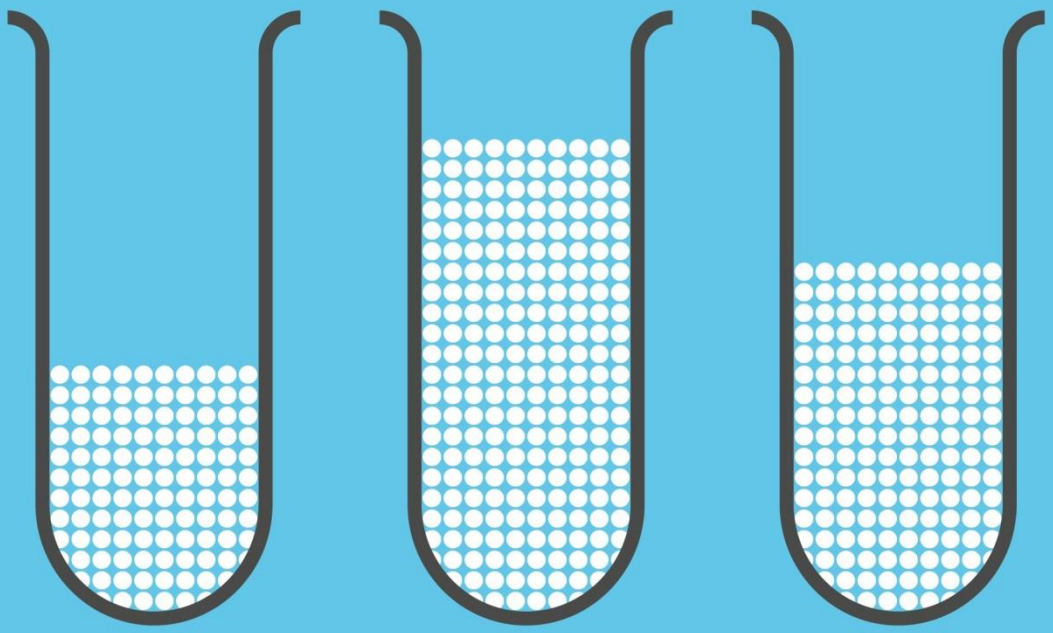
UK NEQAS

International Quality Expertise



UK NEQAS Haematology Participants' Manual

Version 13 (March 2022)

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Version 13, issued March 2022

Document history			
Version	**Published**	**No. Pages**	**Amendment**
13	March 28 2022 Online	72 of text	Corrected Morphology Lead name
12	December 2021 Online	72 of text	Replaces all previous versions
11	February 2021 Online	70 of text	Replaces all previous versions

UK NEQAS controlled document H54

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QUICK REFERENCE

Contact us:

UK NEQAS Haematology
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UK

Telephone: + 44 (0)1923 587111 (Mon – Fri 09:00 – 17:00; voicemail at other times)
Email: haem@ukneqas.org.uk (scientific queries)
ghadmin@ukneqas.org.uk (administrative queries)
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?

Your Participant Reference Number or PRN is a 5 digit reference number or identifier that is unique to your testing site 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 QAPC (formerly JWG) Conditions of Participation?

A link to the Quality Assurance in Pathology Committee (formerly 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 if your specimen package has not arrived 4 days after the distribution date and request a replacement specimen pack.

How can I troubleshoot my EQA results?

Participants are able to trouble-shoot a number of basic EQA problems themselves and UK NEQAS Haematology has developed a troubleshooting guide to assist with this, available from

our website (www.ukneqash.org). Participants can contact the Scheme office if they need additional assistance, preferably by email (haem@ukneqas.org.uk) unless the matter is urgent, as this allows us to track the communications. If you are unable to resolve your concerns with the help from the general team, please contact the Service Manager, Yvonne John, (y.john@nhs.net), or the Scheme Director, Barbara De la Salle (barbara.delasalle@nhs.net).

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. Availability of repeats is dependent 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 repeat specimens.

Repeat specimen requests received up to 12:00 (UK time) will be despatched on the same day by the participants' usual delivery method (post or courier).

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) (UK NEQAS Haematology Instructions for using the web results service; or from the following link: https://www.ukneqash.org/download/193/UKNEQASHaematologyInstructionsforusingthewebresultsservicePDF)

Can I amend an error made when entering my results online?

If you realise you have made an error in your online submission before the survey closing date and you have 'submitted' your results, contact us directly. We are able to reset your web entry page until the closing date, allowing you to resubmit your results.

Under certain circumstances, we are able to amend your results after the closing date, including after the report has been issued, if you have made a data entry error. In general, this is only possible where you can demonstrate you have analysed the specimens before the closing date, the specimens were not transposed and the test is one where results would be passed directly from the analyser to the patient record via a LIMS interface. Any such correction is made at the discretion of the Scheme Director.

How do I change registered contact details? I have forgotten my web-entry log in details.

You can change your registered contact details online via the UK NEQAS Haematology website. Contact the Scheme Office if you need assistance. This includes being resetting forgotten passwords or changing your password to one that you find more convenient.

How do I change registered method or instrument details?

Alterations to your registered instrument or method details or contact details must be received or made online at least 3 weeks before the scheduled distribution date to be effective for that distribution. Registered contact details may be updated online, changes to method details must be notified to the Scheme Office by email.

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 log 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.

How do I find 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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CONTENTS

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 more than 6,500 UK and international registrations and a further 3,000 individual practitioners in our educational Digital Morphology programme

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

The programmes provided are intended as a comprehensive service for diagnostic testing performance assessment. The specimens and slides are included as part of that service and are not provided for sale separately as goods.

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 readily accessible to all users and 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. The website provides service updates, closing date reminders and links to other related organisations or sources of information.

You can also keep up to date with our Digital Morphology services via Facebook and UK NEQAS in general via Twitter.

THE UK NEQAS CHARITY

Improving global diagnostic testing for the benefit of patients through quality assessment and education.

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 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: Mr Liam Whitby
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. Further details of UK NEQAS services offered in all disciplines can be found from the Central Office website.

UK NEQAS Compendium of Quality

The UK NEQAS charity publishes a Compendium of Quality, illustrating the core activities and novel developments within UK NEQAS, including the provision of performance assessment 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. The latest edition of the Compendium is available to download from either the UK NEQAS Haematology website or the UK NEQAS charity website.

The Compendium 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

Two complementary processes, internal quality control (IQC) and external quality assessment (EQA), are used to monitor laboratory or clinical testing performance. The international standard ISO 15189 : 2012 – Medical laboratories – Requirements for quality and competence requires laboratories to participate in an appropriate form of inter-laboratory comparison for the services provided for the laboratory to achieve accreditation. Participation in an accredited EQA scheme (also referred to as proficiency testing) is a means to fulfil this requirement.

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 and retrospective, providing periodic assessments of the way in which the laboratory performs. Inter-laboratory comparisons can be run at various levels: international, national, regional or local. National and regional programmes complement each other, each providing a different aspect of external quality assessment. Regional or local programmes provide a rapid return of the analysis of results; however, such programmes have limitations. Statistical evaluation may be less robust due to the smaller numbers of participants and the educational opportunities may be limited. National programmes are likely to give target results closer to the true value, with data from a larger population.

Although a national programme 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 programme may allow 'state of the art' comparisons of instruments, reagents, control preparations and method procedures etc.

A national programme can be used to coordinate regional, local or organisational reviews of performance or smaller EQA programmes. 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 programme in addition to locally organised or regional programmes 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 programmes or may elect to receive summary reports only ('information only' participants).

There are restrictions on participation in some programmes depending on the availability of assay 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).

QUALITY ASSURANCE IN PATHOLOGY COMMITTEE (FORMERLY THE JOINT WORKING GROUP ON QUALITY ASSESSMENT) CONDITIONS OF PARTICIPATION

Oversight of performance in EQA within the UK is the professional responsibility of the Quality Assurance in Pathology Committee (QAPC) (formerly the Joint Working Group on Quality Assessment (JWGQA)), overseen by the Royal College of Pathologists (RCPath) Professional Standards Committee. The QAPC has established National Quality Assessment Advisory Panels (NQAAPs) for individual 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 QAPC (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 : 2010 – Conformity assessment – General requirements for proficiency testing, with the accredited centre number 7805.

The full and most up to date details of the programmes 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 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. Committee membership includes appropriate clinical and laboratory 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).

At the time of publication, the chair of the Steering Committee is Dr Wayne Thomas, Consultant Haematologist at Derriford Hospital. 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 use the street address

UK NEQAS Haematology and Transfusion
10 Millfield House
Croxley Park
Watford
WD18 8YX
UK

Telephone: Direct line 01923 587111

International + 44 1923 587111

Telephone lines are open between the hours 09:00 and 17:00 (UK time) 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.

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 the surveys for which they wish to register. 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 (ghadmin@ukneqas.org.uk).

Completion of the registration form indicates that the prospective participant agrees to abide by the terms and conditions of registration with the programme, and that any UK participant supplying a direct or indirect clinical service agrees to abide by the Quality Assurance in Pathology Committee's Conditions of Participation.

Links to the UK NEQAS Haematology and Transfusion Terms and Conditions and to the QAPC 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 valid email address for at least the main, laboratory contact, 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 assay material, as long as the registration form is received a minimum of three weeks before the published date of the next distribution. Prospective participants should note that for some programmes, e.g. Automated Differential Leucocyte Count, there is a lead-in time of up to three months for the supply of assay material and we may not be able to accommodate new registrations received after that lead in time. We will inform you as soon as practicable if there is likely to be any delay to registration in a programme.

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 UK 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 for courier delivery or special packaging will be added to the invoice. An additional charge is also made for the provision of paper reports for web-based programmes and any services 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 number. Only one submission is allowed for elements of a programme involving interpretation or diagnosis.

Participants may be registered as part of a 'super-user' group, e.g. an organisation registering multiple point-of-care testing sites. Sites registered as part of a super-user group may have arrangements for specimen delivery, performance reporting and performance assessment that are tailored to the needs of the commissioning organisation. The identity and performance of the individual sites will be known to the commissioning organisation.

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. The Scheme shares premises close to Watford General Hospital with 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 support of the West Hertfordshire Hospitals NHS Trust and 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):	Dr Barbara De la Salle
Service Manager:	Yvonne John
Morphology Lead Scientist(s):	Andrea Teuchert and Jon Sims
Haemoglobinopathy Lead Scientist:	Bashori Rahman
Senior Scientist:	Sheetal Karunanandarajah
Senior Scientist:	Joana Loureiro
Scientist:	Nikki Emodi
Scientist:	Rachel Godden
Associate practitioner:	Paula Dynes
Associate practitioner:	Jazmin Brookes
Associate practitioner:	Sally Burley
Laboratory Assistant:	James Hindell

Staff positions shared with UK NEQAS BTLP:

IT Manager:	Vasilis Rapanakis
Business and Finance Manager:	Nazia Hussain
Office Manager:	Mayuri Wadhia
Executive Assistant:	Isabella De-Rosa
Quality Manager:	Claire Whitham

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 Certus Technology Ltd.

The results for nearly all programmes can be returned using the Web Results Service and reports are available for secure download. Participants are expected to register for web operation where this is available.

Pilot programmes, programmes in development, programmes with complex and extensive data and programmes 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 on each and every occasion.

Data Protection Act 2018

The purpose of the Data Protection Act 2018 (the Act) is to prevent the misuse of personal data held electronically and to ensure that organisations holding such data conform to a required standard. West Hertfordshire Hospitals NHS Trust, the host organisation for UK NEQAS Haematology and Transfusion, is registered as a Data Controller under the Act. The contact details provided by participants at registration are held securely in a database 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 EQA survey results are held securely (as non-personal data) in the database for analysis, performance assessment and report production. Once a contact is notified to us as 'inactive', i.e. they no longer work at the site or no longer have a role involved in EQA, their details will not be used by the Scheme for any purpose and will be deleted one year after they are marked as inactive.

The Scheme will keep performance analysis data and related correspondence for a minimum of eight years (i.e. two full accreditation inspection cycles); however, responsibility for maintaining historical records of individual laboratory performance lies with the participating laboratory. RCPath guidance suggest that laboratories retain EQA records for a minimum of eight years, to ensure continuity of data available for laboratory accreditation purposes over

two inspection cycles and equivalence with performance records for the equipment used. All participants are entitled to view their personal computer records on request.

E-mail addresses supplied by participants are used for contacting participants to inform them of survey distribution and report availability. In addition, these details are used to provide information on meetings and other activities, and to invite participation in on-line surveys specifically relevant to the programme. Email addresses may also be used for contacting participants on national pathology or blood transfusion related matters if consent is given at registration or re-registration.

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 a UK laboratory providing direct or indirect clinical services will be disclosed to the chair of the National Quality Assurance Advisory Panel (NQAAP) in Haematology and, at the discretion of the NQAAP, to the Quality Assurance in Pathology Committee (formerly the JWGQA) and the UK Accreditation Service, in the event of the laboratory being reported to the NQAAP for unresolved persistent unsatisfactory performance. Participants accredited by UKAS may be asked to disclose their UKAS centre number.

The identity of participants in England registered in the Abnormal Haemoglobins, Newborn Sickle Screening and DNA Diagnostics in Haemoglobinopathies programmes 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, with the permission of the head of the participating laboratory.

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.

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

Key Performance Indicators

The Scheme monitors Key Performance Indicators (KPIs) that are reviewed monthly and audited annually for the Annual Management Review, for reporting to the Steering Committee and to the NQAAP. Failure to achieve a KPI is investigated under the Quality Management System.

At the time of publication, the Scheme monitors the following KPIs that relate to the quality of service supplied to participants:

- The achievement of the schedule of distribution dates
- The proportion of specimen packages with errors
- The physical integrity of specimens, as reported by requests for repeat specimens
- The quality of specimens, as reported by participants with their submitted results

- The achievement of turnaround times for reports
- The achievement of notification of out-of-consensus performance
- The timeliness of the response to complaints

Participant Reference Number (PRN)

Each participant is given a unique, five-digit Participant Reference Number (PRN), which should be used in all communications with the Scheme. The PRN is unique within the UK NEQAS organisation. If desired, a participant who is already registered with 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 programme, each analyser or method will be allocated a separate PRN, with the same core, five-digit number but with the addition of a letter suffix. PRNs are not reused, 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. Where possible, the PRN is linked to the analyser's serial number and the analyser is given the same PRN across all programmes. 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 from a pool.

In order for the long-term performance of an individual analyser to be monitored, participants should not 'share' an identifier between different analysers, i.e. should not report results from one analyser in one survey and another analyser in another survey under the same identifier. This will result in any drift in performance not being detected.

Distribution and reporting schedules

The schedules of expected dates for survey distributions and release of reports are available to download from the Documents section of the UK NEQAS Haematology website (www.ukneqash.org) or from the Scheme office. The status of current, open distributions is shown on the front page of the website.

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 at registration to prospective participants or at re-registration to established participants. 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). Other participants will be liable for VAT according to legislation in force at the time of invoicing.

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 programme where web-based operation is available.

Brexit

The UK left the European Union on 31st January 2020. UK NEQAS Haematology is experienced in the provision of services throughout the world and will work with participants and distribution agents to ensure the smooth delivery of our programmes. Further information and updates are provided on the UK NEQAS Haematology website (www.ukneqash.org). Note that UK NEQAS Haematology supplies a comprehensive service and is not a supplier of goods.

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.

Changes to registered information

It is the participating laboratory's responsibility to ensure that the registered information held by the Scheme is complete and up-to-date.

The participant should deactivate individual registered contacts when or if the member of staff retires, resigns or moves to another role that does not require them to have access to UK NEQAS data. Registered contacts who have been deactivated will be removed from the UK NEQAS database after one year. Laboratory managers with staff with nhs.net domain addresses should take particular care to deactivate contacts when staff move to another NHS Trust, as their email address will otherwise remain active on our database and could receive information about their previous registration.

Registered contact details can be amended through the UK NEQAS Haematology website (www.ukneqash.org), where it is also possible to reset or change the password used to log into the results and reports service.

Otherwise, please contact the Scheme office for changes to registered instruments or methods.

A minimum of three weeks' notice must be 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. Changes to registered details notified by other routes, e.g. on the results return page may be overlooked due to the volume of data received and processed.

Participants should be aware that some assay material has a three-month lead-in time for preparation. If changes to a registered instrument require a change in assay material type, the transfer of services may be delayed if assay material is not available.

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 or email, if you wish to cancel your participation in any programme, giving a minimum of three weeks' notice before the next distribution date for the programme. 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 participation in any programme temporarily if the laboratory is not offering the test as a clinical service for any reason, providing that we are notified in writing.

UK laboratories are asked to supply a reason for deregistration from any part of the Scheme's programmes. Deregistration by UK laboratories is summarised to the National Quality Assessment Advisory Panel for Haematology. 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 Quality Assurance in Pathology Committee (formerly 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.

Specimen 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. Assay material is distributed by first class mail within the UK and courier delivery is advised to destinations outside the UK, to maintain the integrity of the assay material and to ensure the timeliness of delivery.

Courier 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 Ltd. Participants may opt to use another courier or their own courier account; in these circumstances, a small administration fee will be applied.

Certificates of registration and participation

A certificate of registration is available to download directly from the UK NEQAS Haematology website (www.ukneqash.org). A certificate of participation is available upon request from the Scheme Office.

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PROGRAMMES 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 programmes 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 programmes**
  - Full Blood Count
  - Blood Component Quality Monitoring
  - Automated Differential Leucocyte Count
  - Reticulocyte Count
  - Point of Care Hb
  - Plasma Viscosity
  - Erythrocyte Sedimentation Rate
  - Infectious Mononucleosis screening pilot*
  - Point of Care WBC* (see note 1)
- **Blood Morphology and related programmes**
  - Blood Films for Morphology Skills and Manual Differential Count
  - Blood Films for Parasite Screening and Identification
  - Blood Films for Cytochemistry (Iron Stain)
  - Rapid Diagnostic Testing for Malaria
  - Digital Morphology for Continuing Professional Development*
- **Haemoglobinopathy programmes**
  - 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 programmes**
  - Red Cell Enzymes: G6PD screening and quantitative assay
  - Red Cell Enzymes: Pyruvate Kinase quantitative assay pilot* (see note 1)

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 programmes.

Notes:

1 This pilot is in development. Participants who are interested in this service should email the scientific team (haem@ukneqas.org.uk) to register their interest.

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 specimens

Survey specimens are obtained from a variety of sources and are designed to be as close to patients' clinical material as practicable. Specimens may be prepared by UK NEQAS Haematology from donated blood components or clinical specimens, purchased commercially or prepared by a sub-contracted organisation. The source of the assay material used and the limitations of its use are outlined under the information provided for each programme.

Programme and specimen identifiers

Each programme 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 programmes are shown in the programme descriptions below.

Specimens are given a unique code, comprising the last two digits of the year, the chronological number of the survey within the year, the two-letter programme or assay material identifier and the specimen number. For example, the full blood count specimens distributed in April 2021, the fourth full blood count distribution of 2021, are coded as 2104FB1 and 2104FB2. The blood films for morphology sent in the second blood films distribution of 2021 are coded as 2102BF1 and 2102BF2.

Where different assay material types (matrices) are supplied within an individual programme, these are identified by the addition of a matrix-dependent suffix, e.g. DLA or DLB in the Automated Differential Leucocyte Counting programme.

Online operation

All programmes are available for online operation unless stated in the programme specific sections.

AUTOMATED COUNTING PROGRAMMES

Full Blood Count (FB)

- **Purpose**

  This programme is designed for users of automated haematology analysers providing full blood count (FBC or CBC) results in clinical, veterinary, research, pharmaceutical and health surveillance settings. Instrument manufacturers are also welcome to join.

  The assay material is suitable for all the major analyser models and individual parameter methods, e.g. microhaematocrit and platelet counting by flow cytometry. The Scheme will advise you in advance of the suitability of the service for any individual analyser.

  Analysers providing a full blood count in point of care testing locations are accommodated in this programme. Analysers providing a Hb estimation only, usually in a POCT setting, should register with the Hb only (HB) programme.

- **Analytes and units**

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

  Participants may register just for the analytes offered by their analyser or method.
  Other parameters are under development.

- **Frequency of distribution**

  Twelve distributions of two specimens each are made each year, on a monthly basis (twenty-four specimens per year).

- **Assay (Survey) material**

  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 the limits of clinical decision-making.

  A single set of specimens is dispatched for multiple analysers, with additional specimens provided for registrations of more than five instruments. Because the assay material is stabilised, it may require special handling on the advice of the instrument manufacturer and this is specified in the instructions.

- **Instrument groups available**

The instrument groupings in use for Full Blood Count are shown in the table below. This information is correct at the time of issue of this manual but may change as a result of instrument registration changes and the review of data by the Scheme. The most up-to-date lists are available from the Scheme office. Participants may register up to three instruments for a single fee, with an additional fee for each instrument above three.

Instruments not listed in the table below may be suitable for registration, subject to review by the Scheme. The Scheme works with manufacturers and advisors to monitor instrument grouping. Ideally, a minimum of twenty instruments is required to form a peer group for the purpose of valid statistical analysis but this may be varied at the discretion of the Scheme.

FBC Instrument Groups (Correct at February 2021)

Instrument group name	Instruments included
Alinity Hq and Sapphire	Abbott Alinity Hq, Sapphire
Beckman Coulter DxH 500/520	Beckman Coulter DxH 500, DxH 520
Beckman Coulter DxH 600/800/900	Beckman Coulter DxH 600, DxH 800, DxH 900
Beckman Coulter LH Series	Beckman Coulter LH500, LH 750, LH 755< LH 780
Cell Dyn 3200	Abbott Cell-Dyn Ruby
HORIBA Pentra Series	Beckman Coulter AC*T 5 Diff, HORIBA Pentra 120, Pentra 60, Pentra 80, Pentra DF 120, Pentra DF Nexu, Pentra XLR, Yumizen H1500, HORIBA Yumizen H2500
Siemens ADVIA	Siemens ADVIA 120, 2120, 2120I
Sight Diagnostics - OLO	Sight Diagnostics – OLO E-1
Sysmex pocH-100i	Sysmex pocH-100i
Sysmex XE	Sysmex XE2100, 2100D, XE5000
Sysmex XN	Sysmex XN 10, XN 20 (and combinations)
Sysmex XNL	Sysmex XN 330, XN 350, XN 450, XN 550
Sysmex XP	Sysmex KX21, XP 300
Sysmex XT Series	Sysmex XS 500i, XS 1000i, XS 800i, XT 1800i, XT 2000i, XT 4000i
Yumizen H500 Series	Yumizen H500 CT, H550CT
Miscellaneous	Various instruments

- **Performance assessment**

Participants are asked to perform a single analysis on each specimen, as for a patient's sample. Performance assessment is undertaken on a 'state-of-the-art' basis against an

assigned target derived from the consensus mean of participants' results, trimmed to remove outliers. Participants are performance monitored for analytical performance by instrument group, as listed above, where there sufficient instruments of comparable technology registered. Where there are insufficient instruments registered to form a peer group, performance assessment is against the all methods results. A full description of the method of survey data analysis and performance assessment is described later in this manual, as the methods are common to more than one survey.

Active participation and return of results is expected and a participation score is provided.

Point of Care Hb (HB)

- **Purpose**

  This programme is designed for instruments that produce haemoglobin (Hb) concentration only and is suitable for all the major analyser models, including most blood gas analysers. The Scheme will advise you in advance of the suitability of the service for any individual analyser.

- **Analytes and units**

	Units
o Haemoglobin (Hb)	g/L

- **Frequency of distribution**

  Twelve distributions of two specimens each are made each year, on a monthly basis (twenty-four specimens per year).

- **Assay (Survey) material**

  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, treated with antibiotics but not fixed. Haemoglobin concentration is varied to test performance at the limits of clinical decision-making.

  A single set of specimens is dispatched for each analyser, making this option convenient for users with analysers in multiple point-of-care testing locations.

- **Instrument groups available**

  The instrument groupings in use for the Hb Only programme are shown in the table below. This information is correct at the time of issue of this manual but may change as a result of instrument registration changes and the review of data by the Scheme. The most up-to-date lists are available from the Scheme office. Participants may register up to three instruments for a single fee, with an additional fee for each instrument above three.

  Instruments not listed in the table below may be suitable for registration, subject to review by the Scheme. The Scheme works with manufacturers and advisors to monitor instrument grouping. Ideally, a minimum of twenty instruments is required to form a peer group for the purpose of valid statistical analysis but this may be varied at the discretion of the Scheme.

  Hb Only Instrument Groups (Correct at February 2021)

Instrument group name	Instruments included
DiaSpect Medical	Diaspect CompoLab TS, DiaSpect Tm, Fresenius Kabi Compolab, Prospect Haemoglobin
HemoCue Hb 201	HemoCue Hb 201+, B-Hemoglobin
HemoCue Hb 301	HemoCue Hb 301, Hb 801
Miscellaneous	Various instruments

- **Performance assessment**

  Participants are asked to perform a single analysis on each specimen, as for a patient's sample. Performance assessment is undertaken on a 'state-of-the-art' basis against an assigned target derived from the consensus mean of participants' results, trimmed to remove outliers. Participants are performance monitored for analytical performance by instrument group, where there are sufficient instruments of comparable technology registered. Where there are insufficient instruments registered to form a peer group of twenty, performance assessment is against the all methods results. A full description of the method of survey data analysis and performance assessment is described later in this manual, as the methods are common to more than one survey.

  Active participation and return of results is expected and a participation score is provided.

Automated Differential Leucocyte Count or ADLC (DL)

- **Purpose**

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

  The programme is suitable for all the major analyser models. The Scheme will advise you in advance of the suitability of the service for any individual analyser.

- **Analytes and units**

  - Three or five population differential leucocyte count, as performed using an automated haematology analyser
  - Automated differential count in absolute units ($x10^9$/L)

  Nucleated red blood cell counting (NRBC) is available within this programme for Sysmex, Beckman-Coulter and Abbott instruments. The provision of NRBC performance assessment is dependent upon the availability of survey material.

- **Frequency of distribution**

  Six distributions are made per year, on alternate months, with two specimens per distribution (twelve specimens per year).

- **Assay (Survey) material**

  Commercially prepared assay material is provided and the choice of material type (matrix) is instrument dependent. Each material type is analysed independently as the assay values of each material type are different.

  A single set of assay material is dispatched for multiple instruments, with additional material supplied for registrations of five or more analysers or where a participant registers analysers that require different matrices.

  Because the assay material is fully stabilised, it may require special handling on the advice of the instrument manufacturer and this is specified in the instructions.

- **Instrument groups available**

  The instrument groupings in use for the ADLC programme are shown in the table below. This information is correct at the time of issue of this manual but may change as a result of instrument registration changes and the review of data by the Scheme. The most up-to-date lists are available from the Scheme office. Participants may register up to three instruments for a single fee, with an additional fee for each instrument above three.

  Instruments not listed in the table below may be suitable for registration, subject to review by the Scheme. The Scheme works with manufacturers and advisors to monitor instrument grouping. Ideally, a minimum of twenty instruments is required to form a peer group for the purpose of valid statistical analysis but this may be varied at the discretion of the Scheme.

ADLC Instrument Groups (Correct at February 2021)

Instrument group name	Instruments included
Matrix A	Abbott Cell-Dyn Emerald 18 Sysmex KX21, pocH-100i, XP-300
Matrix B	Beckman Coulter AC*T Diff, AC*T Diff 2 HORIBA Micros 60, Microsemi CRP, Nihon Kohden Celltac MEK 6400
Matrix C	Abbott Cell-Dyn 3700, Emerald 22, Ruby, Sapphire Diatron Abacus 5 Siemens ADVIA 560
Matrix CA	Abbott Alinity Hq
Matrix D	Siemens ADVIA 120
Matrix DA	Siemens ADVIA 2120, 2120i
Matrix E	Beckman Coulter DxH 600, DxH 800, DxH 900, LH 500, LH 750, LH 755, LH 780
Matrix EA	Beckman Coulter DxH 500, DxH 520
Matrix G	HORIBA Pentra 120, DF 120, DF Nexus, DX 120, DX Nexus
Matrix GA	Beckman Coulter AC*T 5 Diff HORIBA Pentra 60, Pentra 80, Pentra XLR
Matrix GB	HORIBA Yumizen H1500, Yumizen H2500
Matrix GC	HORIBA Yumizen H500 CT, Yumizen H550 CT
Matrix J	Mindray BC-6200, BC-6800, BC-6800 Plus Sysmex XE2100, XE2100D, XE5000, XE1800i, XE2000i, XT4000i
Matrix JA	Sysmex XS500i, XS1000i, XS800i
Matrix JB	Sysmex XN10, XN20
Matrix JC	Sysmex XN330, XN350, XN450, XN550

- **Performance assessment**

Participants are asked to perform a single analysis on each specimen, as for a patient's sample. Performance assessment is undertaken on a 'state-of-the-art' basis against an assigned target derived from the consensus mean of participants' results, trimmed to remove outliers. Performance is monitored for the analytical performance of neutrophil and lymphocyte counts, with NRBC on a shadow basis, at the time of publication. A performance score for other cell types is provided for information and is under review for active performance assessment.

Analysis of results and performance assessment is by material type and in some cases is further subdivided by individual instrument type.

A full description of the method of data analysis and performance assessment is described later in this manual, as the methods are common to more than one survey.

Active participation and return of results is expected and a participation score is provided.

Reticulocyte Count (RE)

- **Purpose**

  This programme is designed for the performance monitoring of reticulocyte counting by all the major automated analyser models. The Scheme will advise you in advance of the suitability of the service for any individual analyser.

- **Analytes and units**

	Units
o Reticulocyte count	10^9/L

- **Frequency of distribution**

  Six distributions are made per year, on alternate months, with two specimens per distribution (twelve specimens per year).

- **Assay (Survey) material**

  Assay specimens may be prepared by UK NEQAS Haematology from partially fixed human blood components, as for the full blood count specimens, or commercially prepared whole blood material, depending upon the reticulocyte concentration and the instrument type.

  A single set of assay material is dispatched for multiple instruments with additional material for registrations of 5 or more analysers and/or where a participant registers instruments that require different material types.

  Because some assay material is stabilised, it may require special handling, it may require special handling on the advice of the instrument manufacturer and this is specified in the instructions.

- **Instrument groups available**

  The instrument groupings in use for the Reticulocyte Count programme are shown in the table below. This information is correct at the time of issue of this manual but may change as a result of instrument registration changes and the review of data by the Scheme. The most up-to-date lists are available from the Scheme office. Participants may register up to three instruments for a single fee, with an additional fee for each instrument above three.

  Instruments not listed in the table below may be suitable for registration, subject to review by the Scheme. The Scheme works with manufacturers and advisors to monitor instrument grouping. Ideally, a minimum of twenty instruments is required to form a peer group for the purpose of valid statistical analysis but this may be varied at the discretion of the Scheme.

Reticulocyte Instrument Groups (Correct at February 2021)

Instrument group name	Instruments included
Alinity Hq	Abbott Alinity Hq
Beckman Coulter DxH	Beckman Coulter DxH 600, DxH 800, DxH 900
Cell Dyn Ruby	Abbott Cell-Dyn Ruby
Cell-Dyn 4000 & Sapphire	Abbott Cell-Dyn Sapphire
Horiba Pentra	HORIBA Pentra 120, DX Nexus, XLR, Yumizen H2500
Siemens ADVIA	Siemens ADVIA 120, 2120, 2120i
Sysmex X-Class	Sysmex XE2100, XE5000, XN10, XN20, XN350, XN550, XT2000i, XT4000i
Miscellaneous	Various instruments

- **Performance assessment**

  Participants are asked to perform a single analysis on each specimen for each instrument, as for a patient's sample. Performance assessment is undertaken on a 'state-of-the-art' basis against an assigned target derived from the consensus mean of participants' results, trimmed to remove outliers. Participants are performance monitored for analytical performance by instrument group, where there are sufficient instruments of comparable technology registered. Where there are insufficient instruments registered to form a peer group, performance assessment is against the all methods results. A full description of the method of survey data analysis and performance assessment is described later in this manual, as the methods are common to more than one survey.

  Active participation and return of results is expected and a participation score is provided.

Blood Component Quality Monitoring (CM)

- **Purpose**

  This programme is designed as a supplement to the Full Blood Count programme for organisations that prepare blood components for therapeutic use. The programme supplies specimens for haemoglobin, haematocrit and platelet count at concentrations beyond the normal physiological ranges.

  The programme is suitable for all the major analyser models. The Scheme will advise you in advance of the suitability of the service for any individual analyser.

- **Analytes and units**

	Units
o Haemoglobin (Hb)	g/L
o Haematocrit (Hct)	L/L
o Platelet count (PLT)	10^9/L

- **Frequency of distribution**

  Four distributions, each containing two red cell specimens for haemoglobin/haematocrit and two platelet concentrate specimens for platelet count, are made each year.

- **Assay (Survey) material**

  Assay 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.

  A single set of specimens is provided for multiple analyser registrations. Participants wishing to register more than three instruments under one registration should contact the Scheme office.

- **Instrument groups available**

  All instruments are monitored in the same instrument group. Participants may register up to three analysers or modes of analysis for a single fee. The range and number of instruments returning results is available.

- **Performance assessment**

  Participants are asked to perform a single analysis on each specimen. Performance assessment is undertaken on a 'state-of-the-art' basis against an assigned target derived from the consensus of participants' results, trimmed to remove outliers. For this programme the target is the all-methods trimmed mean and participants are performance monitored for analytical performance in a single instrument group.

  A full description of the method of survey data analysis and performance assessment is described later in this manual, as the methods are common to more than one survey.

  Active participation and return of results is expected and a participation score is provided.

Plasma Viscosity (PV)

- **Purpose**

  This programme is designed for the performance monitoring of plasma viscosity.

- **Analytes and units**

	Units
o Plasma viscosity	mPas

- **Frequency of distribution**

  Twelve distributions are issued each year, on a monthly basis, each containing two plasma specimens (twenty-four specimens per year).

- **Assay (Survey) material**

  Assay 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 is treated with antibiotics and an antifungal agent. Specific instructions are provided for the preparation of material prior to analysis.

Although the assay material is manipulated to increase the viscosity, it is not possible to simulate the extreme raised values that may be found in some clinical scenarios, unless assay material prepared from clinical plasmapheresis material is available.

- **Instrument groups available**

  All instruments are monitored in the same instrument group. Participants may register up to three analysers for a single fee.

- **Performance assessment**

  Participants are asked to perform a single analysis on each specimen for each instrument, as for a patient's sample. Performance assessment is undertaken on a 'state-of-the-art' basis against an assigned target derived from the all-methods mean of participants' results, trimmed to remove outliers.

  Descriptive statistics may be supplied for instruments of a similar technology, for information, where there are sufficient numbers of participants registered.

  A full description of the method of survey data analysis and performance assessment is described later in this manual, as the methods are common to more than one survey.

  Active participation and return of results is expected and a participation score is provided.

Erythrocyte Sedimentation Rate (ES)

- **Purpose**

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

- **Analytes and units**

	Units
o ESR	mm/hour

- **Frequency of distribution**

  Four distributions are issued each year, on a quarterly basis; the number of specimens distributed depends on the registration module (eight or twelve specimens per year).

- **Assay (Survey) material**

  Two modules are available, using different assay material:

  ES module: This module is suitable for all instruments except Alifax methods. Assay material is commercially prepared, whole blood. One set of assay material is distributed per instrument.

  ESX module: This module is suitable for Alifax instruments. At the time of publication, instruments in the ESX module receive three specimens of commercially prepared, latex based material per distribution. One set of specimens is issued for multiple instruments. The Scheme is reviewing the introduction of commercially prepared, whole blood material in place of latex suspension for this module.

Where the assay material requires special preparation or handling, this is described in the programme instructions.

Participants may register one analyser in the ES module and multiple instruments in the ESX module for a single fee.

- **Instrument groups available**

The instrument groupings in use for the Erythrocyte Sedimentation Rate programme are shown in the table below. This information is correct at the time of issue of this manual but may change as a result of instrument registration changes and the review of data by the Scheme. The most up-to-date lists are available from the Scheme office.

Instruments not listed in the table below may be suitable for registration, subject to review by the Scheme. The Scheme works with manufacturers and advisors to monitor instrument grouping. Ideally, a minimum of twenty instruments is required to form a peer group for the purpose of valid statistical analysis but this may be varied at the discretion of the Scheme.

ESR Instrument Groups (Correct at February 2021)

Instrument group name	Instruments included
Alifax	Alifax
BD Seditainer	Becton Dickinson Seditainer, Sedi-15
Sarstedt Sedivette	Sarstedt S-Sedivette, SediPlus S200, SediPlus S2000
Starrsed	RRMechatronics Starrsed Compact, RL, RS, ST Sarstedt Starrsed TL1
VES-MATIC	Diesse VES-matic 20, VES-matic 30, VES-Matic Easy
VES-MATIC CUBE	Diesse VES-Matic Cube 200, 30, 80
Westergren	AQUISEL Pipette P-4 Disera Vacusera 30 Guest Medical Dispette, Dispette2, Micro-Dispette Polymedco SEDIPLAST Sarstedt Microvette CB200 Vital Diagnostics MixRate
Miscellaneous	Various instruments

- **Performance assessment**

Participants are asked to perform a single analysis on each specimen for each analyser. Performance assessment is undertaken on a 'state-of-the-art' basis against an assigned target derived from the consensus of participants' results.

Participants are performance monitored for analytical performance by instrument group, where there are sufficient instruments of comparable technology registered. Where there are insufficient instruments registered to form a peer group, performance assessment is against the all methods results for the module.

A full description of the method of survey data analysis and performance assessment is described later in this manual, as the methods are common to more than one survey.

Active participation and return of results is expected and a participation score is provided.

Infectious Mononucleosis Screening (MN)

- **Purpose**

  This programme is designed for the performance monitoring of the detection of heterophile antibodies as part of infectious mononucleosis screening.

  At the time of publication, this programme is not part of the UK NEQAS Haematology scope of accreditation to ISO 17043: 2010 but will be submitted in early 2021.

- **Analytes and units**

  - Infectious Mononucleosis Screening

- **Frequency of distribution**

  Four distributions are issued each year, each with three specimens (twelve specimens per year).

- **Assay (Survey) material**

  Assay material is human plasma, either positive or negative for heterophile antibodies. Participants receive one set of assay material per laboratory.

- **Instrument groups available**

  Participants may register more than one kit method but must identify the results generated from each kit registered. Results are grouped by kit for information on the reports.

- **Performance assessment**

  Participants are asked to perform a single analysis on each specimen. Performance assessment is undertaken on a 'state-of-the-art' basis against the consensus of all participants' results.

  Active participation and return of results is expected and a participation score is provided.

BLOOD MORPHOLOGY AND RELATED PROGRAMMES

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

- **Purpose**

  This programme 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. 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 Parasites 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 programme 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)
  - Peripheral blood films for the detection of blood parasites and the species identification of malaria (PA slides)
  - A parasitaemia count (%) is requested as part of the species identification registration, if *Plasmodium falciparum* or *Plasmodium knowlesi* is present

- **Frequency of distribution**

  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).

- **Assay (Survey) material**

  Films for morphology and differential counting (BF/DF slides) are prepared by UK NEQAS Haematology from clinical cases supplied by participants' laboratories.

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

- **Instrument groups available**

  There are no instrument groupings for this programme.

- **Performance assessment**

  Participants are performance monitored for the parts of the programme they are registered for and assessment is of the organisation rather than an individual practitioner. The films may be viewed by any grade and number of staff at the discretion of the participant.

  Participants in Blood Films for Morphology are monitored for 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 at the time of publication.

  Participants in Blood Films for Parasites are performance scored for the detection of the parasite type present against the expected target in the Screening part of the programme. 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.

  Active participation and return of results is expected and a participation score is provided.

Cytochemistry (CY)

- **Purpose**

  This programme is designed to monitor the performance and interpretation of iron staining of bone marrow and urinary haemosiderin. This programme is under major revision and restructuring at the time of publication.

- **Analytes and units**

  - Iron stain (Perls' stain)
  - Assessment of stained slides or images for iron stores

- **Frequency of distribution**

  At the time of publication, there are 2 distributions each per year each containing one to two cases.

- **Assay (Survey) material**

  At the time of publication, the use of digital images is in development for the assessment and interpretation of iron stores is in development.

  The Scheme is reviewing the use of various iron-containing tissue sections and urinary deposit slides for the assessment of iron-staining by the laboratory.

- **Instrument groups available**

  There are no instrument groupings for this programme.

- **Performance assessment**

  Performance assessment is of the organisation rather than an individual practitioner. The films may be viewed by any grade and number of staff at the discretion of the participant.

  The development of scoring for Iron Stain is in development pending restructuring of the programme. The programme is intended to have a strong educational element.

  Active participation and return of results is expected and a participation score is provided.

Rapid Diagnostic Testing for Malaria (RD)

- **Purpose**

  This programme 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 for Morphology, Manual Differential and Parasite Identification programme.

- **Analytes and units**

  - Detection of species specific malarial antigen in blood using lateral flow testing

- **Frequency of distribution**

  Two specimens of freeze-dried whole blood are distributed 4 times a year (8 specimens per year.

- **Assay (Survey) material**

  Assay material is freeze-dried, whole blood prepared from blood from donors negative for malaria, patients infected with malaria or from normal donated blood spiked with recombinant malarial antigen. Malarial antigen concentrations represent the range of clinically significant parasite concentrations and different parasite species.

  Preparation of assay material is sub-contracted to UK NEQAS Parasitology, who also provide the identification of the *Plasmodium* species present.

- **Instrument groups available**

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

- **Performance assessment**

  Participants are expected to test the specimen by the kits they would use for a patient's specimen. Results are returned as positive or negative for different malaria infections, depending on the kit. An analysis of results is reported by kit. Performance is assessed by the result that would be reported to the requesting clinician, i.e. on the outcome of whatever combination of kits is used.

  Active participation and return of results is expected and a participation score is provided.

Digital Morphology (DM)

The Digital Morphology Programme 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 programme 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. Six 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 recent back cases for which they have been registered.

The programme is suitable for continuing professional development.

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

This programme is operated entirely online.

HAEMOGLOBINOPATHY PROGRAMMES

Abnormal Haemoglobins (AH)

- **Purpose**

  This programme 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**

	Units
o Sickle screening test (SS specimens)	
o Hb variant identification: adult (AH) specimens	
o Hb variant identification: liquid newborn (LN) specimens	
o Quantification of Hb A_2, Hb F and Hb S (AH)	**% total Hb**
o Assessment of Hb A_2 and Hb F in terms of the participant's reference range (AH)	
o Interpretation of results (AH and LN)	

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, such as a lateral flow test) 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 programme 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 population screening using dried blood spots (dbs).

- **Frequency of distribution**

  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.

- **Assay (Survey) material**

  The assay material is human whole blood, manipulated where necessary to simulate different conditions. All specimens are prepared by UK NEQAS Haematology. Assay 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. Assay material is treated with antibiotics but not fixed.

  The concentrations of Hb A_2, Hb F and Hb S in AH specimens may be manipulated by mixing blood components from different donors. The concentration of Hb S in SS specimens may be manipulated but the Hb S% will be greater than the recognised sensitivity of current testing methods (approximately 20%) unless the specimen is designed for educational purposes. In this situation (i.e. Hb S concentration less than 20%) it will usually be withdrawn from scoring.

- **Instrument groups available**

  Participants in the SS option register the kit in use, for information.

  Participants for fraction identification in the AH and LN options are expected to select the methods they would use depending on the nature of the initial results obtained, in the same way that they would for a patient's sample. Participants are asked to provide details of the methods used to test each individual specimen.

  Participants register each method they use for fraction quantitation separately and report a result from each method.

- **Performance assessment**

  Participants are expected to test the specimen by the methods they would use for a patient's specimen. Where applicable, performance monitoring is based on the laboratory standards published by the National Sickle and Thalassaemia Screening Programme in England.

  Performance assessment for the SS option is against the expected result (positive or negative). Participants should report only the result obtained from their sickle solubility or similar method and not the result from any confirmatory testing. An analytical performance score is provided for sickle screening against the consensus of participants' results, provided that 85% of participants' returns agree with the consensus result.

  Fraction identification (AH or LN specimens) is performance assessed against the fractions identified as essential for diagnosis for the specimen. At the time of publication, there is no analytical performance score provided for fraction identification but participants are contacted if they fail to return the consensus of fractions essential for diagnosis. As for the sickle screening option, 85% of participants must agree with the consensus result for the specimen to be performance assessed.

  Participants receive cumulative analytical performance scores for Hb A_2 measurement and Hb S measurement, assessed against the all methods mean for each parameter, trimmed to remove outliers. Descriptive statistics are provided for the main method principles (High Performance Liquid Chromatography and Capillary Zone Electrophoresis, at the time of publication) and individual instrument models where there are sufficient numbers of an

analyser model registered (usually more than 20). The method and instrument group statistics are provided for information only. A full description of the method of survey data analysis and calculation of the performance score for Hb A_2 and Hb S is described later in this manual.

Gross errors of fraction identification or quantitation will trigger a review of the laboratory's performance, especially where this would have resulted in a potential misdiagnosis.

Active participation and return of results is expected and a participation score is provided.

Newborn Sickle Screening (NH)

- **Purpose**

  This programme 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 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

- **Frequency of distribution**

  12 distributions are made per year on a monthly basis. Each distribution contains 3 dried blood spot newborn screening cards (36 specimens annually).

- **Assay (Survey) material**

  Dried blood spot newborn screening cards are prepared from anti-coagulated umbilical cord blood. The specimens are suitable for screening by high performance liquid chromatography (HPLC), isoelectric focusing (IEF), capillary electrophoresis (CE) and tandem mass spectrometry (TMS).

  Dried blood spot cards may contain EDTA anticoagulant, which will cause a suppression of the signal obtained by TMS, although the qualitative result obtained will be correct.

  Each card is accompanied by the gestational age, birthweight and family origin of the infant.

- **Instrument groups available**

  There is no instrument or method grouping for this programme, although participants are asked to state the methods used.

- **Performance assessment**

  Participants are expected to test the specimen by the methods they would use for a patient's specimen. Where applicable, 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.

Participants receive an analytical performance score for fraction identification and interpretation against the expected phenotypic result for the case, provided 85% of participants' results are in consensus with the expected result.

Active participation and return of results is expected and a participation score is provided.

DNA Diagnostics for Haemoglobinopathies (DN)

- **Purpose**

  This programme is designed to performance assess the identification of mutations of the alpha and beta globin genes 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.

  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.

  At the time of publication, online operation is in development for this programme. In the meantime, the data return form is distributed electronically and emailed back to UK NEQAS; reports are returned by email as PDF documents.

- **Analytes and units**
  - Globin gene mutational analysis for alpha and / or 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

- **Frequency of distribution**

  3 distributions are made per year with two specimens per distribution (6 specimens annually).

- **Assay (Survey) material**

  Assay 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 assay material may limit the availability of specimens for repeat testing.

  At the time of publication, the programme is assessing the use of DNA from cell lines as assay material.

- **Instrument groups available**

  There is no instrument or method grouping for this programme, although participants are asked to state the methods used and the information is used in the assessment and discussion of the results.

- **Performance assessment**

  Participants are expected to test the specimen by the methods they would use for a patient's specimen and are encouraged to return a laboratory report in addition to the results sheet.

  Participants receive a cumulative analytical performance score for mutational analysis and interpretation, which is actively performance assessed. A score is supplied for the recommendations, the annotation and the use of HGVS nomenclature for information only. A separate guidance document is available for participants explaining reporting and performance assessment, in addition to this Manual.

  Active participation and return of results is expected and a participation score is provided.

RED CELL ENZYMOPATHY PROGRAMMES

Red Cell Enzymes (G6)

- **Purpose**

  This programme monitors the screening and/or quantitative assay of the red cell enzyme glucose-6-phosphate dehydrogenase (G6PD).

- **Analytes and units**

G6PD	Units
o Qualitative screening test	
o Quantitative assay	**IU/gHb**
o Assessment of quantitation in terms of the participant's reference range	

- **Frequency of distribution**

  Six distributions of 2 specimens each are made per year.

- **Assay (Survey) material**

  The specimens are prepared by UK NEQAS Haematology from human whole blood or animal (ovine) whole blood. The assay material is treated with antibiotics but is not fixed.

  The assay 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.

- **Instrument groups available**

  There is no instrument or kit grouping for performance assessment of this programme, although participants are asked to state the method used. Participants' results are grouped according to the temperature at which results are reported to the requesting clinician. Where appropriate, results are reported by kit or method principle for information.

- **Performance assessment**

  Participants are expected to test the specimen by the methods they would use for a patient's specimen. Participants receive an analytical performance score for screening and/or quantitative assay, according to their registration.

G6PD screening performance is assessed against the consensus result (or consensus combination of results) for the specimen, where more than 85% of participants agree with that result. In general, where the quantitative assay consensus value at 37 °C is less than 1.5 IU/gHb, the consensus screening test result is deficient; where the value is between 1.5 and 5.0 IU/gHb the consensus screening test result is deficient/intermediate, 5.0 to 8.0 IU/gHb normal/intermediate and greater than 8.0 IU/gHb normal. Occasionally, blood from a female heterozygous for G6PD deficiency is distributed and there may be no clear consensus. In this situation, the results are reported and discussed for educational purposes and not performance scored.

G6PD quantitative assay results are all converted to 37° Celsius for performance assessment. Very few participants report quantitative assay results at temperatures other than 37° Celsius and the number is insufficient to calculate a robust trimmed mean target value at any temperature other than 37°. Although participants may report results at their usual assay temperature, a conversion factor is applied to their submitted results to convert the value to the 37° equivalent prior to calculation of the performance score. All participants are performance assessed against the mean result at 37° Celsius, trimmed to remove outliers.

Active participation and return of results is expected and a participation score is provided.

PARASITOLOGY TEACHING DAY

UK NEQAS Haematology offers participants the opportunity to register for the Blood Parasitology Teaching Day operated by UK NEQAS Parasitology. Although registration and invoicing for the Parasitology Teaching Day is administered by UK NEQAS Haematology, the design and operation of the day is undertaken entirely by 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 subscription fee covers up to two members of staff from each participating laboratory.

Teaching sessions are offered at a variety of locations throughout the UK and Republic of Ireland during the year. At the time of publication, a mixture of face-to-face and video teaching is available to conform to government restrictions in response to the Covid-19 pandemic. Once registered, you will be offered a place that is convenient to your organisation.

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 programme 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 PROGRAMMES

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

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

Further information concerning pilot programmes not described in this Manual may be obtained from the Scheme office or website (www.ukneqash.org).

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. The annual distribution schedule(s) are sent as part of the re-registration process and are available from the Scheme office or website. The website also has reminders of what surveys are currently open and the planned closing dates. All schedules cover the April to March registration period.

Know your expected delivery dates

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

Within the UK, please contact the Scheme office if you do not receive your package within 3 to 4 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 5 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

The survey package will contain the following:

- Specimens for the surveys registered

- Instruction sheet(s) for each programme
- Summary information for the safe handling of assay material (Control of Substances Hazardous to Health (COSHH) information)
- Occasional notifications of any changes to services ('field notices')

Survey packages must be checked upon receipt and the Scheme office (or the distribution agent for non-UK laboratories registered through a local distributor) notified as soon as possible of any missing specimens or documents, or broken, leaking or unlabelled specimens. Replacements are generally available and additional time will be allowed for the return your results, if possible. If this is not possible, any adverse score for non-participation will be suspended.

Check the instructions every time

Separate instruction sheets are provided for each of the surveys for which the participant is registered. Although the instructions may appear similar from distribution to distribution, it is important that they are checked every time as the information may change. The survey instruction sheets all follow the same pattern and consist of six sections:

- ***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.
- ***Section five*** details how to return the results to UK NEQAS Haematology.
- ***Section six*** gives information relating to the next distribution.

Example instruction sheets are available for any programme on request. Where the Scheme has been advised of handling instructions peculiar to one instrument or method for the EQA specimens, these are summarised in the instruction sheet and the full instructions from the manufacturer are available to download from the UK NEQAS Haematology website.

Control of Substances Hazardous to Health (COSHH)

COSHH information is supplied as a printed document with each specimen package.

Covid-19 precautions

UK NEQAS Haematology specimens are a low risk for Covid-19 infection. The specimens are prepared from NHSBT donor blood or purchase commercially. The Covid-19 risk is equivalent to supplies of blood for transfusion, commercial reagents and internal quality control materials. The specimens and paperwork are prepared in Covid-safe facilities used for EQA services only.

Participants should observe their standard precautions when receiving packages as they are sent though Royal Mail or courier delivery services and UK NEQAS Haematology is not responsible for the handling of packages in transit.

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, as far as possible. This may not be practicable because of the volume or type of assay material but participants are asked 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 National Quality Assurance Advisory Panel 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.

Assay material may be produced from a single blood donation or be limited in volume (*e.g.* for the Abnormal Haemoglobins). In this case it is not possible to send the volume that would be expected for a patient's specimen.

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. Specimens may be unavailable or unsuitable for analysis after the survey has closed and surplus specimens are not available for all programmes.

The specimens or the remains of them and the specimen tubes should be retained 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.

Individual human donations are screened for known blood-borne pathogens, to the standard of blood components supplied for therapeutic transfusion. Specimens should be handled and disposed of as clinical waste.

One analyser, one participation number

Each analyser is allocated a separate participation analyser to ensure a long-term, retrospective assessment of performance. Participants should not report results from different analysers under the same identifier as this will result in a performance concern with one instrument to be missed.

Where multiple analysers are registered and test the same specimen, it is good practice to vary the order in which the instruments test the specimens, to avoid any bias resulting from repeated mixing and handling.

Return results promptly

Participants are advised to test and return results as soon as possible after receipt.

Web entry is available for the majority of programmes and participants are strongly encouraged to use this means to return results where it is available. Participants registered as a web user for one survey 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. Paper 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 programmes.

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, participants will receive two emails. The first contains the Participant Reference Number (PRN) and an identifier, generated by the database. The second email contains a link to set up a password. The Scheme office has no access to the password for any contact but the password can be reset through a 'forgotten password' link.

As many members of staff as wished may be registered to access the data entry and reports service. Each member of staff will need their own log in information.

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 choose not to use web entry for programmes 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 where non-web results are returned for reasons beyond the participant's control, e.g. the return of late results or the non-availability of the web service.

Non-web results are returned as scanned, email attachments with the description 'URGENT RESULTS' and the PRN in the subject line. FAX is also available; when sending results by fax it is good practice to send a fax header sheet giving the PRN, a contact fax number and the total number of sheets to be expected.

The use of the postal service is not advised for the return of results, as this may result in delay.

A copy of the results sheet(s) submitted should be kept until the final report has been received.

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 an adverse performance assessment. The units of measurement are those recommended by regulatory bodies or guidelines, either in the UK or internationally, or those used by the majority of participants. The Scheme staff are unable to convert results to different units as errors in the results may

be introduced in the process. The Scheme Office can supply advice on how to convert results to the units specified.

The survey closing date

The closing date for each survey is published on the survey instruction sheet and shown on our website. It is the responsibility of the participant to ensure that results are returned to the programme by the closing date or to notify the Scheme of any unavoidable delay.

The closing dates for surveys are set to accommodate the stability of the assay 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.

If a participant is unable to return on time for any reason, the Scheme Office should be advised as soon as possible as it may be possible to submit results late without penalty. If a participant is unable to return results for a reason beyond their control (e.g. instrument breakdown or replacement, major service changes or significant staffing problems) a blank return, i.e. without results, should be made, stating the reasons for not testing the specimens. This will avoid an adverse participation score for the survey. If the situation continues for several surveys, the Scheme Office will advise on whether participation should be suspended temporarily.

Results returned after the closing date

Participants are encouraged to return results, even if the survey has closed. There are restrictions on whether they will be accepted after the report has been issued and the Scheme Office will advise in this situation. 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 the raw data is captured directly from the analyser and the specimens remain stable.

The assay material may be unsuitable for analysis after the closing date and the Scheme will not accept results in these circumstances.

The data entry website is closed on or shortly after the published closing date. If returning results after the website has been closed, a results sheet is available for download from the data entry website or provided by the Scheme Office. The participant reference number must be shown on any results returned.

When results are returned late, the first report may not show the results and a non-return penalty may be allocated. A second 'late' report, showing the results submitted, will be generated before the next survey is processed. The adverse participation score for the late return will remain, unless the Scheme has agreed to accept the result late without penalty (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.

Review of reports

Every effort is made to return reports promptly and a schedule of closing and reporting deadlines is available. Reports should be available for all the staff in the laboratory and should

be reviewed as soon as they are available. Any errors should be reported immediately. 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. Where possible, we will inform participants if a report is likely to be delayed more than one week past the scheduled publication date and an interim report may be issued if the delay is likely to be extended.

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 programme is shown in appendix 2.

Amending 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.

Participants may amend results online at any time up to the survey closing date. Results that have been saved but not submitted can be amended by the participant directly. Results that have been submitted can be unlocked on request to the Scheme Office, to allow 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 where results are reported directly via the laboratory information management system. In these circumstances, the Scheme will modify results after the closing date, provided evidence is provided 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 Service 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 concerning UK NEQAS Haematology services.

Where participants are concerned about the quality of the specimens received, they are asked to take photographss of the specimens in question, where possible, and to return the photograph with their query. Participants are advised that the nature of the assay material means that they may not appear identical to fresh blood. Photographs of typical, satisfactory survey specimens are available upon request from the Scheme Office, for comparison purposes.

If a participant remains unhappy with the service received, the Scheme Director should be contacted directly by letter, email or telephone. Your complaint will be acknowledged within 5 working days and our performance target is to resolve the problem within 4 weeks. 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 the participant's satisfaction, it may be referred 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.

The participant has 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 assay material, 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 the participant remains dissatisfied with the outcome of the appeal, the final decision and resolution rests with the Chair of the NQAAP in Haematology.

When dealing with complaints or any other correspondence, the Scheme will use the same means of communication (i.e. written letter or email) as used by the participant to contact the Scheme.

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 or qualitative 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 or quantitative data,** e.g. as reported for the full blood count, the target is the consensus result returned by participants. The consensus value is either the mean (trimmed to remove outliers) or the median, calculated for all-methods, the method or the sub-method group, depending on the commutability of the assay material and/or the programme 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.* $\log_e$) may be used to give an approximately symmetrical distribution and to remove the relationship between the mean and the standard deviation for performance assessment. At the time of publication, log transformation is used for all quantitative programmes except ADLC.

Symmetrical trimming of the data set is employed to remove outliers that might unduly affect the consensus mean value. Approximately 10% trimming (5% of results from each end of the data) is employed at present. Because only a whole number of results can be trimmed, the exact % trimming may be variable. Where trimming fails to remove all major blunders (e.g. results reported in units other than those requested by the Scheme or results with an incorrectly placed decimal separator), additional results may be removed but this is always symmetrical.

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 for 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.

[1] Healy MJR (1979) Outliers in clinical chemistry quality control schemes. Clin. Chem. **25**: 675-677

To smooth 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 12 specimens 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 or the number of results is too few to allow for the data to be trimmed, 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).

UK NEQAS Haematology does not currently use the median as target value for any programme; however, it may be used in EQA for small data sets and where the distribution of the results is not normal. In this situation, 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) and the Deviation Index.

$$Estimated\ SD = \frac{IQR}{1.349}$$

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; where data is log transformed for analysis, the log transformed result and target value is used in this calculation:

$$DI = \frac{x_i - x_{pt}}{SD_{pt}}$$

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.

DI	Interpretation
< -3.0	Requiring investigation

[2] Tukey J (1977). Exploratory Data Analysis, Addison-Wesley

-3.0 – -2.0	Borderline
-2.0 – -1.0	Satisfactory
-1.0 – -0.5	Good
-0.5 – 0.5	Excellent
0.5 – 1.0	Good
1.0 – 2.0	Satisfactory
2.0 – 3.0	Borderline
>3.0	Requiring investigation

Participants should note that where the measurand concentration is low, e.g. a platelet count of around 20 x 10^9/L, a result that is relatively close to the target may have a high DI and should take the measurand concentration, their IQC result, the clinical significance of the difference and whether this is a one-off or a trend in performance before taking action.

Bias

UK NEQAS Haematology is developing reports to include a statement of the bias of the result.

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, may be 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 the lack of commutability of assay 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 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. specimen transposition, 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 may 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

Example 1 Deviation indices were obtained as follows for a FBC parameter:

Survey	Specimen FB1	Specimen FB2
1	-0.64	+1.85
2	0.00	+1.13

3	-1.89	+0.64

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:

Survey	Specimen FB1	Specimen FB2
1	-7.05	+2.80
2	+2.89	+4.11
3	-2.64	+2.05

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 A_2 / 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 programme 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 quantitave 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 programme 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 programme
- 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 for Haematology asks the Scheme to provide the following information for UK participants providing a direct or indirect clinical service:

- An annual report on the overall performance of participants

- 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 or a critical error, 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.

Any UKAS accredited laboratory reported to the NQAAP will be asked to confirm and disclose their UKAS centre number to the Scheme at the time of notification to the NQAAP, as this information will be disclosed at the same time as the laboratory's identity.

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 programmes. The identity of an antenatal and newborn screening participant in England who receives an analytical or participation letter in the haemoglobinopathy programmes (AH, NH or DN), or for MCH in the FB programme, may be disclosed to the NHS Sickle and Thalassaemia Screening Programme with the permission of the participating laboratory's head of department.

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. Assay 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 commutablity 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 may produce a greater variation in performance 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 programmes 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 assay 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 assay 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 programmes 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 or a critical error 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.

Instrument or method-related performance concerns

EQA may identify performance problems that are related to an instrument or method, batch of reagent or kit. Depending on the programme design and the method for deriving the target

value (all methods, method group etc.), this may result in the users of the method all becoming out-of-consensus or an increase in the all method CV%, for example. The Scheme Director will follow up method-related performance with the manufacturers and, if necessary, report the concern to the Medicines and Healthcare Regulatory Agency (MHRA) and the NQAAP. Participants with out-of-consensus performance will also be notified in the usual way, even though the matter is to some extent out of their control. The reason for continuing to performance monitor participants in these situations is to ensure that they are aware of any potential risk to patient safety and have taken appropriate steps to mitigate this, e.g. by referring specimens at decision-making concentrations for testing by another method etc. As long as the participant can demonstrate that this risk has been assessed and action taken, the Scheme will not refer the laboratory to the NQAAP.

PERFORMANCE 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 programmes 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: Printed reports are sent to the named laboratory contact and 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.

The expected turnaround times for reports are:

Survey	Final Lab* Report (working days)
FB, HB	Closing day +2
DL, RE, PV	Closing day +3
NH	Closing day +5
DN	Closing day +30
Other	Closing day +11
Pilots	Individual arrangements

Example: Full Blood Count programme reports

This report is described in some detail below as it contains elements that are used in other individual reports. A user guide on understanding reports is available on the UK NEQAS Haematology website (www.ukneqash.org).

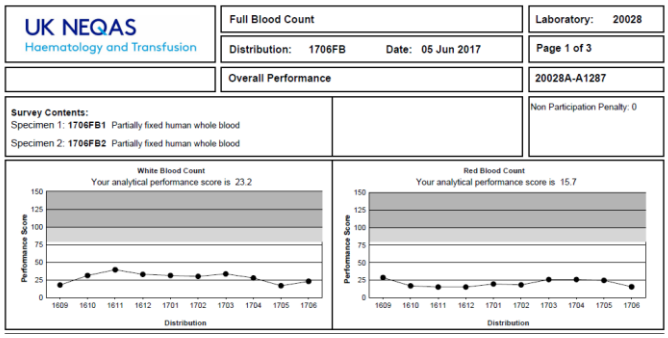
The Full Blood Count programme report is on three pages. At the top of each page is the survey type, the distribution number and date, PRN and page number. The pages contain the following information:

- ***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. Example 2 below shows the display of data on page 1 with the page header and
- ***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

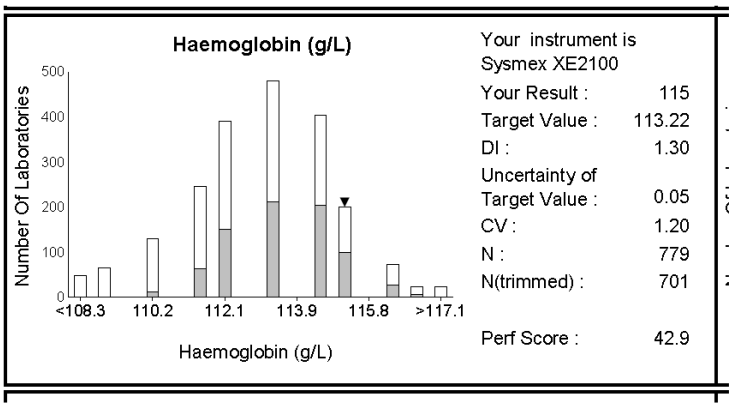
following information is shown (see example 2 for haemoglobin concentration shown below):

- 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

Example 1. The cumulative analysis of performance from the front page of the report



Example 2 The graphical analysis for haemoglobin concentration for a single specimen



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.

TROUBLESHOOTING EQA RESULTS AND REPORTS

The Scheme will assist with troubleshooting EQA results and we ask that your queries are sent to us by email (haem@uknegas.org.uk) where possible. We will follow up by telephone or video call if this is needed. You should include their PRN and the identifier of the individual analyser if applicable.

There are some steps the participant can take to investigate an out-of-consensus EQA result and these are included as a guide that is available from the link on the UK NEQAS Haematology website (www.ukneqash.org). Some of these are basic but they are errors that have all been noted as a cause of an out-of-consensus EQA result.

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.

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. Delivery by courier is essential for international participants to ensure a timely delivery and to preserve the integrity of the specimens. Participants may use their own courier accounts if they wish but should be aware that we make a small administration charge in these circumstances to cover our overheads in liaising with your courier.

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 cost of courier delivery.

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.

WHO COLLABORATING CENTRE FOR QUALITY ASSURANCE IN HAEMATOLOGY

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 programme is designed for laboratories in under-resourced regions, using basic

laboratory techniques, and consists of three to four distributions a year for a limited range of tests.

In some situations this programme 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.

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