

UK NEQAS

Blood Coagulation

UK National External Quality Assessment Scheme for Blood Coagulation

PARTICIPATION MANUAL & GENERAL INFORMATION

LABORATORY PROGRAMMES

2023/24

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About UK NEQAS for Blood Coagulation

Over 50 years of EQA expertise. A programme for External Quality Assessment (EQA) of laboratory testing of blood coagulation testing was originally introduced in the UK in 1967, This programme was recognised as the UK National External Quality Assessment Scheme for Blood Coagulation (UK NEQAS BC) in 1975.

Together with internal quality control (IQC) procedures, EQA is a vital component of laboratory quality assurance. Thus the primary purpose of UK NEQAS BC is to provide EQA for tests of blood coagulation, and other tests of haemostasis, and so promote high standards of performance and practice. Secondly and importantly, UK NEQAS BC also provides an expert led advisory service to participants and, if required, easy availability of repeat testing together with educational activities, including its own scientific meetings, presentations at other scientific meetings worldwide and articles in peer-reviewed publications.

UK NEQAS BC has been accredited as a proficiency testing provider since 1998 (with CPA) and since 2015 has been accredited to ISO17043 through the United Kingdom Accreditation Service (UKAS). Our accreditation is limited to those activities described on our UKAS schedule of accreditation, available here - https://www.ukas.com/wp-content/uploads/schedule_uploads/00013/7873Proficiency-Testing-Multiple.pdf. Currently we provide 12 UKAS accredited EQA programmes covering over 40 different tests and assays of haemostasis. More than 1,000 centres from 38 different countries participate in our laboratory-based programmes. In addition there are over 4600 participants in the UK NEQAS BC Point-of-Care Testing/Near-Patient Testing (POCT/NPT) programmes. In the past 25 years, we have published over 60 articles on EQA in peer reviewed journals and presented in excess of 100 abstracts/posters at national and international meetings.



Professor Isobel Walker, 10.02.23

About the UK NEQAS organisation

For over 50 years members of the UK NEQAS Consortium have provided high quality EQA programmes for all areas of clinical laboratory testing. These programmes have supported healthcare providers in therapeutic decision making and ensuring patients receive appropriate care. The staff and services provided by UK NEQAS for Blood Coagulation form a cornerstone of the UK NEQAS Consortium and their work has highlighted best practice, supported production of guidelines and driven harmonisation on a global level for over five decades. Led by an internationally respected team, UK NEQAS for Blood Coagulation exemplifies the high standards and professionalism of UK NEQAS.



Liam Whitby, President, UK NEQAS 08.12.20

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Participation in UK NEQAS (Blood Coagulation) programmes

Who can participate?

Participation in all our programmes is open to health care professionals practising anywhere in the world and in all areas of clinical and scientific practice, including primary and secondary care. Participation by industrial and other laboratories is welcomed. Registration is open to laboratories and participants in all countries, whether Government supported, private or commercial. UK NEQAS BC is operated on a not-for-profit basis under the auspices of UK National External Quality Assessment Service and professional bodies.

Registration and reregistration

The registration period for all programmes is 1st April to 31st March. Centres registering part way through this period will be charged a pro rata fee for participation. Reregistration is during the period January to March, and participants are invited to confirm reregistration for a further 12 month period. Invoicing for UK participants is through the Sheffield Teaching Hospitals (STH) Finance Department and takes place after confirmation of reregistration.

Registration is also welcomed from centres in countries outside the UK. Currently approximately 40% of UK NEQAS BC laboratory programme participants are based outside the UK. Performance data for all laboratories will remain strictly confidential within UK NEQAS for Blood Coagulation (see confidentiality, below). In some countries, exclusive distributors are currently used. The services provided by these distributors include local distribution and logistics, translation, and in some cases local training or educational support. Please make contact for details of participation and fees.

Conditions of participation

Terms and conditions for participation in UK NEQAS BC programmes can be found on our website (www.neqascoag.org) or directly from the following link;
<https://www.neqascoag.org/terms-and-conditions/>

As part of registration, participants in the UK are requested to formally agree to adhere to the Joint Working Group's Conditions of Participation in UK EQA Schemes (<https://www.rcpath.org/uploads/assets/9dc66c91-95c3-4d49-b8fe0222f605d70b/Joint-Working-Group-on-Quality-Assurance-Conditions-of-EQA-Scheme-Participation.pdf>).

Please also note the following requirements of laboratory participation in EQA under ISO15189: *“The laboratory shall not communicate with other participants in the interlaboratory comparison programme about sample data until after the submission date”, and “The laboratory shall not refer interlaboratory comparison samples for confirmatory examinations before submission of the data, even if this would be routinely done with patient samples”.* Where evidence of collusion is found, participant performance will be scored as a fail for that survey.

Use of UK NEQAS (Blood Coagulation) data

We welcome use and sharing of data from our EQA programmes, as an educational resource. However, all published UK NEQAS BC data are subject to copyright, and data from summary reports should not be presented outside of departmental reviews without permission from us – please make contact (neqas@coageqa.org.uk) or download a permission form from the website:

www.neqascoag.org/app/download/10487822/Template+Request+to+use+UK+NEQAS+BC+data+v1.1.doc

Confidentiality

Participation in our programmes, and information and data from participants are treated with strict confidentiality except where there may be concern that patient safety may be compromised. However, participants are encouraged to share their EQA performance data both within and outside of their department.

Registered participants are given a unique participation number, which should be quoted in all correspondence. Use of this number will assist in maintaining confidentiality in survey correspondence. UK NEQAS BC survey reports are posted to named individuals for each registered participant number, or to the secure online data entry system, accessible only by participant number and unique password. UK NEQAS BC does not share participant information with any 3rd party, except (for UK participants only) where unresolved performance issues which may put patient safety in jeopardy require reporting to the National Quality Assurance Advisory Panel (<https://www.rcpath.org/uploads/assets/9dc66c91-95c3-4d49-b8fe0222f605d70b/Joint-Working-Group-on-Quality-Assurance-Conditions-of-EQA-Scheme-Participation.pdf>).

UK NEQAS BC will prepare overall/summary reports, manuscripts, abstracts for scientific meetings, and present data at national and international meetings. In all these cases, data will be anonymised, and no identifiable individual participant data will be shared or presented.

Details of our privacy policy can be accessed from the website www.neqascoag.org or directly from the following url:

<https://www.neqascoag.org/privacy-policy/>

Blood Samples used in UK NEQAS (Blood Coagulation) programmes

Samples used in UK NEQAS BC laboratory programme exercises are derived from human plasma or whole blood. Donations are obtained following ethical approval and informed donor consent. All donations are screened for antibodies to hepatitis C and HIV, and for Hepatitis B surface antigen. Samples collected after September 2019 are also screened for covid-19 RNA. Participants are advised however to handle and dispose of materials as if unscreened. Donor samples from individuals with haemostatic disorders are used as far as possible; where spiked or adapted samples are employed, commutability is investigated to avoid inappropriate conclusions from EQA exercises (see I Jennings et al, Int J Lab Hematol 2015; 37: 495-502). Samples in each programme are investigated for homogeneity and stability, according to ISO13528. Plasma samples are buffered and lyophilised to ensure stability; sample preparation is subcontracted to Diagnostic Reagents Ltd, Thame, UK and Hart Biologicals Ltd., Hartlepool, UK. Haemostasis testing including homogeneity and stability tests is subcontracted to the coagulation department and virology testing to the Microbiology department at Sheffield Teaching Hospitals (STH) NHS Trust.

Full instructions are provided with each sample/exercise distribution. Unless directed otherwise, participants are expected to perform testing in the same way that a clinical sample would be tested, using the methods in routine use.

PROGRAMMES

Laboratory programme – screening tests

Laboratory programme – assays

Tests covered in these programmes are detailed in table 1 below.

Survey frequency: Six survey exercises are distributed each year. Each survey includes both screening tests and factor assays. Details of tests to be included in each survey are indicated in survey newsletters three months prior to survey distribution. A schedule of the planned surveys can also be downloaded from our website www.uknegasbc.org. Table 1 indicates the current frequency of distribution for each test/assay per year.

Table 1.	Annual frequency	Scoring method used	Peer group analysis?
Screening tests			
INR (venous and/or capillary methods) for Vitamin K antagonist (VKA) monitoring	6	% deviation	By reagent
Prothrombin time (PT) (diagnostic)	4	% deviation	By reagent
Activated Partial Thromboplastin Time (APTT)	6	% deviation	By reagent
Heparin Dosage Assessment (HDA) – APTT for Unfractionated Heparin (UFH)	2	% deviation	By reagent
Heparin Assay (HA) – anti-Xa assay for Low Molecular Weight Heparin (LMWH)	2	A-E grading	Kit/reagent
Thrombin Time (TT)	2	% deviation	By reagent
Fibrinogen assay (Clauss methods)	4	% deviation	Overall
D-Dimer	4	A-E grading	Kit/reagent and units
Assays			
Factor II assay	2	A-E grading	All data
Factor V assay	2	A-E grading	All data
Factor VII assay	2	A-E grading	All data
Factor VIII assay	4	A-E grading	All 1-stage assay data
Factor IX assay	2	A-E grading	All data
Factor X assay	2	A-E grading	All data
Factor XI assay	2	A-E grading	All data
Factor XII assay	2	A-E grading	All data
Von Willebrand factor antigen (VWF:Ag)	2	A-E grading	All data
VWF activity assay (VWF:RCO;VWF:GPIbR;VWF:GPIbM)	2	A-E grading	Method subgroup
VWF collagen binding assay (VWF:CB)	2	A-E grading	All data

Sample details: All samples are of lyophilised plasma. In the majority of cases, samples are from single donations. Full instructions on storage, reconstitution and testing are provided with each survey distribution.

Reporting results: Data reporting is online, through a secure portal and participant login via unique passwords. Participants are asked to complete the online results forms, including method details for each test they perform, and are asked to check their method details for accuracy to ensure analysis in appropriate peer groups. For the majority of tests the participant is invited to provide an interpretation of their results – there is no performance assessment of these interpretations, but comparison with the overall interpretations can help indicate the clinical relevance of any results.

The closing date for these surveys is 3 weeks from the date of distribution. Participants are provided with email alerts at the time of survey distribution, and survey closing date reminders are also sent by email. Participants are required to return results for any test included in a survey, for which they have registered. Failure to return a result for which a centre is registered is logged as a non-return. Results can be returned at any time up until the survey is formally closed. Once the survey is reported, changes to results are not possible.

Performance analysis: Performance for each assay is determined using one or more of the following scoring systems:

% deviation A – E grading z Scores

Performance is defined for single surveys, but in addition, cumulative performance based on consecutive surveys is also determined. Full details of these statistical methods can be found on page 21. These methods are also as described in ISO13528.

Performance is assessed against either all participant data returned for a test/assay, or against data from a peer group of centres using the same methodology. Table 1 above shows the scoring system and grouping used for data analysis currently employed in these programmes.

Reports: Participant reports are made available online within 2 weeks of the closing date of the survey. Reports show the sample details, median results, and an indication of performance for each test/assay registered. Historic performance and histograms of results from all participants form part of the report. A survey newsletter provides further information with respect to performance assessment and interpretation of results. An overall report detailing results for all methods for each test, along with statistical analysis details, is made available within a month of individual report issue.

Laboratory programme – thrombophilia screening

Tests covered in these programmes are detailed in table 2 below.

Survey frequency: Four survey exercises are distributed each year. Each survey includes a sample for analysis of

- Protein C antigen
- Protein C activity
- Protein S total antigen
- Protein S free antigen
- Protein S activity
- Antithrombin antigen
- Antithrombin activity
- Activated Protein C resistance
- Plasminogen

Details of tests to be included in each survey are indicated in survey newsletters three months prior to survey distribution. A schedule of the planned surveys can also be downloaded from our website www.ukneqasbc.org

Sample details: All samples are of lyophilised plasma, from patients with known thrombophilic defects, or normal donors. Full instructions on storage, reconstitution and testing are provided with each survey distribution.

Reporting results: Data reporting is online, through a secure portal and participant login via unique passwords. Participants are asked to complete the online results forms, including method details for each test they perform, and are asked to check their method details for accuracy to ensure analysis in appropriate peer groups. For the majority of tests the participant is invited to provide an interpretation of their results – there is no performance assessment of these interpretations, but comparison with the overall interpretations can help indicate the clinical relevance of any results. An overall interpretation is also requested.

The closing date for these surveys is 4 weeks from the date of distribution.

Participants are provided with email alerts at the time of survey distribution, and survey closing date reminders are also sent by email. Participants are required to return results for any test included in a survey, for which they have registered. Failure to return a result for which a centre is registered is logged as a non-return. Results can be returned at any time up until the survey is formally closed. Once the survey is reported, changes to results are not possible.

Performance analysis: Performance for each assay is determined using one or more of the following scoring systems:

A – E grading z Scores

Performance is defined for single surveys, but in addition, cumulative performance based on consecutive surveys is also determined. Full details of these statistical methods can be found on page 21. These methods are also as described in ISO13528.

Performance is assessed against either all participant data returned for a test/assay, or against data from a peer group of centres using the same methodology. This is based on whether results are expected to be commutable and comparable between different methods. Below are the groupings used for data analysis currently employed in this programme.

Protein C antigen – all data
Protein C activity – chromogenic or clot-based assay
Protein S total antigen – all data
Protein S free antigen – all data
Protein S activity – not assessed
Antithrombin antigen – units (u/dl or mg/dl)
Antithrombin activity – assay substrate source (Xa/bovine thrombin/human thrombin)
Activated Protein C resistance. – kit/reagent and unit of reporting
Plasminogen – all data

Reports: Participant reports are made available online within 2 weeks of the closing date of the survey. Reports show the sample details, median results, and an indication of performance for each test/assay registered. Historic performance and histograms of results from all participants form part of the report. An overall report detailing results for all methods for each test, along with statistical analysis details, is made available within a month of individual report issue.

DOAC assays programme: Dabigatran, Rivaroxaban, Apixaban, Edoxaban

The DOAC (direct oral anticoagulant) assays programme comprises 4 exercises per year, each including samples for assay of dabigatran, rivaroxaban, apixaban, and edoxaban. A schedule of the planned surveys can be downloaded from our website www.uknegasbc.org.

Participants register for only the DOAC assays they perform in their department.

Sample details: All samples are of lyophilised plasma, from donors receiving treatment with direct oral anticoagulants. Where commutability with clinical samples has been demonstrated, samples spiked with DOAC may also be used. Full instructions on storage, reconstitution and testing are provided with each survey distribution.

Reporting results: Data reporting is currently paper-based. Participants are asked to complete the method details for each test they perform and are asked to check their method details for accuracy to ensure analysis in appropriate peer groups.

The closing date for these surveys is 6 weeks from the date of distribution.

Participants are provided with email alerts at the time of survey distribution, and survey closing date reminders are also sent by email. Participants are required to return results for each survey for any DOAC assay for which they are registered. Failure to return a result is logged as a non-return. Results can be returned at any time up until the survey is formally closed. Once the survey is reported, changes to results are not possible.

Performance analysis: Performance for DOAC assays is determined using z scores. Performance is defined for single surveys, but in addition, cumulative performance based on consecutive surveys is also determined. Full details of these statistical methods can be found on page 21. These methods are also as described in ISO13528. Performance is assessed against all assay data returned for a survey.

Reports: Participant reports are made available online within 3 weeks of the closing date of the survey. Reports show the sample details, median results, and an indication of performance, along with breakdowns of results returned for each method.

FXIII assays programme

The FXIII assays programme comprises 2 exercises per year, each including two samples for FXIII clot solubility testing and/or FXIII assay. A schedule of the planned surveys can be downloaded from our website www.ukneqasbc.org.

Sample details: All samples are of lyophilised plasma, from donors with congenital or acquired FXIII deficiency or normal donors. Full instructions on storage, reconstitution and testing are provided with each survey distribution.

Reporting results: Data reporting is online, through a secure portal and participant login via unique passwords. Participants are asked to complete the online results forms, including method details for each test they perform, and are asked to check their method details for accuracy to ensure analysis in appropriate peer groups.

The closing date for these surveys is 6 weeks from the date of distribution.

Participants are provided with email alerts at the time of survey distribution, and survey closing date reminders are also sent by email. Participants are required to return results for each survey. Failure to return a result is logged as a non-return. Results can be returned at any time up until the survey is formally closed. Once the survey is reported, changes to results are not possible.

Performance analysis: Performance for FXIII assays is determined using z scores. Performance is defined for single surveys, but in addition, cumulative performance based on consecutive surveys is also determined. Full details of these statistical methods can be found on page 21. These methods are also as described in ISO13528. Performance is assessed against all assay data returned for that survey. Performance is not assessed for clot solubility test results.

Reports: Participant reports are made available online within 2 weeks of the closing date of the survey. Reports show the sample details, median results, and an indication of performance, along with breakdowns of results returned for each method.

ADAMTS13 assays programme

The ADAMTS13 assays programme comprises 2 exercises per year, each including samples for assay of ADAMTS13 antigen, ADAMTS13 activity and ADAMTS13 inhibitors. A schedule of the planned surveys can be downloaded from our website www.ukneqasbc.org.

Sample details: All samples are of lyophilised plasma, from donors with and without TTP. Full instructions on storage, reconstitution and testing are provided with each survey distribution.

Reporting results: Data reporting is currently paper-based. Participants are asked to complete the method details for each test they perform and are asked to check their method details for accuracy to ensure analysis in appropriate peer groups.

The closing date for these surveys is 6 weeks from the date of distribution.

Participants are provided with email alerts at the time of survey distribution, and survey closing date reminders are also sent by email. Participants are expected to return results for each survey for any ADAMTS13 assay they perform. Failure to return a result is logged as a non-return. Results can be returned at any time up until the survey is formally closed. Once the survey is reported, changes to results are not possible.

Performance analysis: Performance for ADAMTS13 assays is determined using z scores. Performance is defined for single surveys, but in addition, cumulative performance based on consecutive surveys is also determined. Full details of these statistical methods can be found on page 21. These methods are also as described in ISO13528. Performance is assessed against method specific assay data.

Reports: Participant reports are made available online within 2 weeks of the closing date of the survey. Reports show the sample details, median results, and an indication of performance along with breakdowns of results returned for each method.

Lupus Anticoagulant programme

The Lupus Anticoagulant programme comprises 2 exercises per year, each including one or two samples for Lupus Anticoagulant screening, including solid phase assays. A schedule of the planned surveys can be downloaded from our website www.uknegasbc.org.

Sample details: All samples are of lyophilised plasma, from donors with lupus anticoagulant, other inhibitors, factor deficiency or normal donors. Full instructions on storage, reconstitution and testing are provided with each survey distribution.

Reporting results: Participants are able to return results for APTT (2 reagents), DRVVT, Silica Clotting time, Kaolin Clotting time, and solid phase assays for Anticardiolipin and B2gp1 antibodies. Data reporting is online, through a secure portal and participant login via unique passwords. Participants are asked to complete the online results forms, including method details for each test they perform, and are asked to check their method details for accuracy to ensure analysis in appropriate peer groups.

The closing date for these surveys is 6 weeks from the date of distribution.

Participants are provided with email alerts at the time of survey distribution, and survey closing date reminders are also sent by email. Participants are required to return results for each survey. Failure to return a result is logged as a non-return. Results can be returned at any time up until the survey is formally closed. Once the survey is reported, changes to results are not possible.

Performance analysis: Performance for Lupus anticoagulant screening exercises is based on the overall interpretation. Performance is defined for single surveys, but in addition, cumulative performance based on consecutive surveys is also determined. Full details of these statistical methods can be found on page 23.

Reports: Participant reports are made available online within 2 weeks of the closing date of the survey. Reports show the sample details, median results, and an indication of performance along with breakdowns of results returned for each method.

Homocysteine assays programme

The homocysteine programme comprises 4 exercises per year, each including a sample for homocysteine assay. A schedule of the planned surveys can be downloaded from our website www.uknegasbc.org.

Sample details: All samples are of lyophilised plasma, with either normal or elevated levels of plasma homocysteine. Full instructions on storage, reconstitution and testing are provided with each survey distribution.

Reporting results: Data reporting is online, through a secure portal and participant login via unique passwords. Participants are asked to complete the online results forms, including method details for each test they perform, and are asked to check their method details for accuracy to ensure analysis in appropriate peer groups.

The closing date for these surveys is 4 weeks from the date of distribution.

Participants are provided with email alerts at the time of survey distribution, and survey closing date reminders are also sent by email. Participants are required to return results for each survey. Failure to return a result is logged as a non-return. Results can be returned at any time up until the survey is formally closed. Once the survey is reported, changes to results are not possible.

Performance analysis: Performance for homocysteine assays is determined using one or more of the following scoring systems:

A – E grading z Scores

Performance is defined for single surveys, but in addition, cumulative performance based on consecutive surveys is also determined. Full details of these statistical methods can be found on page 21. These methods are also as described in ISO13528. Performance is assessed against all assay data returned for that survey.

Reports: Participant reports are made available online within 2 weeks of the closing date of the survey. Reports show the sample details, median results, and an indication of performance along with breakdowns of results returned for each method.

Molecular Genetics of Thrombophilia programme

The Molecular Genetics of Thrombophilia programme comprises 3 exercises per year, each including 3 samples for investigation for Factor V Leiden (FVL) and the P20210A Prothrombin gene polymorphism. Participants can request to receive samples for MTHFR measurement. A schedule of the planned surveys can be downloaded from our website www.ukneqasbc.org.

Sample details: All samples are prepared from whole blood donations, from donors with FVL and/or P20210A polymorphisms, or from donors with neither polymorphism. The nature of the material, as freshly aliquoted whole blood, precludes any requirement for homogeneity testing. Stability of samples for the duration of the survey is determined. Full instructions on storage and testing are provided with each survey distribution.

Reporting results: Data reporting is online, through a secure portal and participant login via unique passwords. Participants are asked to complete the online results forms, providing an interpretation (Homozygous/Heterozygous/Absent) for the presence of the relevant mutation. Method details for are requested for each test they perform.

The closing date for these surveys is 6 weeks from the date of distribution.

Participants are provided with email alerts at the time of survey distribution, and survey closing date reminders are also sent by email. Participants are expected to return results for each survey. Failure to return a result is logged as a non-return. Results can be returned at any time up until the survey is formally closed. Once the survey is reported, changes to results are not possible.

Performance analysis: Performance for the Molecular Genetics of Thrombophilia is determined based on agreement with the consensus interpretation (homozygous/heterozygous/absent). Performance is defined for single surveys, but in addition, cumulative performance based on consecutive surveys is also determined. Full details of these statistical methods can be found on page 23.

Reports: Participant reports are made available online within 2 weeks of the closing date of the survey. Reports show the sample details, interpretations, and performance based on comparison of interpretations with the majority view. A commentary is included with each report.

Genetics of Heritable Bleeding and thrombotic disorders programme

The Genetics of Heritable Bleeding and thrombotic disorders programme comprises 2 exercises per year, each including samples for investigation of the *F8*, *F9* or *VWF* gene. In addition, up to two paper-based exercises are included, based on a selection of clinical scenarios for other haemostasis gene investigations. A schedule of the planned surveys can be downloaded from our website www.ukneqasbc.org.

Sample details: All samples are prepared from whole blood donations, from donors with haemophilia A or B, or von Willebrands disease, or from carriers or normal donors. The nature of the material, as freshly aliquoted whole blood, precludes any requirement for homogeneity testing. Stability testing is not routinely carried out due to sample size limitations, however stability studies have demonstrated consistent genetics results after over 6 weeks of storage at ambient temperature.

Each survey distribution includes full instructions on storage and testing of samples, including any recommended gene regions, such as specific exons, to be investigated. A clinical scenario and question is provided with each exercise.

Reporting results: Participants are required to prepare a report on their investigation, based on the gene analysis data and the question posed in the clinical scenario. Reports can be uploaded online, through a secure portal and participant login via unique passwords or emailed.

The closing date for these surveys is 6 weeks from the date of distribution.

Participants are provided with email alerts at the time of survey distribution, and survey closing date reminders are also sent by email. Participants are expected to return results for each survey. Failure to return a result is logged as a non-return. Results can be returned at any time up until the survey is formally closed. Once the survey is reported, changes to results are not possible.

Performance analysis: Performance for the Genetics of Heritable Bleeding and thrombotic disorders programme is determined on consensus scores from the Specialist Advisory Group. Performance scores are based on clerical, genetic analysis, and interpretation accuracy. Performance is defined for single surveys, but in addition, cumulative performance based on consecutive surveys is also determined. Full details of these statistical methods can be found on page 23.

Reports: Individual participant reports are made available online within 2 weeks of the performance review by the Specialist Advisory Group. Reports show the performance score obtained for each category (clerical, genetic analysis and interpretation accuracy). A commentary report is also provided to participants.

Heparin Induced Thrombocytopenia (HIT) programme

The HIT programme comprises 2 exercises per year, each including one or two samples for HIT screening. A schedule of the planned surveys can be downloaded from our website www.uknegasbc.org.

Sample details: All samples are of lyophilised plasma, from donors with HIT antibodies or normal donors. Full instructions on storage, reconstitution and testing are provided with each survey distribution.

Reporting results: Data reporting is currently paper-based. Participants are asked to complete the method details for each test they perform and are asked to check their method details for accuracy to ensure analysis in appropriate peer groups.

The closing date for these surveys is 6 weeks from the date of distribution.

Participants are provided with email alerts at the time of survey distribution, and survey closing date reminders are also sent by email. Participants are required to return results for each survey. Failure to return a result is logged as a non-return. Results can be returned at any time up until the survey is formally closed. Once the survey is reported, changes to results are not possible.

Performance analysis: Performance for HIT screening exercises is based on the overall interpretation plus quantitative data for methods if $n \geq 10$. Performance is defined for single surveys, but in addition, cumulative performance based on consecutive surveys is also determined. Full details of these statistical methods can be found on page 23.

Reports: Participant reports are made available within 3 weeks of the closing date of the survey. Reports show the sample details, median results, and an indication of performance, along with breakdowns of results returned for each method.

Other laboratory programmes

The following programmes are not currently included in the UKAS schedule of accreditation.

FVIII & IX treatment monitoring

Sample details: Participants will receive samples of treatment products for which they have registered (max n=5). All samples are of lyophilised haemophilic plasma, from donors containing FVIII or FIX drug treatments at various levels. Where commutability with clinical samples has been demonstrated, deficient plasma spiked with FVIII/FIX drugs will be used. Full instructions on storage, reconstitution and testing are provided with each survey distribution.

There will be 4 surveys per year.

Reporting results: Data reporting is currently paper based. Each survey includes specific instructions for performing assays and recording results. Participants are asked to complete the method details for each test they perform, to ensure analysis in appropriate peer groups.

Participants are provided with email alerts at the time of survey distribution, and survey closing date reminders are also sent by email. Participants are required to return results for each survey. Failure to return a result is logged as a non-return. Results can be returned at any time up until the survey is formally closed. Once the survey is reported, changes to results are not possible.

Performance analysis: If a recommended laboratory monitoring method is used performance assessment will be applied including median, % deviation, Z-score and a performance comment. Performance will be based on z scores. Further details can be found on page 22 of this document. Cumulative performance will also be provided after 3 consecutive surveys. If a non- recommended monitoring method and reagent are used, there will be no performance assessment.

Reports: Individual participant reports are prepared, along with an overall summary report for each exercise. These are made available and sent out to participants 3 to 4 weeks after the closing date of the survey.

FVIII inhibitors assay

Sample details: All samples are of lyophilised plasma, from haemophilic donors with or without FVIII inhibitors at various levels. Full instructions on storage, reconstitution and testing are provided with each survey distribution.

There will be 2 surveys per year.

Reporting results: Data reporting is currently paper based. Each survey includes specific instructions for performing assays and recording results. Participants are asked to complete the method details for each test they perform, to ensure analysis in appropriate peer groups.

Participants are provided with email alerts at the time of survey distribution, and survey closing date reminders are also sent by email. Participants are required to return results for each survey. Failure to return a result is logged as a non-return. Results can be returned at any time up until the survey is formally closed. Once the survey is reported, changes to results are not possible.

Performance analysis: Performance assessment will be applied including median, % deviation, Z-score and a performance comment included if the statistical data group allows. Performance will be based on z scores. Further details can be found on page 22 of this document. Cumulative performance will also be provided after 3 consecutive surveys.

Reports: Individual participant reports are prepared, along with an overall summary report for each exercise. These are made available and sent out to participants 3 to 4 weeks after the closing date of the survey.

Emicizumab assay

Sample details: All samples are of lyophilised haemophilic plasma, from donors containing Emicizumab drug treatments at various levels. Where commutability with clinical samples has been demonstrated, samples spiked with Emicizumab drugs will be used. Full instructions on storage, reconstitution and testing are provided with each survey distribution.

There will be 4 surveys per year.

Reporting results: Data reporting is currently paper based. Each survey includes specific instructions for performing assays and recording results. Participants are asked to complete the method details for each test they perform, to ensure analysis in appropriate peer groups.

Participants are provided with email alerts at the time of survey distribution, and survey closing date reminders are also sent by email. Participants are required to return results for each survey. Failure to return a result is logged as a non-return. Results can be returned at any time up until the survey is formally closed. Once the survey is reported, changes to results are not possible.

Performance analysis: If a recommended laboratory monitoring method is used performance assessment will be applied including median, % deviation, Z score and a performance comment. Performance will be based on z scores. Further details can be found on page 22 of this document. Cumulative performance will also be provided after 3 consecutive surveys. If a non-recommended monitoring method, there will be no performance assessment.

Reports: Individual participant reports are prepared, along with an overall summary report for each exercise. These are made available and sent out to participants 3/4 weeks after the closing date of the survey.

Anytest programme

This programme is designed for centres performing tests or assays that are not covered by any of the programmes described above. Participants are provided with samples of human plasma and invited to perform whichever test(s) they choose. Data are collated and a summary report is prepared detailing median results and ranges for each test performed on the plasma.

Point of Care Testing programmes

We also provide EQA programmes for a range of point of care testing (POCT) investigations.

These include:

POCT INR – for CoaguChek XS, XS Plus, XS Pro and Pro II devices, iSTAT, Xprecia Stride, Lumira DX

POCT D-DIMER – for Triage and Cobas h232 devices

POCT ACT+ & ACT-LR – for Hemochron devices; ACT for i – Stat1 and i - Stat Alinity devices

POCT ROTEM & TEG – for TEG, TEG6, Rotem Delta and Rotem Sigma devices

We also carry out regular evaluations of EQA material for POCT devices. For further information, visit the Point of Care Testing pages on the website www.negascoag.org

Performance analysis – detailed information

The following performance analysis tools are employed in the UK NEQAS BC laboratory programmes. (*note, some programme reports show analysis using several of the methods below; the method employed for performance assessment is indicated in the relevant programme section*)

% deviation

Calculation: The % deviation of a result (x) from the median (y) is calculated: $((x/y)-1)*100$

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

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

- The **reagent median** if the number of users of that reagent is equal to or greater than 10 or
- The **overall median** if the number of users of the reagent is less than 10.
- Results >15% deviation from the median are considered “*outwith consensus*.”

For Heparin Dosage Assessment (HDA) and thrombin times, modified criteria apply. In both cases, results >20% deviation from reagent medians for majority groups is considered *outwith consensus*. Marked differences in the heparin sensitivity of APTT reagents have led to the conclusion that it is inappropriate to assess minority reagent users against the overall median. No performance analysis is applied to minority groups, although % deviation from reagent and overall medians are recorded on individual reports.

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

Cumulative performance criteria: This is based on results from 3 consecutive surveys. If results from all 3 surveys are ‘outwith consensus’, the cumulative performance is flagged as ‘persistently outwith consensus’, prompting a letter from the Scheme Director to the head of department, offering assistance.

A-E (quantile) grading

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

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

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

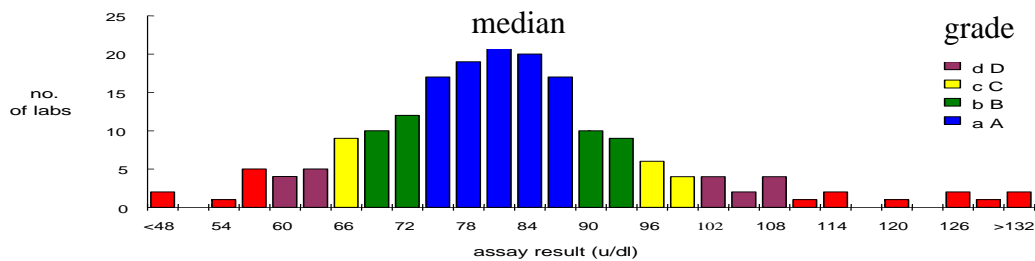
Group B: The next 10% of results above (B) and below (b) the median (i.e. 20% of results);

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

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

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

This is illustrated below:



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

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

Cumulative performance criteria: *Persistent "outwith consensus" performance* is defined as two consecutive *"outwith consensus"* performances, where the order in which the grades were assigned does not affect the overall performance. This will arise from three consecutive performances with the following combinations of grades (upper case only shown):

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

Participants recording these grades will receive a letter from the Scheme Director to the head of department, offering assistance. A **non-return** for a registered test will be graded as 'F' and taken as equivalent to an E grading..

In some cases, significant differences have been noted between different methodologies. Where this occurs on a consistent basis, separate analysis of the groups is carried out using medians specific to each method group. However, the system is only effective if the number of participants is greater than 20; consequently, grading analysis is not applied to groups of results from fewer than 20 centres. In these cases we recommend that the participant compares their result with the median for users of the same method, alongside the overall assay median and evaluates whether any differences from these results have clinical relevance. We recommend this approach for *all* participants, including those receiving a performance assessment of their results.

Z scores

Calculation: The robust mean and standard deviation (excluding outliers) are determined (see ISO 13528). Z scores are determined from the result (a) the robust mean (x) and robust SD (s): $(a-x)/s$.

Performance criteria: , z scores are assigned a performance flag, as detailed in the table 2 below.

z score	< -3	< -2	-2 to +2	> +2	> +3
Performance	Outwith consensus	Outwith consensus	Within consensus	Outwith consensus	Outwith consensus
Performance flag	Action required	Warning		Warning	Action required

Warning flags in consecutive surveys are also assigned an "action required" flag. Where 2 samples are distributed in a survey, the above criteria apply to either result.

A failure to return results is assigned a z score of 2.1

Cumulative performance criteria: This is based on results from 2 or more surveys.

Interpretation (Molecular Genetics of thrombophilia programme)

For the Molecular Genetics of thrombophilia programme – The consensus view for the presence or absence of the mutation is used to assign the ‘correct’ interpretation (homozygous, heterozygous or absent). If the consensus view is below 80% of responses, performance will not be assessed.

Performance criteria: Participant performance is considered ‘satisfactory’ if in agreement with the consensus view (‘correct’ interpretation). If not in agreement, performance is ‘unsatisfactory’, Failure to return any results is flagged as a non return.

Cumulative performance criteria: Performance is deemed ‘persistent’ if two unsatisfactory results are recorded in a five year period. A letter from the Scheme director will be sent to the head of department for any unsatisfactory performance, or for any two consecutive non returns.

Report content and format (Genetics of heritable bleeding and thrombotic disorders programme)

For the Genetics of heritable bleeding and thrombotic disorders programme –

Reports are anonymised and then scored by the Specialist Advisory Group. In line with Clinical Molecular Genetics Society (CMGS) policy each report is scored on the basis of:

- i) Clerical Accuracy
- ii) The results of genotyping
- iii) Interpretation of the genetic results in the context of the clinical history, relevant factor assays and in particular, whether it answers the clinical question that was posed.

Maximum score for each category is 2, and where a report is considered to have an error in any of the above categories, marks will be deducted. If the score for any category is below 1, this is deemed a fail, and failure in any one category confers an overall fail for the exercise.

For the paper-based exercises, since the genotyping results are provided with the exercise, performance is only scored for clerical accuracy and interpretation.

Laboratories that participate in the scheme but fail to return a report within the designated time frame are deemed to have failed that particular exercise. Any centre failing an exercise will receive a letter from the Scheme Director offering support.

Interpretation (Lupus Anticoagulant Screening programme, HIT programme)

For the Lupus anticoagulant (LA) screening and HIT programmes – the consensus view for the presence or absence of LA or HIT is used to assign the ‘correct’ interpretation. If the consensus view is below 80% of responses, performance will not be assessed.

Performance criteria: Participant performance is considered ‘within consensus’ if in agreement with the consensus view (‘correct’ interpretation). If not in agreement, performance is ‘outwith consensus’, Failure to return any results is flagged as a non return.

Cumulative performance criteria: Performance is deemed ‘persistent’ if three ‘outwith consensus’ results are recorded in consecutive surveys.

A letter from the Scheme director will be sent to the head of department for any persistently outwith consensus performance, including persistent non returns.

Troubleshooting and Support

The aim of UK NEQAS (Blood Coagulation) is to provide support, advice and guidance to participants who record outwith consensus, unsatisfactory or failing results.

This support can take the form of advice from a team of internationally recognised experts in the field of laboratory haemostasis. Additional data analysis, advice on assay design, and provision of repeat samples to investigate outwith consensus performance is available to all participants. Letters from the Scheme Director offer assistance if required, and further information is available to participant via the website, together with forms to help structure investigations.

Complaints and appeals policy

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

Address for complaints:

UK NEQAS (Blood Coagulation), 3rd Floor, Pegasus House, 463A Glossop Road, Sheffield S10 2QD, UK

Tel: +44 (0)114 267 3300

E-mail: neqas@coageqa.org.uk

Appeals based on reports received may be made by email neqas@coageqa.org.uk. All appeals will be considered, and participants will receive a response to their appeal within 2 weeks of receipt.

Late results, errors and blunders

Where errors are identified prior to survey closing and report being issued, we are able to amend results; once reports are issued, we are unable to accept results or changes to results and re-issue reports; however participants are able and encouraged to test samples and compare their results to the target values for that exercise. Advice may be found on the UK NEQAS BC website related to late or amended results:

<https://www.negascoag.org/contact/faqs/>

UK NEQAS Blood Coagulation: Oversight, advice and accreditation

UK NEQAS BC is part of Sheffield Teaching Hospitals NHS Trust, and all staff hold contracts with the Trust. Accreditation with UKAS (see below) is based on our position within the Trust, with whom a service level agreement is in place. UK NEQAS BC is a member of the UK NEQAS Consortium, a charitable organisation of EQA providers across the many disciplines of pathology.

We receive advice and support from a Steering Committee, comprised of clinical and scientific experts in the field of haemostasis, with whom regular meetings are held. Please see below for the current members of this Committee. In addition, we receive specialist genetics guidance and advice from a Specialist Advisory Group, comprised of clinicians and scientists with specific expertise in genetic disorders of haemostasis. We receive further oversight in the UK from the National Quality Assurance Advisory Panel for Haematology (NQAAP) and the Joint Working Group (JWG) of the Royal College of Pathologists.

We are accredited to ISO 17043 through the United Kingdom Accreditation Service (UKAS). The current certificate of accreditation can be found here

https://www.ukas.com/wp-content/uploads/schedule_uploads/00013/7873Proficiency-Testing-Multiple.pdf

UK NEQAS BC Staff

Professor I D Walker is Director of UK NEQAS for Blood Coagulation, 3rd Floor, Pegasus House, 463A Glossop Road, Sheffield S10 2QD UK.

Members of UK NEQAS for Blood Coagulation personnel include:

Dr I Jennings	Manager & Deputy Director
Dr C Reilly-Stitt	Deputy Manager
Dr S Kitchen	Scientific Director
Ms D P Kitchen	Scientific Lead, Point of Care (POC) programmes
Ms S Munroe-Pearl	Quality Manager & Biomedical Scientist
Ms L Brown	Biomedical Scientist
Ms A Williams	Scientific Lead, Haemophilia programmes
Ms J Foster	Office Manager
Ms J Ogden	EQA Programme Co-ordinator / Deputy Quality Manager
Ms S Shikdar	IT Specialist
Ms S Burdett	MLA
Ms C Mather	MLA
Ms T Withington	MLA
Ms H King	Secretary / Receptionist

STEERING COMMITTEE MEMBERS

Dr W Lester (Chair)
Dr G Evans
Dr H Lyall
Mr S Platton
Dr H Wilmot
Dr A Wood
Dr P Baker (representing BSH Thrombosis & Haemostasis Task Force)
Mr S MacDonald (representing NQAAP)
Dr M Sutherland (chair of SAG)

Dr I Jennings	UK NEQAS Blood Coagulation, Sheffield
Ms D P Kitchen	UK NEQAS Blood Coagulation, Sheffield
Dr S Kitchen	UK NEQAS Blood Coagulation, Sheffield
Mr C Reilly-Stitt (secretary)	UK NEQAS Blood Coagulation, Sheffield
Professor I D Walker	UK NEQAS Blood Coagulation, Sheffield

SPECIALIST ADVISORY GROUP MEMBERS

Dr Megan Sutherland (chair)
Dr Ruth Wheeler (secretary)
Dr K Gomez
Dr Carolyn M Millar
Dr Andrew Page

Dr I Jennings	UK NEQAS Blood Coagulation, Sheffield
Dr S Kitchen	UK NEQAS Blood Coagulation, Sheffield
Mr C Reilly-Stitt	UK NEQAS Blood Coagulation, Sheffield
Professor I D Walker	UK NEQAS Blood Coagulation, Sheffield

UK NEQAS BC EDUCATIONAL ACTIVITIES

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

Well established Annual Scientific Meetings include presentations from nationally and internationally renowned speakers, in addition to data from survey distributions and open debate on EQA issues.

SUPPLEMENTARY EXERCISES

Supplementary exercises are carried out to address topical issues in haemostasis testing. Recent exercises have included diagnostic challenges, and exploration of pre-analytical variables with haemolysed samples.

QUESTIONNAIRES

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

PUBLICATIONS

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

UK NEQAS BC is also represented by the scientific team on a number of national and international scientific committees, including the WFH IEQAS and Laboratory programme committees, UKHCDO, BSH Haemostasis and Thrombosis Task Force, EQATH executive committee. UK NEQAS BC scientists have co-authored many national and international guidelines on haemostasis and thrombosis practice.

Selected recent publications:

Kitchen S, Bowyer A, Lowe A, Jennings I, Walker ID. External quality assessment for one-stage and chromogenic factor IX assays in samples containing Alprolix (rFIXFc) or Idelvion (rIX-FP) and evidence that UK National External Quality Assessment Scheme for blood coagulation samples are commutable with patient samples. *Int J Lab Hematol*. 2022 Jan 17. doi: 10.1111/ijlh.13795. Epub ahead of print. PMID: 35040275.

Reilly-Stitt C, Kitchen S, Jennings I, Horner K, Jones R, Makris M, Walker ID. Anti-PF4 testing for vaccine-induced immune thrombocytopenia and thrombosis and heparin induced thrombocytopenia: Results from a UK National External Quality Assessment Scheme exercise April 2021. *J Thromb Haemost*. 2021 Sep;19(9):2263-2267

Batty P, Riddell A, Kitchen S, Sardo Infirri S, Walker I, Woods T, Jennings I, Hart DP. Factor VIII/IX inhibitor testing practices in the United Kingdom: Results of a UKHCDO and UKNEQAS national survey. *Haemophilia*. 2021 May;27(3):490-499.

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Jennings I, Kitchen S, Menegatti M, Palla R, Walker I, Peyvandi F, Makris M. Potential misdiagnosis of dysfibrinogenaemia: Data from multicentre studies amongst UK NEQAS and PRO-RBDD project laboratories. *Int J Lab Hematol*. 2017; 39(6):653-662.

Jennings I, Perry D, Watson H, Alikhan R, Laffan M, Gomez K, Kitchen S, Walker I; Haemostasis and Thrombosis Task Force of the British Society for Haematology & UK NEQAS for Blood Coagulation. Quality assurance and tests of platelet function. *Br J Haematol*. 2018; 181(4):560-561.

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Kitchen S, Jennings I, Makris M, Kitchen DP, Woods TA, Walker ID. Factor VIII assay variability in postinfusion samples containing full length and B-domain deleted FVIII. *Haemophilia*. 2016; 22(5):806-12.

Kitchen DP, Kitchen S, Jennings I, Woods TA, Makris M, Walker ID. Quality control of point of care INR devices is essential. *BMJ*. 2016; 12;353

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