK NEQAS services can be obtained from the UK NEQAS Charity office.

UK NEQAS Compendium of Quality

UK NEQAS has published a Compendium of Quality, illustrating the core activities of UK NEQAS, including the provision of performance data for tests across the whole of pathology and for scrutiny of quality by the UK Accreditation Service (UKAS), the Care Quality Commission (CQC), the Medicines and Healthcare products Regulatory Agency (MHRA), provider governance systems and commissioners of services.

This Compendium ably demonstrates that the activities of UK NEQAS are much broader than assessing the technical accuracy and precision of results. UK NEQAS provides electronic learning facilities, meetings and websites to support improvement in quality management. It is at the forefront of the development of digital imaging techniques to provide educational packages for personal performance and development. Advances in new technology and processes (genomics, molecular pathology, point of care testing, digitisation, informatics) require a strengthened quality assurance framework and the Compendium provides examples of how new approaches to EQA are being developed.
WHY PARTICIPATE IN EQA?

Helping to ensure clinical laboratory test results are accurate, reliable and comparable wherever they are produced.

QUALITY ASSURANCE is the combination of measures taken to ensure reliability and relevance of laboratory results, from the collection of the specimen to the delivery of the report to the clinician. The component steps in this process include:

- The selection of the test
- The identification of the patient
- The provision of suitable containers and collection of the specimen
- The transportation of the specimen
- The reception of the specimen in the laboratory
- The analytical procedures
- The validation of the results
- The interpretation and presentation of the results
- The delivery of the report to the clinician
- The appropriate and timely action on the test results

Within the laboratory, two complementary processes, internal quality control (IQC) and external quality assessment (EQA) are used to monitor performance.

Internal Quality Control is intended to ensure that consistent, reproducible results are achieved on a day-to-day basis. An analytical error should be promptly identified and corrected before the test result is issued.

External quality assessment is intended to achieve inter-laboratory and, if possible, inter-instrument harmonisation of results, and to monitor the general level of performance in a laboratory. This assessment is long-term, retrospective and provides periodic assessments of the way in which the laboratory performs. Inter-laboratory surveys can be run at various levels: international, national, regional or local. National and regional schemes complement each other, each providing a different aspect of external quality assessment. Regional or local schemes have the advantage of speed in giving participants the analysis of results; however, such schemes have limitations. Statistical evaluation may be less robust due to the smaller numbers of participants and even a few outliers may distort the results. Furthermore, results may be biased by a consistent error, which will not be detected until comparison is made with results obtained from a larger population in a national scheme. The latter are more likely to be closer to the true value.

Although a national scheme may have a longer turnaround time for reports due to the large numbers of participants, participating laboratories can check their performance with that of the whole country and with other laboratories using similar equipment and procedures. The data from a national scheme may allow ‘state of the art’ comparisons of instruments, reagents, control preparations and method procedures etc.

A national scheme can be used to coordinate regional, local or organisational reviews of performance or smaller EQA schemes. In some regions, participants may ask for a copy of their normally confidential results to be sent to a designated regional quality control officer for review. The surveys may also provide a means by which control or calibration materials
under development can be evaluated in an independent critical study. Taking part in a national scheme in addition to locally organised or regional schemes is thus essential. It is also necessary to register for all tests available within a Scheme, if such tests are included in the clinical services offered by the laboratory.

Comprehensive EQA services, as provided by UK NEQAS, test the quality of laboratory medicine services beyond the analytical phase, with a scope that extends to case interpretation, education and monitoring the pre and post analytical phases.

UK NEQAS Haematology provides surveys at a national and international level.

ELIGIBILITY FOR PARTICIPATION

Participation in UK NEQAS Haematology is open to all diagnostic testing service providers, veterinary laboratories, academic and commercial institutions in the UK and overseas. Manufacturers are actively encouraged to participate in all appropriate schemes or may elect to receive summary reports only (‘information only’ participants).

There are restrictions on participation in some schemes depending on the availability of survey material, the instruments or kits used and the geographical location of participants. Where possible, any such restrictions are described in the relevant part of the ‘Surveys Offered’ section.

The Scheme office will advise if you have any queries about the suitability of any particular survey for your needs. Participants are asked to review the UK NEQAS Haematology and Transfusion terms and conditions before registration (available from www.ukneqash.org).

JOINT WORKING GROUP ON QUALITY ASSESSMENT CONDITIONS OF PARTICIPATION

Oversight of performance in EQA within the UK is the professional responsibility of the Joint Working Group on Quality Assessment in Pathology (JWG), a committee of the Royal College of Pathologists (RCPath). The JWG has established National Quality Assessment Advisory Panels (NQAAPs) for specific disciplines to monitor the performance of UK laboratories providing a direct or indirect clinical service and to offer advice to any laboratory with persistent unsatisfactory performance (PUP). By registering with the Scheme, UK participants who provide a clinical service agree to be bound by the JWG Conditions of Participation, a link to which may be found on the UK NEQAS Haematology and Transfusion website (www.ukneqash.org). These include the NQAAP being informed of the identity of any UK participants with unresolved performance issues.
UK NEQAS HAEMATOLOGY ACCREDITATION

The West Hertfordshire Hospitals NHS Trust operating UK NEQAS Haematology and Transfusion is accredited by the UK Accreditation Service (UKAS) against ISO 17043, with the accredited centre number 7805.

A copy of the accreditation certificate is available from the UK NEQAS Haematology and Transfusion website (www.ukneqash.org). The full and most up to date details of the schemes included in the scope of the accreditation are available from the UKAS website (www.ukas.com).

UK NEQAS HAEMATOLOGY STEERING COMMITTEE

All UK NEQAS Schemes are supported by advice from an appropriate UK NEQAS Steering Committee. Membership of the Steering Committee is ratified by and accountable to the UK NEQAS Charity’s Board of Trustees, which provides the terms of reference for individual UK NEQAS Steering Committee and Scientific Advisory Groups.

The Steering Committee Chair is independent of UK NEQAS operational interests and membership includes appropriate experts, participants and advisors. They sit in their own right and not as representatives of any professional or other group. However, they may fulfil an invaluable liaison function with such groups and UK NEQAS Haematology tries to ensure the representation of significant stakeholders in the membership of its Steering Committee and Scientific Advisory Groups.

UK NEQAS Haematology operates with the advice of an over-arching Steering Committee and three Scientific Advisory Groups (SAGs): the General Haematology SAG, the Morphology SAG and the Special Haematology SAG. The Steering Committee and SAGs have representatives from participants, the professions and observers from the NQAAP, in addition to expert scientific and clinical advisors. Their purpose is to advise the Scheme Director and staff on scientific, technical and organisational matters.

Steering Committees and SAGs do not consider the performance of individual participating laboratories, except in advising on performance criteria or where performance may indicate a failure in the operation of the Scheme (and even in such cases the laboratories will not be identifiable).

Details of Steering Committee and Scientific Advisory Group membership and the contact details of the Steering Committee Chair are available from the UK NEQAS Haematology and Transfusion website (www.ukneqash.org) or the Scheme office.
CONTACTING UK NEQAS HAEMATOLOGY

UK NEQAS Haematology aims to offer a participant driven Scheme. Participants are encouraged to contact UK NEQAS Haematology with comments and queries, as feedback helps participants to use the Scheme fully and Scheme staff to plan appropriate developments.

Postal address: UK NEQAS Haematology
PO Box 14
WATFORD
WD18 0FJ
UK

Courier delivery: To send anything to us by courier please contact the Scheme office for the street address

Telephone: Direct line 01923 217878
International + 44 1923 217878

Telephone lines are open between the hours 09:00 and 17:00 Monday to Friday, with voice mail and email at other times and on UK public holidays.

Callers will be transferred to the appropriate member of staff according to their enquiry. Participants are requested to have their Participant Reference Number (PRN) available when contacting the Scheme. All calls are logged.

Fax: Direct line 01923 217879
International + 44 1923 217879

E-mail: haem@ukneqas.org.uk

Website: www.ukneqash.org
REGISTRATION PROCEDURES

All prospective, individual participants registering directly in the Scheme receive by email a link to the electronic copy of this Manual, a registration form, the fees for the current UK financial year (1st April to 31st March) and the annual schedule(s) of distribution dates.

Prospective participants should use this manual to decide whether the services provided are appropriate to them and what surveys they wish to register for. We welcome any queries you may have at this stage (haem@ukneqas.org.uk). Where requested, the Scheme office will supply a formal quotation of costs for the services required.

Completion of the registration form indicates that the prospective participant agrees to abide by the terms and conditions of registration with the scheme, and that any UK participant supplying a direct or indirect clinical service agrees to abide by the Joint Working Group (JWG) on Quality Assessment’s Conditions of Participation.

Links to the UK NEQAS Haematology and Transfusion Terms and Conditions and to the JWG Conditions of Participation can be found on the UK NEQAS Haematology website (www.ukneqash.org).

Participants must provide contact details for a named laboratory contact (main contact) to whom the specimens will be sent, and are encouraged to provide details of a named consultant or quality manager contact to whom correspondence concerning performance will be sent, as well as an invoicing contact. The laboratory contact must supply a functioning email address as much of the Scheme’s operation is conducted electronically. The participant may register additional contacts, who will be able to submit results and access reports online.

A new participant is included in the next available distribution, subject to the availability of survey material, as long as the registration form is received a minimum of three weeks before the published distribution date. We will inform you immediately if there is likely to be any delay to commencement of your participation.

Following receipt of the completed registration form, an invoice is issued to the participant’s finance address. The invoice total is calculated pro rata to the number of distributions remaining for the current financial year (April - March). First class postal delivery in the UK for survey packages is included in the fee; any additional carriage or postage costs will be added to the invoice. An additional charge is also made for the provision of paper reports for web-based schemes and any services (e.g. inclusion of cold packs) that are not covered by the standard fee.

The Scheme reserves the right not to confirm registration of a participant until an official purchase order number or payment has been received.

The Scheme will register multiple sites and analysers, subject to the conditions listed in the Surveys Offered section. In general, the Scheme will register as many instruments providing a numerical result as the participant requires, under the same participation. Only one submission is allowed for elements of a scheme involving interpretation or diagnosis.

The arrangements for registration through one of our recognised distribution agents may differ, depending upon the agent.
GENERAL ADMINISTRATION

Location and Host Organisation

UK NEQAS Haematology is operated by the West Hertfordshire Hospitals NHS Trust at Watford General Hospital, where it shares premises with the UK NEQAS for Blood Transfusion Laboratory Practice (BTLP). The Scheme has dedicated secure office, laboratory and logistics facilities.

The UK NEQAS services are part of the Clinical Support Division of the West Hertfordshire Hospitals NHS Trust and all staff are Trust employees. In accordance with Department of Health (DH) guidance, the Scheme is wholly self-financing and is a cost-neutral activity for the Trust.

The Scheme gratefully acknowledges the hospitality of the West Hertfordshire Hospitals NHS Trust and the support of colleagues in the Clinical Support Division.

Scheme Staff

UK NEQAS Haematology is staffed by the following healthcare scientist and administrative staff, some of whom are shared with UK NEQAS BTLP. The list below is correct at the time of issue of this version of the Manual; the most up to date list is available from the Scheme office. Other clerical and logistics support staff are employed jointly with UK NEQAS BTLP, maximising the cost effective use of staff in shared functions such as administration, packing and dispatch.

Director (organiser): Barbara De la Salle
Data Manager: Paul McTaggart
Morphology Lead Scientist: Jon Sims
Automated Counting Lead Scientist: Vatsala Soni
Haemoglobinopathy Consultant: Barbara Wild
Scheme Scientist: Nikki Emodi
Scheme Scientist and Quality Lead: Zeno Abid
Associate practitioner: Gulala Karim
Associate practitioner: Paula Dynes
Laboratory Assistant: James Hindell
IT Manager *: Vasilis Rapanakis
Logistics Coordinator *: Stephen Herbert
Business Manager *: Vacancy
Executive Assistant *: Isabella De-Rosa
Office Manager*: Mayuri Wadhia
Quality Manager *: Clare Milkins

*Staff position shared with UK NEQAS BTLP.

Computer Systems, web operation and communications

All Scheme data is held securely and backed up daily. Data processing is performed using bespoke software, which has been developed in association with the software company KPMD (IT Solutions) Ltd. Digital Morphology is hosted by SlidePath, a subsidiary of Leica Biosystems, utilising their Digital Slidebox™ application.
For most surveys, results may be returned using the Web Results Service and reports are available for secure download. It is the objective of UK NEQAS Haematology to operate all schemes on the web and participants are encouraged to register for web operation where this is available.

Pilot schemes, schemes in development, schemes with complex and extensive data and schemes with a very small number of participants may not be available through our Web Results service. Where possible, we aim to offer alternative electronic means of results return and reporting in these situations.

UK NEQAS Haematology issues all communications by email unless this risks confidentiality or financial security. All participants must supply a valid email address and keep this up to date. The Scheme records email addresses for the purpose of notifying participants of survey distribution and report availability; email addresses will also be used to inform participants of UK NEQAS meetings and other EQA and pathology related activities unless the participant has requested otherwise. Participants’ email contact details are not shared with other organisations without the direct permission of the individual laboratory.

Confidentiality

Registration information, raw data and performance details are confidential between the individual participant, the Scheme Director and designated UK NEQAS staff. The identity, performance details (and some relevant raw data) of any UK participant may be shared with the NQAAP as part of the reporting of persistent unsatisfactory performance. Performance data may be shared with local management, regional QA officers, regulatory and accrediting bodies and suppliers of equipment and reagents, where appropriate and necessary, but only with written permission from the participant. The identity of participants in England registered in the Abnormal Haemoglobins, Newborn Sickle Screening and DNA Diagnostics in Haemoglobinopathies schemes and offering services covered by the National Sickle Cell & Thalassaemia Screening Programme in England may be disclosed to the National Programme Manager in the event of unsatisfactory performance unless the participant has advised the Scheme at registration that this information may not be shared.

As a part of its host NHS Trust, UK NEQAS Haematology is subject to the Freedom of Information Act regulations.

Data Protection Act (1998)

The purpose of the Data Protection Act is to prevent the misuse of personal data held on computers and to ensure that organisations holding such data conform to a required standard. The West Hertfordshire Hospitals NHS Trust, the host organisation for UK NEQAS Haematology, is registered as a data user under the terms of the Data Protection Act. Information provided by participants on their registration forms is held on a computer in order to identify those participants registered for a given activity and to generate address labels for the dispatch of material or reports. In addition, the survey results are held (as non-personal data) on a computer for analysis. All participants are entitled to view their personal computer records on request.
Participant Reference Number (PRN)

Each participant is given a unique Participant Reference Number (PRN), which should be used in all communications with the Scheme. The PRN issued is unique within the UK NEQAS organisation. If desired, a participant who is already registered at another UK NEQAS centre can use the PRN from that centre to register with UK NEQAS Haematology.

Where a participant registers more than one analyser or method in a scheme, each analyser or method will be allocated a separate PRN, with the same core number but with the addition of a letter suffix. Where possible, we link the PRN to the analyser’s serial number and give the analyser the same PRN across all schemes. We do not reuse PRNs, to avoid confusion.

Where instruments are under the same PRN but on different sites, the participant must be able to process the specimens through all the analysers and return results by the closing date.

The Scheme operates a one analyser, one identifier policy and asks for a serial number to be supplied with each analyser registered. When an analyser is replaced, a new analyser identifier is issued for the replacement instrument. The only exception to this arrangement is for some point of care testing sites, where the analysers are regularly exchanged.

Post and courier delivery

The Scheme has its own PO Box number and its own post room for the franking of outgoing mail, which is collected directly by the Royal Mail or courier. Survey material is distributed by first class mail within the UK and we advise courier delivery to most destinations outside the UK. The Scheme office will advise of the best delivery options at registration.

Courier and postage costs for delivery of specimen packages outside the UK are charged in addition to the Scheme’s published fees. The exact cost of delivery depends upon the destination and the Scheme office will advise on this.

The Scheme’s courier of choice is DHL International. Participants may opt to use another courier or their own courier account; in these circumstances, a small administration fee will be applied.

Where web based operation is available for a survey, participants are charged an additional fee if they opt not to use this facility, to cover the costs of printing, packing and posting paper reports. UK NEQAS Haematology reserves the right not to offer paper based operation in any scheme or to any particular destination.

Distribution schedules

Distribution schedules for all our surveys and reports are available to download from the Documents section of the UK NEQAS Haematology website (www.ukneqash.org) or from the Scheme office.
Annual re-registration

Between January and March of each year, participants that register directly with the Scheme are contacted with details of the coming year’s services, asked to confirm their re-registration details online and to provide a purchase order number, which is used to raise an invoice in April or May. Re-registration of participants registered through a distribution agent or other group participation is completed by the agent on behalf of the group.

Subscription fees and VAT

The fees for participation in UK NEQAS Haematology are set annually on a not-for-profit basis. Details of fees are supplied to prospective participants or at re-registration by the Scheme office. Fees for participants joining part way through the year are charged pro rata.

All UK EQA providers are required by Her Majesty’s Revenue and Customs (HMRC) to charge Value Added Tax (VAT). In accordance with VAT regulations, VAT is not charged to participants based in the same health service as UK NEQAS Haematology (NHS England); VAT will be applied to all other participants where it is applicable (non-NHS in England, all participants in Scotland, Wales, Northern Ireland and the European Union). Participants outside the UK who are registered for VAT will be liable to account for VAT under the reverse charge mechanism.

Changes to registered information

Alterations to your registered instrument or method details should be sent to us in writing, either by letter, fax or email, signed or sent by one of the named contacts, the head of the laboratory or laboratory manager. You may notify us of a change at short notice by telephone, but we will ask you to confirm in writing as soon as possible for audit purposes.

We are in the process of allowing you to retrieve forgotten PRN / Identities, reset forgotten passwords and amend contact details through our website. These facilities will be available later in 2016 and you should visit the Haematology FAQ section of the website (www.ukneqash.org) for the most up-to-date information.

Otherwise, please contact the Scheme office.

We request that 3 weeks’ notice is given for changes to be effective, i.e. changes sent by the end of the first week in the month will take effect from the distribution for the following month. We regret that we cannot guarantee to process changes to registered details notified on your results return page or results sheet, as this delays data entry and may be overlooked due to the volume of that is received and processed.

Delay in notification of changes to your registered details may result in additional charges, inappropriate data analysis or adverse performance assessment.

Cancellation or suspension of participation

Please notify the Scheme office in writing, either by letter, fax or email, if you wish to cancel your participation in any survey, giving a minimum of three weeks’ notice before the next distribution date for the survey. Services cancelled without this notice period will be charged for. The Scheme may apply an administration charge, equivalent to one quarter’s registration fee, for deregistration in the second half of the participation year.
You may suspend your participation in any survey temporarily if your laboratory is not offering the test as a clinical service for any reason or your analyser is out of service, providing that you notify us in writing.

UK laboratories are asked to supply a reason for deregistration from any part of the Scheme’s services. Deregistration by UK laboratories is summarised to the National Quality Assessment Advisory Panel for Haematology on a quarterly basis. Deregistration by a UK participant with performance problems is notified to the NQAAP immediately.

The Scheme will cancel the registration of any participant who fails to pay the appropriate charges. Any UK laboratory under the remit of the Joint Working Group on Quality Assessment will be notified to the NQAAP for Haematology in the event that services are cancelled due to non-payment of subscription fees.

Certificate of registration

A certificate of registration is available once the payment for services has been received. From the autumn of 2016, it will be possible to download a certificate of registration directly from the UK NEQAS Haematology website (www.ukneqash.org).
SURVEYS OFFERED

UK NEQAS Haematology is the expert centre within UK NEQAS for all aspects of general haematology diagnostic testing EQA. UK NEQAS Haematology offers a wide range of related EQA schemes from which participants may select any combination that fits their laboratory profile. This makes the Scheme flexible and adaptable to participants’ needs.

The Scheme provides the following categories of EQA:

- **Automated Counting surveys**
  - Full Blood Count
  - Full Blood Count: Hb only option
  - Blood Component Quality Monitoring
  - Automated Differential Leucocyte Count
  - Reticulocyte Count
  - Plasma Viscosity
  - Erythrocyte Sedimentation Rate
  - Nucleated Red Cell Count pilot*

- **Blood Morphology and related surveys**
  - Blood Films for Morphology Skills and Manual Differential Count
  - Blood Films for Parasite Screening and Identification
  - Blood Films for Cytochemistry
  - Rapid Diagnostic Testing for Malaria
  - Digital Morphology for Continuing Professional Development*

- **Haemoglobinopathy surveys**
  - Abnormal Haemoglobins, including sickle solubility screening only and liquid newborn testing options
  - Newborn Sickle Screening using dried blood spot specimens
  - DNA Diagnostics for the Haemoglobinopathies

- **Other specialist haematology surveys**
  - Red Cell Enzymes: G6PD screening and quantitative assay

Surveys marked with an asterisk (*) are not included in the scope of the UK NEQAS Haematology accreditation to ISO 17043 at the time of publication. These services are operated to the same quality management system as the accredited schemes.

The Scheme offers services and educational activities in collaboration with other UK NEQAS centres where diagnostic tests related to these areas cover more than one pathology discipline.

**Survey material**

Survey material is obtained from a variety of sources and is designed to be as close to patients’ clinical material as practicable. Material may be prepared by UK NEQAS Haematology, purchased commercially or prepared by a sub-contracted organisation. Blood films for morphology and cytochemistry are prepared either by UK NEQAS Haematology or by the laboratory submitting the case. All slides are stained on-site, with the exception of those for blood parasite identification.
Scheme and survey material pool identifiers

Each scheme is identified by a two letter code, e.g. FB for full blood count, DL for automated differential leucocyte counting. The codes for the individual schemes are shown in the scheme descriptions below. Where different survey material types (matrices) are supplied within an individual scheme, these are identified by the addition of a matrix dependent suffix, e.g. DLA or DLB in the automated differential counting scheme.

Survey material pools are given a unique code, comprising the last 2 digits of the year, the chronological number of the survey within the year, the 2 letter scheme or survey material identifier and the specimen number. For example, the full blood count specimens distributed in April 2016, the fourth full blood count distribution of 2016, were coded as 1604FB1 and 1604FB2. The blood films for morphology sent in the second blood films distribution of 2016 were coded as 1602BF1 and 1602BF2.

Online operation

All schemes are available for online operation unless stated in the scheme specific sections.
AUTOMATED COUNTING SURVEYS

Full Blood Count (FB), including the Hb only (HB) option

- **Purpose**
  This scheme is designed for users of automated haematology analysers providing full blood count (FBC or CBC) data in clinical, veterinary, research, pharmaceutical and health surveillance settings.

  The survey material is suitable for all the major analyser models and individual parameter methods, e.g. microhaematocrit and platelet counting by flow cytometry.

  Point of care testing analysers are accommodated in this scheme, either in the full blood count (FB) option, or in the haemoglobin only (HB) option, depending on the instrument and the analytes produced.

- **Analytes and units**
  - White blood count (WBC) \(10^9/L\)
  - Haemoglobin (Hb) \(g/L\)
  - Red blood count (RBC) \(10^{12}/L\)
  - Haematocrit (Hct) \(L/L\)
  - Mean cell volume (MCV) \(fL\)
  - Mean cell haemoglobin (MCH) \(pg\)
  - Mean cell haemoglobin concentration (MCHC) \(g/L\)
  - Platelet count (PLT) \(10^9/L\)

  Other parameters are under development.

- **Scheme design and survey material**
  **Full blood count (FB) option:** Two whole blood specimens are issued per distribution, with 12 distributions per year on a monthly basis (24 specimens per year). All participants receive the same material type, although instruments are grouped for performance analysis. The specimens are prepared by UK NEQAS Haematology from pooled human blood components, partially fixed and treated with antibiotics. Haemoglobin concentration, red blood count, white blood count and platelet count are varied to test performance at different levels of clinical decision making. Participants may register up to 3 instruments for a single fee, with an additional fee for each instrument above 3. A single set of survey material is dispatched for multiple analysers, with additional specimens provided for registrations of more than 5 instruments. Point of care instruments that provide a full blood count result, i.e. more than a haemoglobin result, may register in this scheme.

  **Hb only (HB) option:** Participants with point of care instruments that only produce a haemoglobin concentration are registered in the Hb only (HB) option of the scheme. Two whole blood specimens are provided 12 times per year. The specimens are prepared by UK NEQAS Haematology from donated human blood components and treated with antibiotics but not fixed. Participants may register up to 3 instruments for a single fee, with an additional charge for each instrument above 3. A single set of specimens is dispatched for each analyser, making this option convenient for analysers in multiple point of care testing locations.
Participants are performance monitored for participation and for analytical performance by instrument group.

- **Instrument groups available**
  The instrument groupings in use for Full Blood Count and any other scheme where participants are grouped by instrument, method or material type for the purpose of performance assessment are available from the Scheme office.

**Blood Component Quality Monitoring (CM)**

- **Purpose**
  This scheme is designed as a supplement to the Full Blood Count scheme for organisations that prepare therapeutic blood components. The scheme supplies specimens for haemoglobin concentration, haematocrit and platelet count beyond the normal physiological ranges.

- **Analytes and units**
  - **Units**
  - Haemoglobin (Hb)  g/L
  - Haematocrit (Hct)  L/L
  - Platelet count (PLT)  $10^9$/L

- **Scheme design and survey material**
  Four distributions, each containing 2 red cell specimens for haemoglobin/haematocrit and 2 platelet concentrate specimens for platelet count, are made each year. Survey material is prepared by UK NEQAS Haematology from donated human blood components. Red cell specimens are not stabilised but are treated with antibiotics. Platelet concentrate specimens are fully fixed. Participants may register up to 3 analysers or modes of analysis for a single fee. One set of specimens is provided for multiple analyser registrations. Participants wishing to register more than 3 instruments under one registration should contact the Scheme office.

  Participants are performance monitored for participation and for analytical performance in a single instrument group.

  This scheme is not currently available for online operation.

**Automated Differential Leucocyte Count (DL)**

- **Purpose**
  This scheme is designed to complement the Full Blood Count scheme for any participant who offers an automated differential count as part of their extended full blood count.

- **Analytes and units**
  - Three or five population differential leucocyte count, as performed using an automated haematology analyser
  - Automated differential count in absolute units ($\times 10^9$/L)
• **Scheme design and survey material**

Two specimens of commercially prepared whole blood material are distributed, six times per year (12 specimens per year). Seven types of commercially prepared survey material are available at the time of publication and the choice of material type (matrix) is instrument dependent. The matrices distributed and the instruments covered by each matrix are available from the Scheme office or the UK NEQAS Haematology website.

Participants may register up to 3 instruments for a single fee, with an additional fee for each instrument above 3. A single set of survey material is dispatched for multiple instruments, with additional material supplied for registrations of 5 or more analysers; where a participant registers analysers that require different matrices, these are supplied at no additional cost.

Participants are actively monitored for participation and the analytical performance of neutrophil and lymphocyte counts. A performance score for other cell types is provided for information at the time of publication and is under review for active performance assessment. Analysis of results is by material type, and in some cases is further subdivided by individual instrument type.

**Reticulocyte Count (RE)**

• **Purpose**

This scheme is designed for the performance monitoring of reticulocyte counting by automated analysers or visual microscopy (‘manual’ counting).

• **Analytes and units**

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reticulocyte count</td>
<td>$10^9/L$</td>
</tr>
</tbody>
</table>

• **Scheme design and survey material**

Two whole blood specimens are distributed six times per year (12 specimens per year). For analysers other than Beckman Coulter LH series, four specimens per year are commercially produced and the remainder are prepared by UK NEQAS Haematology from partially fixed human blood components, as for the full blood count specimens. Both types of material should be suitable for and automated reticulocyte counts and visual microscopy. Beckman Coulter LH series analysers require a separate, commercially-produced survey material type (matrix X), which is supplied for all specimens. Participants may register up to 3 instruments for a single fee, with an additional fee for each instrument above 3. A single set of survey material is dispatched for multiple instruments with additional material for registrations of 5 or more analysers; where a participant registers instruments that require different matrices, these are supplied at no additional cost.

Participants are performance monitored for participation and analytical performance. Performance monitoring for automated counting methods is by instrument group and visual microscopy methods are analysed in a single group.
Plasma Viscosity (PV)

- **Purpose**
  This scheme is designed for the performance monitoring of plasma viscosity.

- **Analytes and units**
  
<table>
<thead>
<tr>
<th>Units</th>
</tr>
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<tbody>
<tr>
<td>Plasma viscosity</td>
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</tbody>
</table>

- **Scheme design and survey material**
  Two specimens are distributed 12 times per year (24 specimens per year). Survey material is prepared from donated human fresh frozen plasma or plasma obtained from therapeutic plasmapheresis. The viscosity of normal plasma may be manipulated by the addition of glycerol and all material treated with antibiotics and an antifungal agent.

  Participants may register up to 3 instruments for a single fee.

  Participants are performance monitored for participation and analytical performance. Performance is monitored against all methods and instrument group, where sufficient instruments are registered.

Erythrocyte Sedimentation Rate (ES)

- **Purpose**
  This scheme is designed for the performance monitoring of erythrocyte sedimentation rate (ESR) by automated or manual methods.

- **Analytes and units**
  
<table>
<thead>
<tr>
<th>Units</th>
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<tbody>
<tr>
<td>ESR</td>
</tr>
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</table>

- **Scheme design and survey material**
  4 distributions per year are made at time of publication but this is under review for 2017 – 18. There are 2 modules: the general module (ES) with 2 specimens per distribution and the Alifax module (ESX) with 3.

  Survey material is commercially prepared.

  Participants may register 1 instrument for a single fee, with an additional fee for each extra instrument registration. A separate set of specimens is despatched for each instrument registered in the ES module; a single set of specimens is distributed for multiple analyser registrations in the ESX module.

  Participants are performance monitored for participation and analytical performance. Performance is monitored by module and instrument group, where sufficient instruments are registered.

  This scheme is available for online operation.
Nucleated Red Blood Cell Count (NR) Pilot

- **Purpose**
  
  This scheme is designed for the performance monitoring of nucleated red blood cell count (NRBC) by automated methods.

- **Analytes and units**

<table>
<thead>
<tr>
<th>Units</th>
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<tbody>
<tr>
<td>NRBC</td>
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- **Units**

<table>
<thead>
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<th>Units</th>
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<tr>
<td>$10^9$/L</td>
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- **Scheme design and survey material**

  This is a pilot scheme and is in development.

  The pilot scheme is available for Sysmex instruments only at the time of publication due to the availability of survey material but this is under review. The Scheme office is able to supply the most up-to-date information.

  The scheme is not available for online operation at present.

  As a pilot scheme, this scheme is not included in the current UK NEQAS Haematology scope of accreditation.
BLOOD MORPHOLOGY AND RELATED SURVEYS

Blood Films for Morphology (BF), Differential Counting (DF) and Parasite Screening / Identification (PA)

- **Purpose**

  This scheme is designed to maintain and improve blood film morphology skills, manual differential counting and blood parasite screening and identification. Participation is by organisation.

  Participants are encouraged to indicate a possible condition (‘morphological syndrome’) on the Blood Films for Morphology cases based on the blood morphology, although this is not performance assessed.

  Participants may register in Blood Films for Parasites either for Parasite Screening only or for Parasite Screening and Identification. At the Screening stage participants are asked to screen the slides for the presence of blood parasites and identify the type of parasite present, i.e. whether malaria, microfilaria, trypanosome or other. Participants who identify the malaria species in-house using blood films and are authorised to report the species to the requesting clinician without prior referral to an expert centre should register for Parasite Species Identification in addition to Parasite Screening.

  Participants may opt out of the Blood Films for Parasite option, if this is not a service that is offered as part of their clinical repertoire; however, many sites in this situation choose to remain in this part of the scheme for educational purposes.

- **Analytes and units**

  - Peripheral blood films for the identification of significant morphological features (BF slides)
  - A white cell differential count is requested on selected blood films (DF surveys) and results are returned as both percentage and absolute counts
  - Peripheral blood films for the detection and species identification of blood parasites (PA slides)
  - A parasitaemia count (%) is requested if *Plasmodium falciparum* or *Plasmodium knowlesi* is present

- **Scheme design and survey material**

  Two blood films for morphology comments are distributed eight times per year (16 BF slides per year). A WBC differential is requested on four of the BF slides each year (4 DF cases per year). Two blood films (thick or thin preparations) for blood parasites are distributed four times per year (8 PA slides per year).

  Films for morphology and differential counting (BF/DF slides) are made, fixed and stained by UK NEQAS Haematology; on occasion, slides may be made at the referring laboratory prior to staining at UK NEQAS Haematology.

  Preparation and staining of films for parasites (PA slides) is sub-contracted to UK NEQAS Parasitology at the Hospital for Tropical Diseases (HTD) in London. The parasite species is
confirmed by polymerase chain reaction (PCR) testing at HTD, who also provide a reference value for the parasitaemia count where applicable.

Participants are performance monitored for participation in all parts of the scheme they are registered for.

Participants in Blood Films for Morphology are monitored for participation and the identification of significant morphological features against the consensus opinion and that of an expert panel (performance scoring in development at the time of publication). DF surveys are reported in summary format only, without individual participant performance assessment.

Participants in Blood Films for Parasites are monitored for participation and analytical performance of detection of the correct parasite type against the expected target in the Screening part of the scheme. Participants registered for species identification receive an adverse notification if they fail to identify *Plasmodium falciparum* or *Plasmodium knowlesi* infection or if they return an out-of-consensus percentage parasitaemia. Performance scoring for Parasite Identification is in development at the time of publication.

This scheme is available for online operation.

**Cytochemistry (CY)**

- **Purpose**
  
  This scheme is designed to monitor the performance of iron staining for bone marrow and urinary haemosiderin, and the performance of Sudan Black B (SBB) or myeloperoxidase (MPO) stain.

- **Analytes and units**
  
  - Iron stain (Perls’ stain)
  - Sudan Black B (SBB) or Myeloperoxidase (MPO)

  Participants may register for one slide type or both. For Iron Stain, participants are asked to stain the films for iron and to score the strength of the staining reaction; additionally, they are asked to report the presence of sideroblasts. For SBB/Myeloperoxidase, participants are asked to stain the films and report the results as positive or negative and the strength of the staining reaction in specific cell groups.

- **Scheme design and survey material**
  
  Two slides of either bone marrow or peripheral blood are issued per distribution for either Iron Stain or SBB/Myeloperoxidase, with four distributions per year (8 slides per year in total). Bone marrow slides for Iron Stain are fixed in methanol; peripheral blood films for SBB are unfixed and are accompanied by a methanol fixed film of the same case for Romanowsky staining.

  Participants are performance monitored for participation. The development of scoring for Iron Stain is under review.

  This scheme is available for online operation for data entry. Online reports are in development at the time of publication.
Rapid Diagnostic Testing for Malaria (RD)

- **Purpose**
  
  This scheme is designed to assess the performance of rapid diagnostic tests for malaria detection. It is operated in collaboration with UK NEQAS Parasitology and is offered to UK NEQAS Haematology participants registered in the Blood Films scheme.

- **Analytes and units**
  
  - Detection of species specific malarial antigen in blood

- **Scheme design and survey material**

  Participants may register more than one kit method but must identify the results generated from each kit registered.

  Two specimens of lysed whole blood are distributed 4 times a year, either negative or positive for different concentrations of malarial antigen, with each distribution of Blood Films for Parasites distribution. Survey material may be prepared from blood from patients infected with malaria or from normal donated blood spiked with recombinant malarial antigen. Preparation of survey material is sub-contracted to UK NEQAS Parasitology at the Hospital for Tropical Diseases in London, who also provide the identification of the *Plasmodium* species present.

  Results are returned as positive or negative for different malaria infections, depending on the kit.

  Participants are performance monitored for participation. Shadow analytical scoring is in place.

  This scheme is not available for online operation but this is in development.

Digital Morphology (DM)

The Digital Morphology Scheme provides the opportunity for individual practitioners to maintain and develop morphology and interpretive skills for the purpose of continuing professional development (CPD). Participants can register as individuals or a laboratory manager can register a group of staff with their other UK NEQAS Haematology services. Individuals may register directly on the Digital Morphology web pages (accessed from the Digital Morphology link on www.ukneqash.org) and pay securely using PayPal.

This interpretive scheme offers the following benefits to participants:

- Teaching, training and self-assessment
- Maintenance of competency
- High quality images
- Same image viewed by all
- State of the art virtual microscope software
- Wide variety of cases
- Secure online registration and participation
Each case comprises a virtual microscope slide, with brief patient history and blood results. 6 cases are offered each year.

Participants examine the large scale, stitched digital slide with the assistance of virtual microscope software, select the relevant morphological features and offer a diagnosis. Each case also includes a small number of follow up questions.

Results are submitted through a secure online account and participants receive immediate feedback via case annotations. Final results and feedback are provided at the close of the case, when participants can add their own reflective comments and download a participation certificate.

Participants have access to the cases issued from their point of registration.

The scheme is suitable for continuing professional development.

The scheme is not included in the UK NEQAS Haematology scope of accreditation.

This scheme is operated entirely online.
HAEMOGLOBINOPATHY SURVEYS

Abnormal Haemoglobins (AH)

• Purpose
This scheme is designed to assess the performance and interpretation of non-molecular detection techniques in screening and diagnostic testing for the haemoglobinopathies, using liquid blood specimens.

• Analytes and units

<table>
<thead>
<tr>
<th>Units</th>
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<tbody>
<tr>
<td>Sickle screening test (SS specimens)</td>
</tr>
<tr>
<td>Hb variant identification: adult (AH) specimens</td>
</tr>
<tr>
<td>Hb variant identification: liquid newborn (LN) specimens</td>
</tr>
<tr>
<td>Quantification of Hb A₂, Hb F and Hb S (AH) % total Hb</td>
</tr>
<tr>
<td>Assessment of Hb A₂ and Hb F in terms of the participant’s reference range (AH)</td>
</tr>
<tr>
<td>Interpretation of results (AH and LN)</td>
</tr>
</tbody>
</table>

• Scheme design and survey material

There are several options for participation:

**Option 1: Sickle screening only (SS specimens)**, for participants who perform sickle solubility testing only (or other similar technique) for the detection of the presence of sickle haemoglobin (Hb S).

**Option 2: Full participation (SS and AH specimens)**, for participants who undertake haemoglobin variant detection and identification (adult specimens) and / or fraction quantification. Participants are asked to supply an interpretation of their results and are given background case details to assist with this. Participants may opt out of any element of the scheme that they do not offer as part of their testing repertoire.

**Option 3: Liquid newborn screening (LN specimens)**, for participants who undertake diagnostic testing of newborn infants’ specimens for haemoglobin variants using liquid blood specimens. UK laboratories who wish to receive this option must register as full participants and add the LN specimens to their services received. Laboratories outside the UK may register for LN specimens as a stand-alone option. This option is not suitable for laboratories that undertake dried blood spot (dbs) testing.

There are 6 distributions per year of each option. Sickle screening only participants receive 3 specimens in each survey (SS specimens). Full participants receive the specimens for sickle screening, plus an additional 3 specimens (AH specimens) for Hb variant identification using any of their available methods, fraction quantification and case interpretation. Participants registered for the liquid capillary newborn specimens (LN) receive an additional 6 distributions per year of 2 specimens for haemoglobin variant identification and
interpretation. The AH and LN specimens are accompanied by relevant background details, including full blood count, age, gender, ethnic group and the indications for testing.

The survey material is human whole blood, manipulated where necessary to simulate different conditions and treated with antibiotics but not fixed. All specimens are prepared by UK NEQAS Haematology. Survey material is usually prepared from a single donation and therefore it is not possible to supply the volume of blood that would be provided from a clinical sample; however, sufficient is always provided for current laboratory techniques.

Participants are monitored for participation and analytical performance of sickle solubility test, Hb A₂ measurement and Hb S measurement, depending on their registration. Fraction identification (AH or LN specimens) is performance assessed but there is no numerical performance score provided at present. Gross errors of Hb F or Hb A₂ quantification or case interpretation will trigger a review of the laboratory’s performance. Where applicable, performance monitoring is based on the laboratory standards published by the National Sickle and Thalassaemia Screening Programme in England.

**Newborn Sickle Screening (NH)**

- **Purpose**
  This scheme is designed to performance assess the detection of clinically significant variant haemoglobins using dried blood spot cards and the interpretation of the results. It is intended for laboratories that offer newborn sickle screening, either as a primary testing or a confirmatory testing site.

- **Analytes and units**
  - Identification of sickle haemoglobin and other clinically significant variant haemoglobins using dried blood spot cards
  - Interpretation of results obtained

- **Scheme design and survey material**
  12 distributions are made per year on a monthly basis. Each distribution contains 3 dried blood spot newborn screening cards prepared from anti-coagulated umbilical cord blood (36 specimens per year). The specimens are suitable for screening by high performance liquid chromatography (HPLC), isoelectric focusing (IEF), capillary electrophoresis (CE) and tandem mass spectrometry (TMS).

Participants are monitored for participation and analytical performance of fraction identification and interpretation. The performance monitoring is based on the laboratory standards published by the National Sickle and Thalassaemia Screening Programme in England; however, it can be adapted to accommodate the objectives of other national screening programmes.
DNA Diagnostics for Haemoglobinopathies (DN)

- **Purpose**
  This scheme is designed to performance assess the identification of thalassaemia mutations of the globin genes, with occasional samples for the identification of variant haemoglobins, and the interpretation of the results obtained in context of the patient’s clinical background and other haematology. It is suitable for specialist laboratories that offer molecular haemoglobinopathy testing as part of their diagnostic repertoire.

- **Analytes and units**
  - Globin gene mutational analysis for alpha and beta thalassaemia, with occasional specimens for variant haemoglobins
  - Interpretation of results obtained
  - Recommendations for follow up
  - Annotation of results, with the correct use of HGVS nomenclature

- **Scheme design and survey material**
  Three distributions, each containing 2 specimens, are made per year (6 specimens in total). Survey material is supplied as DNA in Tris-EDTA (TE) buffer and is suitable for all molecular haemoglobinopathy techniques. Each specimen is supplied with clinical case details, gender and ethnic background and haematology results.

  Survey specimens are prepared by UK NEQAS Haematology from patients’ material surplus to the requirements for diagnostic testing. The volume of survey material may limit the availability of specimens for repeat testing and a waiting list for participation may be implemented if demand for registration is high. Registered participants who do not participate regularly will be asked to deregister.

  Participants may register for full participation or for alpha or beta thalassaemia mutational testing only. All receive the same samples.

  Participants are monitored for participation and analytical performance. Analytical performance is against a model answer defined by the Scheme’s expert advisors for this survey.

  This scheme is not operated online because of the extent and complexity of the data returned. To facilitate communications, the data return form is distributed electronically and emailed back to UK NEQAS; reports are returned by email as PDF documents.
OTHER SPECIALIST HAEMATOLOGY SURVEYS

Red Cell Enzymes (G6)

- **Purpose**
  This scheme monitors the screening and/or quantitative assay of red cell enzymes. These surveys are currently restricted to glucose-6-phosphate dehydrogenase (G6PD) specimens only.

- **Analytes and units**
  
<table>
<thead>
<tr>
<th>G6PD</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Qualitative screening test</td>
<td></td>
</tr>
<tr>
<td>Quantitative assay</td>
<td>IU/gHb</td>
</tr>
<tr>
<td>Assessment of quantitation</td>
<td></td>
</tr>
<tr>
<td>of the participant’s reference range</td>
<td></td>
</tr>
</tbody>
</table>

- **Scheme design survey material**
  Six distributions of 2 specimens each are made per year. The specimens are prepared by UK NEQAS Haematology from human whole blood or animal whole blood. The survey material is treated with antibiotics but is not fixed.

  The survey material is suitable for most recognised methods currently available, although variable results have been reported with screening methods based on dye decolourisation. For this reason, this method is not actively performance assessed.

  Participants may register for the screening test or the quantitative assay or both. The same fee is charged in all cases. Participants are monitored for participation and analytical performance of screening and quantitative assay.
PARASITOLOGY TEACHING DAY

The Parasitology Teaching day is offered in conjunction with UK NEQAS Parasitology. The day covers all aspects of blood parasite identification and each participant receives a teaching manual and set of teaching slides to keep. The participant fee covers up to two members of staff. Teaching sessions are offered at a variety of locations throughout the UK and Republic of Ireland during the year. Once registered, you will be offered a place at the geographical location closest to your organisation.

Although registration and invoicing for the Parasitology Teaching Day is administered for UK NEQAS Haematology participants through UK NEQAS Haematology, the design and operation of the day is operated entirely by UK NEQAS Parasitology.

PRE- AND POST-ANALYTICAL PERFORMANCE MONITORING SERVICE (PREPQ)

UK NEQAS has developed a pan-disciplinary service that allows participants to monitor the incidence of adverse events in the pre- and post-analytical phases. The service is operated online and results are reported using Sigma metrics. The scheme is currently available to participants in the UK and the Republic of Ireland. If you would like more information, please contact the Scheme office or the UK NEQAS Charity office or email prep@ukneqas.org.uk.

PILOT SCHEMES

New schemes are operated on a pilot basis during their development. Pilot schemes may or may not be charged for depending upon the degree of development and the availability of alternative sources of funding.

Pilot schemes are not formally performance assessed and performance is reported to the participant for information only. Any scheme operated on a pilot basis is indicated in the description.

EXPERIMENTAL TRIALS

Experimental trials are designed to identify specific sources of error or to test new materials and assay procedures. They are distributed on an ad hoc basis as additional, free of charge, surveys to selected participants. Participation in these studies is voluntary. Individual laboratory performance is NOT assessed and no result is attributed to any individual participant without their knowledge or consent.

Some trials may involve the use of questionnaires, which are distributed electronically. Again, participation is usually voluntary.

UK NEQAS Haematology greatly appreciates the effort and support of participants in any development work.
INFORMATION FOR SUCCESSFUL PARTICIPATION

Regular participation is important

Regular participation is essential to gain maximum benefit from registration. You will be sent the annual distribution schedule(s) as part of the annual re-registration process. This schedule lists the date and content for each distribution in the following registration year (April – March). The participation schedules are also available to download from the Documents section of the UK NEQAS Haematology website if additional copies are needed. The website also has reminders of what surveys are currently open and the planned closing dates.

Know your expected delivery dates

Survey packages are sent by first-class post within the UK and courier delivery is advised for most non-UK destinations.

Within the UK, please contact the Scheme office if you do not receive your package within 3 days of the distribution date and also check your organisation’s internal post room or delivery service. If your survey specimens are frequently delayed please contact the Scheme to discuss the problem. Within the UK, Royal Mail Special Delivery can be used for a small additional charge.

Outside the UK, please contact the Scheme office if you do not receive your package within 4 days of the distribution date. Again, please check your organisation’s internal delivery service or post room. Packages may be despatched early if you regularly experience a delay in receipt. We are also able to track delivery of packages sent by courier and advise you if there has been a problem or delay.

Check your package as soon as it arrives

Your survey package will contain the following:

• Specimens for the surveys you are registered for
• Instruction sheet(s)
• Summary information for the safe handling of survey material (Control of Substances Hazardous to Health (COSHH) information)

Please check your survey package upon receipt and notify the Scheme office as soon as possible of any missing specimens or documents, or broken, leaking or unlabelled specimens. We will dispatch replacements immediately and will allow you additional time to return your results, if possible. If this is not possible, we can suspend any adverse score for non-participation.

Check the instructions every time

Separate instruction sheets are provided for each of the surveys for which you are registered. Although the instructions may appear similar from distribution to distribution, it is important that you check them every time as the information may change. The survey instruction sheets all follow the same pattern and consist of six sections. An example instruction sheet is shown in appendix 1.
Section one describes the contents of the distribution package; this information is common to all the instruction sheets in the distribution.

Section two refers to the relevant information for COSHH. Detailed COSHH information is contained in the standard COSHH information sheet included in each survey package.

Section three describes the intended use of the survey specimens.

Section four describes the survey and gives any specific information that may be required for the handling and analysis of the specimens, e.g. patient data, method codes.

Section five details how to return the results to UK NEQAS Haematology.

Section six gives information relating to the next distribution.

Handle the specimens as instructed

To give a true assessment of performance in a laboratory, EQA specimens should be treated in the same way as patients’ samples. We appreciate that this may not be possible because of the volume or type of survey material but we ask participants to avoid repeat testing, unless this would be done for patients’ material. Collusion between participants is strongly discouraged. Any collusion involving a UK participant, if confirmed, will be reported to the NQAAP for Haematology.

Some specimens must be stored, mixed or analysed in a prescribed way to ensure that results are comparable; this will be described in the instructions.

Survey material (e.g. Abnormal Haemoglobins) may be produced from a single blood donation and limited in volume. In this case it is not possible to send the volume that you would receive for a patient’s specimen. Please contact the Scheme if you use a manual method that requires a larger volume than contained in one standard specimen as it may be possible to dispatch an additional specimen with your survey package, subject to availability of survey material.

Repeat specimens are generally available throughout the survey period to replace specimens received in an unsatisfactory condition (i.e. broken, leaking, unlabelled, haemolysed or clotted) and to replace those accidentally damaged or misplaced in the laboratory. Please contact the Scheme office as soon as you realise you need repeat specimens. Specimens may be unavailable or unsuitable for analysis after the survey has closed.

You should retain the specimens or the remains of them and the specimen tubes until the report of the survey is received, in case of any query.

The materials distributed are provided as specimens for the sole purpose of enabling external quality assessment of laboratory performance during the current distribution. They are not suitable for any other purpose.

Although all our product pools are screened for microbial contamination and individual human donations are screened for HIV I/II antibodies, HCV antibodies and for HBsAg, you should handle and dispose of the specimens as clinical waste.
Return results promptly

Web entry is available for the majority of schemes and you are strongly encouraged to use this means to return results where it is available. If you are registered as a web user for one survey, you will automatically be registered for web operation in all other surveys where this is available.

Data entry screens and results sheets vary with the tests, but a standard layout has been used as far as possible. Results sheets are not supplied to registered web users, although a results document for internal use may be downloaded from the data entry website for most schemes.

Additional information may be requested for some tests, including details of the method used, an assessment of results submitted in terms of the normal reference range in use in the laboratory, or an interpretation of the results. Specific directions will be included in Section 4 of the instruction sheet for the survey.

Web results service

Once registered as a web user, you will be sent an email with your log in information, containing:

- your Participant Reference Number (Laboratory Code)
- a five digit number (Identity)
- a seven character password

You may register as many members of staff as you wish to access the data entry and reports service. Each member of staff will need their own log in information.

Instructions for using the web results service are available to download from the Documents section of our website (www.ukneqash.org). If you experience problems returning results using the web results service, you should contact the Scheme office for advice.

Results submitted after the web results service has been closed for a particular survey should be returned as non-web results (see below).

Non-web results

An additional fee is charged to participants who do not use web entry for schemes where it is available. This is a single, annual fee and it covers the additional costs to the Scheme of manual data entry, printing, packing and posting of paper reports. This fee is not applicable if you have to return results by fax or email on occasion for reasons beyond your control, e.g. the return of late results or due to the non-availability of the web service.

You should return non-web results by fax to the number shown on the results sheet, as posted results often arrive after the closing date. When sending results by fax it is good practice to send a fax header sheet giving your details, including your PRN, a contact fax number and the total number of sheets to be expected. If possible, we will attempt to contact you if we receive incomplete or illegible results. If you fax results, please do not post them as well.

If fax return is not available, you can return a scanned copy of the results sheet by email to haem@ukneqas.org.uk with the description ‘URGENT RESULTS’ in the subject line.
You should keep a copy of the results sheet(s) submitted and the fax confirmation, where applicable, until you receive and have checked your report.

**Use the units of measurement requested by the Scheme**

The units used by the Scheme are shown in the ‘Surveys Offered’ section of this Manual. Results in other units are not accepted and their use may result in your receiving an adverse performance assessment. The units of measurement will be those recommended by regulatory bodies or guidelines, either in the UK or internationally, or those used by the majority of participants. We regret that we cannot accept results in other units and convert them as we may introduce errors in your results in the process. If you would like advice on how to convert your results to the units specified, please contact the Scheme office.

**Check the survey closing date**

The closing dates for surveys are set to accommodate the stability of the survey material and the requirement of the majority of participants to receive a report as soon as possible after submission of results. They may not be convenient for all participants on all occasions, especially for some of the non-FBC surveys. If you have problems returning results by the closing date, please contact the Scheme office.

The closing date for each survey is published on the survey instruction sheet and a full list of closing dates for the year is available to download from our website. If you are unable to return on time for any reason, let us know as soon as possible as you may be able to submit your result late without penalty.

**If you are unable to return results by the closing date**

You are encouraged to return your results, even if the survey has closed. There are some restrictions on whether we will accept them after the report has been issued and you should contact the Scheme office to check this. In general, results will not be accepted if the specimens have been analysed after the report has been issued, although this may not apply if you can show that the raw data is captured directly from the analyser and the specimens remain stable.

The survey material may be unsuitable for analysis after the closing date because of stability problems and the Scheme will not accept results in these circumstances. You are advised to contact the Scheme office before analysing specimens after the closing date.

The data entry website is closed on or shortly after the published closing date. If returning results after the website has been closed, you should use a results sheet (available for download from the data entry website) or contact the Scheme office for a results sheet. Make sure your participant reference number is shown on any results returned.

When you return results late, the first report you receive may not show your results. A second ‘late’ report, showing your results, will be generated before the next survey is processed. Unless we have agreed to accept your results late without penalty, you will receive an adverse participation score for the late return (see Performance Monitoring).

The Scheme reserves the right to reject results submitted after the subsequent survey has been dispatched, regardless of the analysis date, unless this is necessary to correct an error made by the Scheme.
If you are unable to return results for a reason beyond your control, e.g. instrument breakdown or replacement, major service changes or significant staffing problems, you should submit a blank return stating the reasons for not testing the specimens. This will avoid your being given an adverse participation score for the survey. If the situation continues for more than one survey, contact the Scheme office for advice as we are able to suspend your participation temporarily, again avoiding penalties for non-participation.

**Review your reports**

We make every effort to return reports promptly and a schedule of closing and reporting deadlines is available from the Scheme website. Reports should be available for all the staff in the laboratory to review.

You are advised to review your reports as soon as they are available and advise the Scheme immediately if you have any queries or note an error, as these are more easily dealt with the sooner we are aware of them. Web users are notified by email when new reports are available.

Reports that require in-depth analysis or expert commentary take longer to prepare and are sometimes delayed. Occasionally, reports are delayed due to changes in report format or performance assessment. We will inform you if a report is likely to be delayed more than one week past the scheduled publication date and will issue an interim report if the delay is more than 2 weeks.

Opting for web operation, where available, removes additional delays resulting from postal delivery of reports. Web users are notified by email when reports are published.

An example report from the Full Blood Count scheme is shown in appendix 2.

**If you wish to amend a result**

The Scheme will amend results at any time to correct an error by Scheme staff or as a result of a problem with our data processing. If the error occurred more than 6 to 12 months previously, we may not amend and reprocess the results because of the amount of work involved but will provide a written correction that should be appended to the report in question.

You may amend your results online at any time up to the survey closing date. If you have saved but not submitted your results, you can amend them without assistance. If you have submitted your results, you can ask the Scheme to reset your web entry screen to allow you to make an alteration.

Participants may occasionally make an error as a result of the requirement to report EQA results in a different format from that used for patients’ samples. A typical example would be a transcription error in the manual data entry of full blood count results, a circumstance that would not occur with a patient’s sample where results are reported directly via the laboratory information management system. In these circumstances, the Scheme will modify results after the closing date, provided you can submit evidence that the specimens had been analysed correctly up to the point of reporting. A copy of the instrument printout showing that the samples were analysed before the survey closing date and in the correct order would be evidence to support a request for amendment.
Results are only amended after the closing date with the agreement of the Scheme Director or a senior manager. The Scheme reserves the right not to correct results if a participant asks for this action regularly.

The Scheme will not amend results that arise from specimen transposition or mislabelling or where the correct identification and manual transcription of results is an integral part of the procedure, e.g. for molecular testing.

**COMPLAINTS AND APPEALS**

The Director and staff welcome the opportunity to discuss any problem or query you may have concerning UK NEQAS Haematology services.

If you remain unhappy with the service you have received, you should contact the Scheme Director directly by letter, email or telephone. We will acknowledge your complaint within 5 working days and make every effort to resolve the problem within 4 weeks. We will usually respond to you via the same means of communication as used to contact us. All complaints are reviewed formally by the Scheme Director and an annual audit of complaints is reported to the Steering Committee.

In the event that the complaint is not resolved to your satisfaction, you may refer it to the Chair of the Steering Committee, the UK NEQAS President, the Chair of the NQAAP for Haematology or the Chair of the Joint Working Group on Quality Assessment, as appropriate to its nature.

You have the right of appeal against a performance assessment score. This should be addressed to the Scheme Director and the appeal will be dealt with in the same timeframe as a complaint. If the investigation requires repeat testing of the survey material sent to you, this will be undertaken independently and anonymously by a laboratory nominated by the Chair of the Steering Committee or the relevant Scientific Advisory Group. While an appeal is in progress, no further action on performance will be taken, although it will continue to be monitored. If you remain dissatisfied with the outcome of the appeal, the final decision and resolution rests with the Chair of the NQAAP in Haematology.
SURVEY DATA ANALYSIS

Target value

The participant’s individual results are performance assessed against a target value. A separate target value is determined for each analyte (measurand).

For categorical data, e.g. the species of parasite present or the result of a sickle solubility test, the target value is the consensus result returned by participants, unless there is a known ‘true’ value, e.g. the identification of a parasite species by PCR. 85% of participants’ categorical results must be in agreement with the consensus target (75% if the ‘true’ value is available) for the specimen to be used for performance assessment. If this percentage of participants is not in agreement then the target is reported for information only and the specimen withdrawn from performance assessment. This will be stated on the report.

For numerical data, e.g. as reported for the full blood count, the target is the consensus result returned by participants. The consensus value is calculated as either the trimmed mean or the median for all-methods, method or sub-method group, depending on the commutability of the survey material and/or the scheme design.

Statistical processing of numerical data

Statistical analysis is performed on all the results submitted for each analyte to give the all-methods statistics. Results may then be divided into groups and re-analysed to give appropriate method group and in some cases sub-method group statistics.

Using the consensus trimmed mean as target value

Depending on the data, transformation (e.g. loge) may be used to give an approximately symmetrical distribution and to remove the relationship between the mean and the standard deviation for performance assessment.

Symmetrical trimming of the data set is employed to remove outliers that might unduly affect the consensus mean value. 10% trimming (5% of results from each end of the data) is employed at present.

A robust estimate of the standard deviation (RSD) is calculated as recommended by Healy ¹ using the trimmed data and Downton’s method for estimation of the SD, which compensates for the data removed by trimming. The RSD is used to calculate the uncertainty of the target value.

The Geometric Coefficient of Variation (GCV) is the Coefficient of Variation (CV) calculated from data that has been subjected to log transformation.

To smooth out the effects of the variability of the dispersion of the data from survey to survey, an historical SD (HSD) is calculated based on data from the previous 6 surveys (for FB) but excluding the results for the current distribution. The HSD is used to calculate the Deviation Index (DI) for performance assessment of the participants’ results.

Where the HSD is used, the Historical Coefficient of Variation (HCV) is the CV calculated.

Using the consensus median as target value

Where the distribution of the data is problematical, the statistical techniques of Tukey\(^2\) are used to estimate the location and spread of the distribution of results to give the median, the estimated SD and the coefficient of variation (CV).

The reason for using the median rather than the mean is twofold:

- It is not dependent on the shape of the distribution
- It is much less affected by the outlying values and trimming is not necessary.

The spread of the central 50% of the population between the quartiles is the interquartile range (IQR). The IQR is used to give the estimated standard deviation (Estimated SD, a robust standard deviation), which is used to determine the coefficient of variation (CV).

\[
Estimated \ SD = \frac{IQR}{1.349}
\]

Deviation index (DI)

The Deviation Index (DI) is the distance of each result from the trimmed consensus mean or the median, expressed in standard deviation units. The DI is equivalent to the \( z \) score for the result and is used to assess the performance for an individual specimen.

UK NEQAS Haematology calculates the DI using the following formula:

\[
DI = \frac{x_i - x_{pt}}{SD_{pt}}
\]

Where  
\( x_i \) is the laboratory result  
\( x_{pt} \) is the consensus trimmed mean value or median value  
\( SD_{pt} \) is either the HSD or the estimated SD

Interpretation of Deviation Index for FBC parameters

From the equation above, the DI may be either a positive or negative number. The table below gives a guide to interpretation of the DI. This has been adapted from ISO 13528:2015.

<table>
<thead>
<tr>
<th>DI</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;-3.0</td>
<td>Serious problem requiring investigation</td>
</tr>
<tr>
<td>-3.0 – -2.0</td>
<td>Check calibration, check instrumentation</td>
</tr>
<tr>
<td>-2.0 – -1.0</td>
<td>Satisfactory – borderline</td>
</tr>
<tr>
<td>-1.0 – -0.5</td>
<td>Good</td>
</tr>
<tr>
<td>-0.5 – 0.5</td>
<td>Excellent</td>
</tr>
<tr>
<td>0.5 – 1.0</td>
<td>Good</td>
</tr>
<tr>
<td>1.0 – 2.0</td>
<td>Satisfactory – borderline</td>
</tr>
<tr>
<td>2.0 – 3.0</td>
<td>Check calibration, check instrumentation</td>
</tr>
<tr>
<td>&gt;3.0</td>
<td>Serious problem requiring investigation</td>
</tr>
</tbody>
</table>

\(^2\) Tukey J (1977). Exploratory Data Analysis, Addison-Wesley
Uncertainty of the assigned (target) value

Uncertainty of measurement provides a quantitative estimate of the quality of a test result, and therefore is a core element of a quality system for laboratories. The same principle applies to EQA where the uncertainty of the assigned or target value is a measure of the quality of the EQA material. ISO 13528:2015 states, “If the standard uncertainty of the assigned value is large in comparison with the performance evaluation criterion, then there is a risk that some participants will receive action and warning signals because of inaccuracy in the determination of the assigned value, not because of any cause of the participant.”

The standard uncertainty of the assigned value in EQA depends upon the method used to derive the assigned value, the number of laboratories (consensus values) and other factors including inhomogeneity, transport and instability. Where the assigned value and standard deviation are determined from a consensus of participants’ results, the uncertainty of the assigned value is assumed to include the effects of inhomogeneity, transport and instability.

The standard uncertainty of the assigned value is calculated using the formula:

\[
u(x_{pt}) = 1.25 \times \frac{S^*}{\sqrt{p}}\]

Where
- \( u(x_{pt}) \) = standard uncertainty of the assigned value \( x_{pt} \)
- \( S^* \) = robust standard deviation (RSD) of the data
- \( p \) = number of results

According to ISO 13528:2015, the uncertainty of the assigned value may be considered to be negligible and need not be included in the interpretation of EQA performance if it is less than 0.3 times the standard deviation of the results (\( SD_{pt} \)). The \( SD_{pt} \) is the standard deviation used to calculate the deviation index (for UK NEQAS Haematology surveys using the consensus trimmed mean value this is the historical SD) or the robust SD.

The uncertainty of each assigned or target value is stated on the survey report.
PERFORMANCE SCORING

External quality assessment provides a long term, retrospective assessment of laboratory performance. Individual laboratory performance in all surveys is assessed against the target result for the survey and a scoring system is used to achieve this objectively.

The Scheme employs expert statistical advice for the development and review of performance scoring. The advice and opinion of the Steering Committee or relevant Scientific Advisory Group and the NQAAP is sought before implementation of new or amended performance assessment criteria. Any scoring system in development is operated on a shadow basis, for information only.

The performance scoring system consists of two parts: a non-participation score and an analytical performance score. The non-participation score is applied to the overall survey; the analytical performance score to the individual analyte or measurand.

Some analytes may not be given an analytical performance score; however, performance is still assessed and the laboratory receives an outlier letter if their result is out of consensus. The number of outlier letters sent to a laboratory for any survey type is monitored.

Group performance of instruments and methods

EQA specimens, especially those used for automated cell counting, are usually stabilised in some way to ensure their viability during the survey period. This stabilised material may not be commutable and there may be performance differences between different methods and instruments, which may not be apparent with clinical blood specimens. Performance may therefore be monitored using method or sub-method group statistics, to overcome any lack of commutability of survey material. Where applicable, instrument grouping is summarised in the description of each survey type. Instrument grouping is dynamic, depending on the methods and numbers of instruments registered at any one time and up-to-date details of current instrument grouping are available from the Scheme office.

UK NEQAS Haematology usually requires a minimum of 20 instruments registered to form an instrument group for statistical analysis. Where there are insufficient users of a methodology registered to form a group, their performance is analysed against the all-methods statistics. Instrument grouping is decided on an evidence-based process, using advice from the instrument manufacturers, expert users from the Steering Committee and Scientific Advisory Groups and evaluation of UK NEQAS Haematology data. A request to amend instrument grouping may be made to the Scheme Director by UK NEQAS Haematology staff, the instrument manufacturer, a Scheme advisor, a participant or other stakeholder. Changes to instrument grouping are reviewed by the appropriate Scientific Advisory Group and reported to the Haematology NQAAP.
Non-participation score

Participation in any survey will be given a nil score and a late or non-return result a score of 50. The total for the most recent three surveys gives the non-participation score. Thus, two late or non-return results out of three surveys will generate a score of 100, which is considered Persistent Unsatisfactory Performance (PUP). A single non-return result will generate a score of 50 and is considered unsatisfactory performance (UP).

Analytical performance score

For numerical data, the analytical performance score is a running score derived from the results for the most recent six specimens for which results have been returned for the analyte. It is calculated from the deviation indices of the six specimens. The calculation of the analytical performance score for numerical data is shown in more detail below.

For categorical data, the analytical performance score is derived from the sum of the adverse scores allocated for different errors. These adverse scores are held as a look-up table of scores for correct and incorrect returns and may be weighted according to their clinical significance. The score for an individual distribution is the sum of the scores incurred in that distribution; this may be truncated and carried forward for summation across 3 surveys to give the running analytical performance score. Truncation is used to avoid a participant being unduly penalised by a single issue that applies equally to all specimens tested at the same time, e.g. an unsatisfactory batch of reagent, an inadequate procedure or a training issue. Where there is no link between the specimens in a survey other than that they have been included in the same distribution package, e.g. blood films, the score allocated per specimen is summed as described but there may be no truncation; thus two errors in the same distribution will result in a persistent unsatisfactory performance score of 100.

Calculation of the analytical performance score for numerical data

All scoring systems for numerical data are based on the longitudinal assessment of how far an individual participant’s results are from the target value for a parameter.

Within UK NEQAS Haematology, the deviation index (DI) is used to determine the distance from the target value for quantitative data and is the basis of the calculation of the analytical performance score as follows:

1. The Deviation Index (DI) for the all-methods, method or sub-method group is calculated as appropriate.
2. The absolute value of the DI is taken (ignoring the sign) and any value greater than 3.5 is truncated to 3.5. This is to avoid a very high DI value, e.g. due to a transcription or transposition error, having an excessive effect on the score.
3. The absolute DI values for the most recent 6 specimens containing the analyte and for which results have been returned are added together and the result multiplied by a multiplication factor to give the performance score. The use of the multiplier is to weight the scores in any survey so that a score of equal to or greater than 100 is the action point for review of performance.
4. Where possible, the performance score is calculated over a rolling-time window of 3 surveys or 6 specimens, whichever is the shorter period.
Example 1  Deviation indices were obtained as follows for a FBC parameter:

<table>
<thead>
<tr>
<th>Survey</th>
<th>Specimen FB1</th>
<th>Specimen FB2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>-0.64</td>
<td>+1.85</td>
</tr>
<tr>
<td>2</td>
<td>0.00</td>
<td>+1.13</td>
</tr>
<tr>
<td>3</td>
<td>-1.89</td>
<td>+0.64</td>
</tr>
</tbody>
</table>

The score is calculated by ignoring the sign, rounding any value > 3.5 down to 3.5 and multiplying the total by 6.

Score = (0.64 + 1.85 + 0.00 + 1.13 + 1.89 + 0.64) x 6 = 37

i.e. Satisfactory performance

Example 2  Deviation indices were obtained as follows for another FBC parameter:

<table>
<thead>
<tr>
<th>Survey</th>
<th>Specimen FB1</th>
<th>Specimen FB2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>-7.05</td>
<td>+2.80</td>
</tr>
<tr>
<td>2</td>
<td>+2.89</td>
<td>+4.11</td>
</tr>
<tr>
<td>3</td>
<td>-2.64</td>
<td>+2.05</td>
</tr>
</tbody>
</table>

The score is calculated by ignoring the sign, rounding any value > 3.5 down to 3.5 and multiplying the total by 6.

Score = (3.50 + 2.80 + 2.89 + 3.50 + 2.64 + 2.05) x 6 = 104

i.e. Unsatisfactory Performance

For the FBC survey, this means that an average absolute DI, after any rounding down, of ≥2.8 will produce a score of ≥100, i.e. (2.8+2.8+2.8+2.8+2.8+2.8) x 6 = 100.8.

The analytical performance score for numerical parameters in all surveys is calculated according to the same principles. The multiplier constants may be modified according to the survey and the number of specimens included in the calculation altered.

The multiplier factor may be altered following consultation with the Scheme’s statistical and scientific advisors and validation of the impact of the change on performance scores. Any change to the multiplier will result in a ‘step change’ in the participant’s performance score and an explanatory notification will therefore be issued.

The current multiplier values used in different survey types at the time of publication are:

- FBC / Hb only / ADLC / Retics/ESR: 6
- Hb A₂ / Hb S: 9
- G6PD quantification: 10
- Plasma viscosity: 6
PERFORMANCE MONITORING: KEY PRINCIPLES

All participants (UK and international)

Participants are encouraged to review their performance report promptly and the scores or commentary it contains.

A participation score is shown in the survey report. A participation score of 100 is regarded as persistent unsatisfactory performance, as it demonstrates late or non-return of results for 2 out of 3 consecutive surveys.

Where an analytical performance score is calculated, it is shown in the participant’s report. Where there is no analytical performance score, the target or expected result and the participant’s result is shown for comparison.

The UK NEQAS Haematology performance algorithms have been developed with a cut off of 100 as the point at which action should be taken on analytical performance for quantitative tests. A score of between 80 and 100 should be regarded as borderline.

For qualitative tests (categorical data) an adverse performance score of 50 indicates an out-of-consensus result and warrants investigation since it might have resulted in an incorrect decision had the specimen been a clinical one. A score of 100 indicates an out-of-consensus result on 2 occasions or for 2 specimens in the current distribution, depending on the scheme design and should be considered persistent unsatisfactory performance.

UK participants

The performance of UK participants offering a direct or indirect clinical service is managed actively by the Scheme Director and staff. The application of the actions listed will take into account any confounding factors.

Unsatisfactory Performance (UP)

This describes a participant with a single instance in a rolling time window where their performance has breached the agreed performance criteria. For UK NEQAS Haematology the rolling time window is usually 6 specimens containing that parameter for quantitative assays, or 6 specimens or 3 consecutive surveys for qualitative parameters and 3 consecutive surveys for non-participation. Examples of unsatisfactory performance would be:

- The first occasion on which the analytical performance score for a quantitative assay passes the 100 point action limit
- Reporting a clinically incorrect qualitative result, e.g. an incorrect sickle screening test or haemoglobin variant
- Failing to return results or returning results after the closing date in any survey where there is a national or professional agreement that a 100% return rate is necessary

Action taken (UK participants): the participant receives a standard notification from the Scheme Director alerting them to the error. The laboratory is asked to contact the Scheme with any further information and help is offered at this point if required. There
is no penalty for non-response, although if the problem persists in subsequent surveys a lack of response is taken into account in deciding the next actions.

**Persistent Unsatisfactory Performance (PUP)**

This term is used when a participant has a second UP occurrence for the same parameter in a rolling time window. Examples of this would be:

- An analytical performance score for a quantitative assay above the 100 action limit on 2 occasions within the period covered by the most recent 6 specimens containing that parameter
- Reporting an incorrect qualitative result for the same parameter in 2 out of 3 consecutive surveys or for 2 specimens, depending on the scheme design
- Failing to return results and/or returning results after the closing date in 2 out of 3 consecutive surveys
- Any other instance that gives the Scheme Director cause for concern, e.g. an UP for analytical performance followed by a non-return of results, a laboratory with clinically significant UP incidents in 2 different parameters within 3 surveys, an UP for analytical performance that would have put a patient’s health and wellbeing at risk, had the same error occurred with a patient’s specimen

**Action taken (UK participants):** the participant receives a letter from the Scheme Director reminding them that they need to take action and warning them that they risk being reported to the NQAAP. If no response is received to this letter, the Scheme Director will contact the participant directly to ensure that the letter has been received and understood.

**Unresolved PUP**

This term is used for a laboratory that incurs a third occurrence of unsatisfactory performance within the rolling time window following a second performance letter. Examples of this would be:

- The performance score for a parameter remaining above 100 and failing to fall, with unsatisfactory DI values, for all surveys or relevant specimens within the rolling time window
- A second letter for 2 different parameters within 3 surveys in the same scheme
- A non-return PUP letter following a second letter for analytical performance
- A third instance of failure to return results within the rolling time window following the second letter

**Action taken (UK participants):** In this instance, the Scheme Director contacts the laboratory to inform them that their performance has failed to improve. If not already received, the laboratory is asked to supply details of any reasons for the performance problem and corrective actions that have been taken. The Scheme Director reviews the performance records, actions taken and communications with the participant directly. The identity of the laboratory may be disclosed to the NQAAP at this point, in line with Joint Working Group on Quality Assessment (JWG) terms of participation.
Criteria for reporting to NQAAP

The National Quality Assessment Advisory Panel asks the Scheme to provide the following information for UK participants providing a direct or indirect clinical service:

- A quarterly anonymous summary of the number of UP, PUP and unresolved PUPs
- The disclosure of the identity of any participating laboratory that breaches the JWG and NQAAP Terms and Conditions of participation
- The disclosure of the identity of any laboratory that is classified as an unresolved PUP and has not taken any effective corrective action to reduce their performance score
- The disclosure of the identity of any laboratory that, in the opinion of the Scheme Director, demonstrates clinically hazardous performance, including attempting to conceal performance problems
- The disclosure of the identity of a laboratory that deregisters from the Scheme with any outstanding performance issues
- The disclosure of the identity of a laboratory that is suspended from UK NEQAS Haematology for non-payment of subscriptions

Action taken (UK participants): The course of action taken by the NQAAP is determined by the NQAAP Haematology Chairman after consultation with other NQAAP members and, if necessary, colleagues on the Joint Working Group on Quality Assessment.

AH, NH and DN participants offering newborn or antenatal screening in English NHS Trusts

The identity of participants in this category who are reported to the NQAAP for AH, NH or DN performance problems will be disclosed to the Manager of the NHS Sickle and Thalassaemia Screening Programme at the same time as the NQAAP is informed.

The Scheme makes a twice-yearly, anonymised summary report to the NHS Sickle and Thalassaemia Screening Programme on the performance of all participants in the AH, NH and DN schemes. The identity of an antenatal and newborn screening participant in England who receives an analytical or participation letter in the haemoglobinopathy schemes (AH, NH or DN), or for MCH in the FB scheme, is disclosed to the NHS Sickle and Thalassaemia Screening Programme at the same time as this report is made.

Confounding factors in performance assessment

Scoring is a long-established means of identifying laboratories with performance that requires additional scrutiny and is a comparator by which the performance of a large number of participants can be examined in a timely, objective and cost effective manner. However, performance must be monitored in the light of confounding factors that may influence the EQA results obtained.

The following factors are taken into account when interpreting the performance score of an individual laboratory:

1. The determination of the target value may be difficult where there is no higher order reference material or method. Within Haematology, target values are generally determined from the consensus trimmed mean (either all-methods or method
specific) of participants’ results. The consensus all-methods mean may be skewed by the instrument or method that has the greatest number in the data set.

2. Survey material, although prepared to be as similar to patients’ samples as possible, may perform differently from clinical material with different technologies (‘matrix effect’). Where this is recognised as significant, methods are grouped based on technology, so that there is a like-for-like comparison.

3. Where there are insufficient participants to form an instrument group, performance is assessed against the all-methods target value, which means that commutability is taken into account. This will have greater impact on some parameters than others and the consistency of performance may be more significant than closeness to the target value.

4. The frequency of the challenge for any single parameter in a series of EQA distributions will affect how rapidly the score responds to corrective action. Within UK NEQAS Haematology, the performance score for any parameter is usually calculated from the most recent 6 specimens that contained that parameter for assay. This will mean that a laboratory’s score will remain above 100 for several consecutive distributions even though adequate corrective action has been taken. In this case, the DI for the each specimen should be reviewed.

5. The difficulty of the challenge: testing at the level of clinical decision making or for rare conditions will produce worse performance scores than testing, for example, in the middle of the normal reference range. UK NEQAS is increasingly targeting this clinical decision range.

6. Where performance overall is very good, a performance score beyond the action limit may be technically undesirable but may not reflect a clinically significant problem.

7. Where performance overall is very poor, a performance score within the action limit may not be a guarantee that the result produced would not be a matter of clinical concern.

8. A single, clinically significant error may not push the performance score beyond the action limit. For this reason EQA schemes may use other means, such as assessment of results against a reference range, to identify performance problems.

Since it is impossible to write guidelines to cover every eventuality, the Scheme Director retains the discretionary authority to contact any laboratory whose performance gives cause for concern in his or her professional judgement.

**Withholding performance letters**

On occasion, a performance letter to a participant may be withheld. The following list gives examples of the circumstances in which letters may be withheld (this list is not exhaustive):

1. Where the participant does not provide a direct or indirect clinical diagnostic service, e.g. manufacturers, pharmaceutical companies, university departments.

2. Where the participant is located outside the UK.

3. Where the participant has informed the scheme that their instrument or method is not in operation.
4. Where an instrument is in operation but is not in clinical service, e.g. the service / instrument is being set up, under evaluation or under repair.

5. Where there is a recognised performance problem for a parameter or instrument related to the commutability of the survey material or the size of the instrument group.

6. Where there have been insufficient challenges for the parameter for the score to have resolved. In this case, the following must be true:
   - The score must be falling
   - The DI value(s) for specimens tested since the most recent UP or PUP letter must be satisfactory
   - The participant must have responded to earlier letter(s), indicating that they are aware of the situation and have taken action

7. Where there is an on-going, identified performance problem, which has been reported to the NQAAP for action. In this case, performance monitoring continues but is reported directly to the participant and the NQAAP.

8. Where the participant has disputed a performance score issued by the Scheme and this is under investigation or has been referred to the Steering Committee or NQAAP for resolution. Performance monitoring continues and is reported directly to the participant and to the NQAAP if appropriate until the matter is resolved.

Withdrawal of results or specimens from scoring

The results from individual participants, groups of participants, individual survey material pools or whole distributions may be withdrawn from scoring if they fail to meet established acceptability criteria. The decision to withdraw a parameter from scoring is taken by the Scheme Director or on his/her behalf by senior Scheme staff. Participants will be notified as soon as the decision is made.

Equivalence with other terms

Different EQA schemes utilise different terminology. The equivalence of the terms, as far as possible, is outlined below:

Poor performance is generally used in the same way as unsatisfactory performance.

‘Outwith’ or ‘out-of-consensus’ indicates a result that is beyond the limits of the acceptable performance criteria. In general, this will be the same as poor or unsatisfactory performance; however, it is possible for the ‘out-of-consensus’ result to be correct, even though it is not in agreement with the results of the majority of other participants.

Hazardous performance is a single error that is of sufficient clinical impact that it could put a patient’s health and wellbeing at risk if the error had been made with a patient’s sample. This equates to a single UP occurrence with potentially serious consequences.
SURVEY REPORTS

Individual reports showing the participant’s results as well as the statistical analysis of the survey are produced for all survey types; there may be an exception to this for schemes in development where only a summary report is provided. The report includes the participant’s participation and analytical performance scores, if applicable. In addition to survey reports the Scheme may issue supplementary and experimental trial reports. These are not performance assessed and give summary statistics and relevant comments only.

Web reports: A Portable Document Format (PDF) copy of the report for each survey is posted to the same web server used for data entry. Reports on the web server are protected by the same level of security as is used for result entry. Registered web users are informed by email of the availability of new reports.

Non-web reports: Two copies of the report for each survey are distributed. One is sent to the named laboratory contact and the second to the named consultant contact. Participants should ensure that their reports are retained and are available to staff. Duplicate copies of reports can be provided if necessary; the Scheme reserves the right to charge for this service.

Example: Full Blood Count survey reports

This report is described in some detail below as it contains elements that are used in other individual reports.

The Full Blood Count survey report (see Appendix 2 for an example) is on three pages. At the top of each page is the survey type, the distribution number and date, PRN and page number. The pages contain the following information:

- **Page one** shows the overall performance. The analytical performance score for each analyte over the previous ten surveys is printed in graphical form. The non-participation score is printed in the top right and the survey contents in the top left.

- **Pages two and three** show the data analysis for specimens one and two respectively. A description of the specimen is given at the top left of the page and a summary of specimen quality at the top right. Each page shows up to eight boxes with the analysis for each registered parameter. Each box contains a graphical representation of the distribution of the data, both the all-method data and the instrument group (shown shaded). A small arrow indicates your position in the distribution and the following information is shown:
  - Your Instrument: The registered instrument type
  - Your result: The result submitted
  - Target value: The Group Trimmed Mean
  - Uncertainty of target value
  - CV: Coefficient of Variation (note that this is the HCV, see p.42)
  - DI: Deviation Index
  - N: Total number of data points in the group
  - N (trimmed): Trimmed number of data points used to calculate the mean
  - Perf. Score: Analytical Performance Score for that parameter
The Scheme can supply PDF examples of other types of survey reports upon request.

**Use of reports**

Reports are copyright and may not be copied, distributed, published or used for publicity and promotion in any form without the written consent of the Scheme Director on each and every occasion, though the participant may share performance data with individual clients (e.g. GPs, clinicians, pharmaceutical companies) without consultation.

**Amended reports**

The Scheme may reissue reports following amendment of data or correction of an error noted after the original report was distributed. The original and amended report are differentiated by the issue date and time on the report and the amended report will be marked ‘Amended’ in the footer. The reason for the amendment of the report is given either on the report or in an accompanying email or letter.
INTERNATIONAL PARTICIPANTS

Most UK NEQAS Haematology schemes or programmes are open to international (non-UK) laboratories. This section of the Manual contains information that is applicable to international laboratories only; otherwise the service supplied to international participants is as described for UK laboratories.

Cost of participation

The costs for international laboratories are based on the UK prices, which are reviewed every year. Additional fees to cover extra postage or courier delivery costs will be charged, as will any additional bank charges that are incurred. Fees are payable by all participants.

A prospective participant will be advised of the current fees at initial registration and again at annual re-registration. Fees are charged pro rata for participation starting part way through the year.

Fees are quoted exclusive of VAT. For participants located within the European Union (EU) and registered for VAT, this will be dealt with under the reverse charge mechanism provided a valid VAT number is supplied at registration. Otherwise, VAT will be applied to at the rate in use in the UK.

Fees are charged in GBP sterling (£). It may be possible to pay in Euros (€) or US dollars ($): the Scheme office should be contacted for further advice.

Registration

International laboratories participate in UK NEQAS Haematology either directly as an individual laboratory or via a recognised distribution agent, if one is available in the country or region. There is no difference in the services provided by UK NEQAS Haematology but the additional services provided by the distribution agent (e.g. registration, translation or delivery) may vary and may be subject to additional charges. Because of difficulties with delivery, customs or payment, UK NEQAS Haematology reserves the right to refuse registrations in some regions unless made through an agent.

Scheme language

All scheme paperwork and reports are written in English. Some distribution agents offer translation services for key documents.

Specimen delivery

International participants receive the same specimens as those distributed in the UK. ‘Tracked and signed for’ delivery may be adequate for destinations in the Republic of Ireland and most of Europe, depending on the survey. In general, delivery by courier is essential for international participants to ensure a timely delivery and to preserve the integrity of the specimens.

Closing dates and return of results

The closing date for international participants is the same as that for UK laboratories and most international participants return their results in time. Late returns will always be
processed, provided the specimen remains viable on the date of analysis and the target results have not been reported to participants. Participation penalties are usually waived for international participants returning results within 48 hours of the closing date.

Reports and performance monitoring

International participants receive the same reports as UK laboratories. However, the Persistent Unsatisfactory Performance criteria for reporting to the NQAAP do not apply, and performance scores (both analytical and participation) are reported for information only.

Confidentiality

Conditions of confidentiality are maintained but, by written agreement with the participant laboratory, arrangements can be made to provide data direct to a national or other relevant body for performance monitoring purposes. Web-entry access details may be made available to a distribution agent responsible for the registration of a participant, with the participant’s permission. This is solely for the purpose of assisting the participant with access to the data entry and report web pages. The distribution agent is required to keep the participant’s details and performance information confidential.

DISTRIBUTION AGENTS

UK NEQAS Haematology uses the services of a number of recognised distribution agents for the distribution of services outside the UK. There are many advantages to this for the participant; in particular, the agent acts as a point of contact in the region, they may offer translation services or assistance with interpretation of documents and may act as a central delivery point, reducing the impact of courier costs.

A participant who registers through a distribution agent is the customer of that agent and is responsible for payment of their subscription fees directly to the agent, in their local currency. The agent has the right to refuse registration to a participant who does not pay their fees and will advise UK NEQAS Haematology to cease dispatch of EQA services.

The fees charged by a distribution agent for UK NEQAS Haematology services may be inclusive of delivery and any additional services provided by the agent and therefore cannot be compared directly to the UK price list.

A UK NEQAS Haematology distribution agent is expected to abide by the UK NEQAS Haematology terms and conditions for agents, which are available from the Scheme office.

In general, UK NEQAS Haematology prefers to work with just one agent in an individual country or region and attempts to use the same agents as other UK NEQAS centres.
UK NEQAS Haematology is the World Health Organisation (WHO) Collaborating Centre for Quality Assurance in Haematology.

The Centre organises a separate International EQA Scheme in Haematology, on behalf of the WHO. This scheme is designed for laboratories in the developing world using basic laboratory techniques and consists of three to four distributions a year for a limited range of tests.

In some situations this scheme is a suitable alternative means of EQA participation for laboratories outside Europe where delivery may be delayed. Participants may either be recommended by the WHO or may pay their own fees. Full details are available from the UK NEQAS Haematology office.
APPENDIX 1: EXAMPLE INSTRUCTION SHEET

UK NEQAS Haematology

SURVEY1604FB: BLOOD COUNT: 4 APRIL 2016

CLOSING DATE: 5pm; 12 APRIL 2016 PRN 00000

1.0 Distribution Package
Distribution 160 includes the following surveys:
1. Full Blood Count
2. ADLC
3. Cytochemistry
4. Abnormal Haemoglobin

A full package comprises a plastic postal bag, containing documentation and a moulded plastic specimen carrier comprising a transparent side holding vials of survey material and/or a slide carrier and an absorbent side that will absorb up to 50ml of liquid, i.e. the entire contents of the package, in the event of a breakage.

Specimens are only included for the tests for which you are registered.

Repeat specimens may be requested if your specimens are received damaged.

Please contact the Scheme by telephone or email using the contact details in the header.

2.0 Information required for Control of Substances Hazardous to Health (COSHH)
This information is printed on a separate information sheet and should be reviewed by your COSHH assessor for consideration of any changes necessary to your local work practices.

3.0 Use of packaged material
This material is for use in External Quality Assessment Surveys to assess laboratory performance.

4.0 Blood Count Survey 1604FB
This survey contains partially fixed human whole blood specimens 1604FB1 and 1604FB2.

Specimen handling and disposal
- On receipt, specimens should be stored at 2 - 8°C until tested
- Allow the material to equilibrate to room temperature for 10 minutes on a roller or similar mixer before testing.
- Sysmex SE, XE, XN and XT instruments: FB specimens should be analysed in the CBC mode NOT the QC mode
- Siemens ADVIA 120 and 2120 instruments: report the Baso channel WBC and if there is a CE error flag against the haemoglobin result, report the Cellular Hb.
- The material should be handled and discarded as patient material.

The specimens for Blood Count are stabilised blood and as such do not react in the same way as fresh EDTA bloods. You may experience ‘caution flags’ and ‘abnormal’ scatter plots. Although this material contains human leucocytes it is not designed to give a differential leucocyte count.

5.0 Return of results
If you find the specimen quality unsatisfactory, tick the ‘unsatisfactory’ box and note details in the Comment box.

Return your results on line at www.ukneqash.org/sampleentry or by fax to +44 (0)1923 217879 using a header sheet giving your PRN and the number of sheets sent.

6.0 Next Distribution:- The next Full Blood Count survey (1605FB) is scheduled for 3 May 2016.

Example results sheet – uncontrolled copy
APPENDIX 2: EXAMPLE REPORT

UK NEQAS Haematology and Transfusion

Full Blood Count
Distribution: 1664FB  Date: 04 Apr 2016

UK NEQAS Haematology
Overall Performance
20028A A1287

Survey Contents:
Specimen 1: 1664FB1  Partially fixed human whole blood
Specimen 2: 1664FB2  Partially fixed human whole blood

Non Participation Penalty: 0

White Blood Count
Your analytical performance score is 44.9

Red Blood Count
Your analytical performance score is 32.5

Haemoglobin
Your analytical performance score is 52.5

Packed cell volume
Your analytical performance score is 30.2

Mean Cell Volume
Your analytical performance score is 26.8

Mean Cell Haemoglobin
Your analytical performance score is 33.2

Mean Cell Haemo Conc
Your analytical performance score is 48.2

Platelet Count
Your analytical performance score is 24.7

Immunoplatelet count for 1504FB1 = 46.8 (10^9/L)

Printed at 9:10 on Thursday, 14 April, 2016 (Final Report)

For information on data analysis and performance assessment see the UK NEQAS Haematology Participants’ Manual (www.ukneqas.org.uk)

Scheme Director: Barbara De la Salie  Authorised by: Paul McTaggart

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Version 7.2
Issued November 2016
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