

# **UK NEQAS**

## Blood Coagulation

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### **UK National External Quality Assessment Scheme for Blood Coagulation**

### **PARTICIPATION MANUAL & GENERAL INFORMATION LABORATORY PROGRAMMES**

**2026/27**

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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/download-schedule/7873/ProficiencyTesting/>. Currently we provide 15 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 4500 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 70 articles on EQA in peer reviewed journals and presented in excess of 120 abstracts/posters at national and international meetings.

## About the UK NEQAS organisation and the UK NEQAS Charity

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

UK NEQAS BC is proud to be a member of the UK NEQAS charity. UK NEQAS is a network of EQA centres offering more than 400 EQA programmes, all overseen by the UK NEQAS educational charity. As a world leader in EQA, providing optimum EQA services since 1969, we deliver an unparalleled, multidisciplinary range of services by a team that really understands the clinical relevance of EQA and how it supports diagnostic testing for the benefit of patients. All UK NEQAS centres are accredited to ISO17043 and are resolutely impartial and independent.

Being part of UK NEQAS means that you have access to the support of hundreds of expert clinical and scientific advisors, wanting to share best practice. This leads to unrivalled opportunities for collaboration within and across disciplines, at home and internationally. Education is placed at the heart of EQA, which empowers you to work smarter. We share our knowledge in partnership, supporting performance improvements through regular quality assessments that challenge testers at critical decision-making performance limits. And with experts at the end of the phone ready to help, you can access the right individual support, as and when it is needed.

Working with us, as part of UK NEQAS, you enjoy the unprecedented benefits from a global EQA leader, a unique, education-focused approach, and proven expertise. You know that you are being compared to the best, by the best.

The UK NEQAS Charity is led by an elected UK 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 in Sheffield.

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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 1<sup>st</sup> April to 31<sup>st</sup> 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. If any amendments to the survey programmes are introduced, participants will be contacted.

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](http://www.neqascoag.org)) or directly from the following link; <https://www.neqascoag.org/terms-and-conditions/>

As part of registration, participants in the UK agree to oversight from the Royal College of Pathologists Quality Assurance in Pathology committee (see <https://www.rcpath.org/profession/committees/qapc.html>)

### 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](mailto:neqas@coageqa.org.uk)) or download a permission form from the website:

<https://www.neqascoag.org/about-1/presenting-neqas-data/>

## 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 3<sup>rd</sup> 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, overseen by the Quality Assurance in Pathology Committee (<https://www.rcpath.org/profession/committees/qapc.html>). In this respect, the process is as follows:

Any centre consistently performing outwith consensus without response will be referred to the Programme Director, who may consider contacting the Advisory Panel. Participants will be warned after 4 consecutive results that their performance may be referred anonymously to the Steering Committee. Following one further outwith consensus result the participant will be discussed anonymously with the Steering Committee.

Information about a participant or customer from a source other than the participant (e.g. complainant or regulator) shall be kept confidential by UK NEQAS BC. The identity of the source shall be kept confidential by UK NEQAS BC and shall not be shared with the participant, unless agreed by the source.

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](http://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, from UK donations or from third party sources. 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. 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; some 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. UK NEQAS BC is responsible for all activities supplied by external providers.

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:** Four survey exercises are distributed each year. Level 1 surveys include all screening tests, and level 2 surveys include all assays. . A schedule of the planned survey distribution dates can be downloaded from our website [www.uknegasbc.org](http://www.uknegasbc.org). Table 1 indicates range of tests included in these exercises, with an indication of the performance analysis approach for each test.

Table 1.	Scoring method used	Peer group analysis?
INR (venous and/or capillary methods) for Vitamin K antagonist (VKA) monitoring	% deviation	By reagent
Prothrombin time (PT) (diagnostic)	% deviation	By reagent
Activated Partial Thromboplastin Time (APTT)	% deviation	By reagent
Fibrinogen assay (Clauss methods)	% deviation	Overall
Thrombin Time (TT)	% deviation	By reagent
Reptilase Time (RT)	% deviation	By reagent
Heparin Dosage Assessment (HDA) – APTT for Unfractionated Heparin (UFH)	% deviation	By reagent
Heparin Assay (HA) – anti-Xa assay for Unfractionated Heparin (UFH)	z score	Kit/reagent
Heparin Assay (HA) – anti-Xa assay for Low Molecular Weight Heparin (LMWH)	z score	Kit/reagent
D-Dimer	z score	Kit/reagent and units
Factor II assay	z score	All data
Factor V assay	z score	All data
Factor VII assay	z score	All data
Factor X assay	z score	All data
Factor VIII assay	z score	Assay method data
Factor IX assay	z score	All data
Factor XI assay	z score	All data
Factor XII assay	z score	All data
Von Willebrand factor antigen (VWF:Ag)	z score	All data
VWF activity assay (VWF:RC <sub>0</sub> ;VWF:GPIbR;VWF:GPIbM)	z score	Method subgroup
VWF collagen binding assay (VWF:CB)	z score	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 individual account details. 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 –comparison with the overall interpretations can help indicate the clinical relevance of any results.

The closing date for these surveys is 5-6 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 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    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 23. 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, along with summary tables of all methods used for each test. A survey newsletter provides further information with respect to performance assessment and interpretation of results.

## 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.uknegasbc.org](http://www.uknegasbc.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 individual account details. 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 – comparison with the interpretations can help indicate the clinical relevance of any results. An overall interpretation is also requested.

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 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 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 23. 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 – result 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, along with summary tables of all methods used for each test.

## 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](http://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 online, through a secure portal and participant login via unique individual account details. 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 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 23. 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 4 exercises per year, each including samples for FXIII assay. A schedule of the planned surveys can be downloaded from our website [www.ukneqasbc.org](http://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 individual account details. 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 23. These methods are also as described in ISO13528. Performance is assessed against method specific assay data returned for that survey. Performance is not assessed for clot solubility test results.

**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.

## ADAMTS13 assays programme

The ADAMTS13 assays programme comprises 4 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.uknegasbc.org](http://www.uknegasbc.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 online, through a secure portal and participant login via unique individual account details. 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 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 23. These methods are also as described in ISO13528. Performance is assessed against method specific assay data.

**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.

## 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.ukneqasbc.org](http://www.ukneqasbc.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.ukneqasbc.org](http://www.ukneqasbc.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 individual account details. 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 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 23. 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](http://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 variant. 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.uknegasbc.org](http://www.uknegasbc.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 4 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.

Paper exercises comprise a clinical scenario together with the results of screening for variants in a specific gene – participants are asked to complete a report on the exercise, and scoring for clerical and interpretation accuracy is performed as above.

## Heparin Induced Thrombocytopaenia (HIT) programme

The HIT programme comprises 4 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.ukneqasbc.org](http://www.ukneqasbc.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 online, through a secure portal and participant login via unique individual account details. 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 HIT screening exercises is based on the overall interpretation, plus quantitative data by z scores is determined 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.

## FVIII and FIX Treatment Monitoring programmes

**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 online, through a secure portal and participant login via unique individual account details. 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. 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/reagent is used these results provide the median. The % deviation ~~and~~, z-score ~~and a performance assessment comment~~ will be calculated ~~including a performance assessment comment~~. If a non-recommended monitoring method and reagent are used, performance is determined against the recommended method median. Performance will be based on z scores. Further details can be found on page 23 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.

## FVIII Inhibitor assay programme

**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 4 surveys per year.

**Reporting results:** Data reporting is online, through a secure portal and participant login via unique individual account details. 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. 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. Participant assay performance for the FVIII inhibitor assay is determined from the submitted BU/ml results in relation to the sample type (Positive or Negative for FVIII Inhibitor). If  $\geq 80\%$  of all results are in agreement, this is defined as the majority view. Participant performance is classified as 'Wwithin consensus' if their result agrees with the majority view, or classed as 'Outwith consensus' if their result falls within the minority view. If results for a sample type are split such that fewer than 80% support any single interpretation, the sample will not be assessed for that survey. Further details can be found on page 23 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 programme

**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 online, through a secure portal and participant login via unique individual account details. 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.

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 participants are using the Modified One-Stage Assay method (MOSA), 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 23 of this document. Cumulative performance will also be provided after 3 consecutive surveys. If ~~a non~~there is a non-recommended monitoring method use by participants, there will be no performance assessment provided.

**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.

### *Other programmes, not currently accredited to ISO17043:*

#### *Platelets Light Transmission Aggregometry*

This programme is designed for UK centres performing light transmission aggregometry for platelet function investigation. Samples are provided by next-day courier delivery for testing, and compared for each agonist. Distributed twice per year.

#### *Prekallikrein / High Molecular Weight Kininogen (PK/HMWK) programme*

This programme is designed for centres performing PK/HMWK assays. Participants are provided with samples of plasma and asked to perform whichever of these assays they perform. Data are collated and an individual report is prepared detailing median results and ranges for each test performed on the plasma along with interpretations. Distributed twice per year.

#### *Mixing Studies programme*

This programme is designed for centres performing mixing studies/correction tests for PT and APTT. Participants are provided with samples of human plasma and asked to perform PT or APTT and where appropriate mixing studies. Data are collated and individual reports are prepared detailing median results and ranges for each test performed on the plasma along with interpretations. Distributed twice per year.

#### *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. Distributed on an ad hoc basis.

### ***Diagnostic Challenge programme***

This programme is designed for centres to make a diagnosis based on appropriate tests performed to supplement clinical information which is provided. Participants are provided with samples of human plasma and invited to perform whichever test(s) they consider necessary to make a diagnosis. Data are collated and a summary report is prepared detailing median results and ranges for each test performed on the plasma. Distributed on an ad hoc basis.

## **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 Prime, 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 TEG6 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.neqascoag.org](http://www.neqascoag.org)

## REGISTRATION FEES 2026-7

Shown below are the fees for participation in the UK NEQAS BC programmes in 2026-7.

**Registration fee** – 1<sup>st</sup> registration for each participant only **£202.00**  
(subsequent registrations at the same address, no fee)

<b>Screening tests programme (Level 1)</b> 4 tests p.a.	£
INR	84.00
INR: Capillary	84.00
Prothrombin Time for diagnosis Activated Partial Thromboplastin Time Fibrinogen estimation (Clauss)	Registration for any 1 of these 3 tests – 84.00 Registration for any 2 of these 3 tests - 162 Registration for all 3 tests -225.00
Heparin dosage assessment APTT	84.00
<b>New: Heparin assay (anti Xa UFH)</b>	<b>42.00</b>
Heparin assay (anti Xa LMWH)	84.00
Thrombin time	84.00
<b>NEW: Reptilase time</b>	<b>42.00</b>
D-Dimer	84.00
<b>Assays programme (Level 2)</b> 4 tests p.a.	£
Factor II assay Factor V assay Factor VII assay Factor X assay	Registration for any 1 of these 4 assays – 86.00 for any 2 of these 4 assays - 162.00 Registration for any 3 of these 4 assays -214.00 Registration for all 4 assays -245.00
Factor VIII assay Factor IX assay	Registration for any 1 of these 4 assays – 86.00 Registration for both assays - 162.00
Factor XI assay Factor XII assay	Registration for any 1 of these 4 assays – 86.00 Registration for both assays - 162.00
von Willebrand factor antigen von Willebrand activity assay von Willebrand collagen binding assay	Registration for any 1 of these 3 assays – 86.00 Registration for any 2 of these 3 assays – 162.00 Registration for all 3 assays -183.00
<b>Thrombophilia programme</b> 4 tests p.a.	
Antithrombin antigen assay	57.00
Antithrombin activity assay	57.00
Protein C antigen assay	57.00
Protein C activity assay	57.00
Protein S total antigen assay	57.00
Protein S free antigen assay	57.00
Protein S activity assay	57.00
Plasminogen assay	57.00
APC resistance assay	57.00

<b>Other laboratory programmes</b> ( <i>surveys p.a.</i> )	<b>£</b>
Thrombophilia Genetics (FVL) (3)	139.00
Lupus Anticoagulant Screening(2)	126.00
FXIII assays(4)	114.00
FVIII inhibitor assays (4)	114.00
ADAMTS13 assays (4)	114.00
DOACs (price per DOAC assay) (4)	101.00
Homocysteine assays (4)	114.00
HIT screening (4)	114.00
FVIII treatment monitoring (4) (price per product)	74.00
FIX treatment monitoring (4) (price per product)	74.00
Emicizumab assays (4)	101.00
Platelets – light transmission aggregometry (2)	430.00
<b>NEW: Mixing Studies exercises (2)</b>	<b>75.00</b>
<b>NEW: PK/HMWK assays (2)</b>	<b>75.00</b>

## 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) thrombin times and reptilase 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 the results reported by minority groups, although % deviation from reagent and overall medians are recorded on individual reports. Performance can be evaluated by comparison of laboratory interpretations with the majority view from interpretations reported by all participants.

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.

### 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.

<i>z score</i>	<i>&lt; -3</i>	<i>&lt; -2</i>	<i>-2 to +2</i>	<i>&gt; +2</i>	<i>&gt; +3</i>
<i>Performance</i>	<i>Outwith consensus</i>	<i>Outwith consensus</i>	<i>Within consensus</i>	<i>Outwith consensus</i>	<i>Outwith consensus</i>
<i>Performance flag</i>	<i>Action required</i>	<i>Warning</i>		<i>Warning</i>	<i>Action required</i>

*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*

For programmes performance assessed by z scores, a minimum of 10 results is required; where the target median is determined from fewer than 10 results, data are for guidance only.

**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 consistent 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 contact from the Scheme Director offering support.

## Interpretations

For some programmes (eg Lupus anticoagulant (LA) screening, FVIII inhibitor, HIT programmes) – where >80% of centres agree on the interpretation for a sample, this consensus interpretation is used to assign the correct interpretation, and the interpretation from the participant will be considered within or outwith consensus. If the consensus view is below 80% of responses, interpretive performance will not be assessed for the exercise. For other tests and assays, in addition to performance based on statistical analysis of results, comparison of local interpretations with the overall interpretation for the sample will give an assessment of performance for the laboratory.

## 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), 3<sup>rd</sup> Floor, Pegasus House, 463A Glossop Road, Sheffield S10 2QD,**

**UK Tel: +44 (0)114 267 3300**

**E-mail: [neqas@coageqa.org.uk](mailto:neqas@coageqa.org.uk)**

Appeals based on reports received may be made by email [neqas@coageqa.org.uk](mailto: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.neqascoag.org/contact/fags/>

## 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 Quality Assurance in Pathology Committee of the Royal College of Pathologists.

We are accredited to ISO 17043:2023 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](https://www.ukas.com/wp-content/uploads/schedule_uploads/00013/7873Proficiency-Testing-Multiple.pdf)

## UK NEQAS BC Staff

UK NEQAS for Blood Coagulation, 3<sup>rd</sup> Floor, Pegasus House, 463A Glossop Road, Sheffield S10 2QD UK.

Members of UK NEQAS for Blood Coagulation personnel include:

Dr W Lester	Clinical Director
Dr I Jennings	Manager & Deputy Director
Mr 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 Stevenson	MLA
Ms T Kelly	MLA
Ms H King	Secretary / Receptionist

## STEERING COMMITTEE MEMBERS

Mr P Baker (Chair)  
Dr D Arachchilage  
Dr J Hermans  
Mr S Platton  
Dr C Bagot (representing UKHCDO)  
Dr H Wilmot  
Dr L Roberts (representing BSH Thrombosis & Haemostasis Task Force)  
Mr S MacDonald (representing NQAAP)  
Dr M Sutherland (chair of SAG)  
Dr Gillian Evans

Dr W Lester	UK NEQAS Blood Coagulation, Sheffield
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
Ms A Williams	UK NEQAS Blood Coagulation, Sheffield

## SPECIALIST ADVISORY GROUP MEMBERS

Dr Megan Sutherland (chair)  
Dr Ruth Wheeler (secretary)  
Dr K Gomez  
Dr Andrew Page  
Dr C Keenan  
Dr Matt Simms

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
Dr W Lester	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 lipaemic 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:

Reilly-Stitt C, Jennings I, Kitchen S, Cahillane M, Saunders C, George C, Scorer T, Walker ID. Cold Stored Platelets: A Solution for Platelet Aggregation External Quality Assessment/Proficiency Testing. *Int J Lab Hematol*. 2025 Mar 10. doi: 10.1111/ijlh.14445. Epub ahead of print.

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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.

Brown L, Jennings I, Kitchen S, Kitchen DP, Woods TAL, Walker ID. Pre-analytical variables in haemostasis: Findings from the United Kingdom National External Quality Assessment scheme for Blood Coagulation (UK NEQAS BC) haemolysis exercise. *Int J Lab Hematol*. 2021 Oct;43(5):1198-1206.

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