

UK NEQAS

Blood Coagulation

2019/20

**U.K. National External Quality Assessment
Scheme for Molecular Genetics**

GENERAL INFORMATION

UK NEQAS for Blood Coagulation
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INTRODUCTION

The purpose of the programme is to provide external quality assessment, as a part of the overall quality assurance, for tests detecting Molecular Genetics defects in the field of Blood Coagulation. The aim of the programme is to promote high standards of performance and practice, achieved with the UK NEQAS primary aim of education, by provision of independent, objective and impartial information.

Two separate programme divisions currently operate: Molecular Genetics of Thrombophilia, covering screening for Factor V Leiden and Prothrombin 20210A mutations, and Genetics of Heritable Bleeding Disorders, for EQA of genetic investigation of haemophilia and other allied disorders. The following details apply to the Molecular Genetics of Thrombophilia Scheme; separate details are available from UK NEQAS for Blood Coagulation for Genetics of Heritable Bleeding Disorders.

The programme is open to all potential participants, whether government supported, private or commercial concerns, and are run on a not for profit basis, under the auspices of the UK National External Quality Assessment Service, and professional bodies

REGISTRATION AND PARTICIPATION

The participant registered should be the centre responsible for performing the tests. Data from participants will be treated with strict confidentiality. Registered participants will be given a unique participation number, which should be quoted in all correspondence. Use of this number will assist in maintaining confidentiality in survey correspondence.

Participating centres will be sent three surveys per year; each survey includes up to three whole blood samples for FV Leiden screening, and P20210A mutation screening. Results are invited to be returned from either or both of these tests for the three samples in each survey, for the three surveys in a participation year. Dates of the surveys are March, July and November each year, distribution dates are determined by availability of donors within these dates.

Samples are obtained from donors who have previously been screened for hepatitis B surface antigen (HBsAg), and for antibodies to hepatitis C virus and human immunodeficiency virus types 1 and 2 (anti-HIV-1+2).

Participants are requested to provide method details, together with an interpretation for each of the samples. A closing date for return of results will be given, normally six weeks after the date of survey distribution. Individual reports based on the analysis of returned results will be sent to participants as soon as possible after the survey closing date.

REGISTERED PARTICIPANTS

Total number of participants (January 2019): 146

PERFORMANCE ANALYSIS

As results are in the form of discreet interpretations, the majority view (>80%) of the presence or absence of a genetic mutation can be taken as the correct value. Centres reporting a different interpretation for any one of the three samples are therefore deemed “unsatisfactory” and a letter is sent from the Scheme Director. Template letters are found in R:\FVL\PUPS. Letters are stored electronically in the relevant survey folder and hard copies in the participants file. Responses to this letter should be recorded as a comment in the cell related to the participant and the current survey in the excel file.

More than one unsatisfactory performance in any fifteen consecutive surveys (i.e. a 5 year period) will be designated as persistent unsatisfactory performance.

Where performance is deemed to be potentially hazardous, or persistent fails are recorded, the SAG will refer the participant anonymously to the Steering Committee and will consider recommendation for referral to the National Quality Assurance Advisory Panel (NQAAP) for Haematology. UK NEQAS for Blood Coagulation has been awarded full Accreditation by Clinical Pathology Accreditation (CPA (UK) Ltd.) in the EQA Scheme Accreditation programme, including the Molecular Genetics of Thrombophilia programme.

Please 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.*

DISTRIBUTION SCHEDULE

Surveys

Three surveys are sent each year, comprising up to 3 samples from donors with and without the FVL and Prothrombin mutations. Samples are usually citrated whole blood, but lyophilised DNA material is used on occasion. Dates of the surveys are March, July and November each year, distribution dates are determined by availability of donors within these dates.

MTHFR

UK NEQAS BC provides samples for MTHFR C677T mutation analysis alongside the FVL and prothrombin mutation samples (therefore 3 times per year). A separate sample specifically for MTHFR gene analysis is provided. Participants are given individual reports indicating their interpretation of the sample and also the consensus interpretation of all centres performing the analysis. Formal performance assessment is not applied to MTHFR analysis.

OTHER PROGRAMMES

UK NEQAS BC also offers EQA for the following programmes:

- Homocysteine
- Genetics of Heritable Bleeding Disorders
- Laboratory Programme for screening tests and assays

For further information on any of our programmes, and details of annual fees, please contact us as follows:

Tel: +44 (0)114 267 3300

UK E-mail: negas@coageqa.org.uk

Countries outside the UK E.mail: equals@coageqa.org.uk

PERSONNEL

Professor I D Walker is Director and Mr T A L Woods Manager & Deputy Director at 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:

| | |
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| Dr I Jennings | Scientific Programme Manager |
| Dr S Kitchen | Scientific Director |
| Mrs D P Kitchen | Senior Biomedical Scientist |
| Mrs S Munroe-Peart | Biomedical Scientist & Quality Manager |

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| Mrs L Brown | Biomedical Scientist |
| Mrs S L Lamb | PA to Scheme Directors |
| Mrs J Foster | PA to Scheme Managers |
| Mrs J Johnson | Company Administrator-(EQUALS BC) |
| Mr S Asif | Medical Laboratory Assistant |
| Mrs J Ogden | Clerical Officer |
| Mr P Brown | Computing Systems |
| Mrs S Burdett | Assistant Clerical Officer |
| Mrs C Mather | Assistant Clerical Officer |
| Mrs R L Longden | Assistant Clerical Officer-(EQUALS BC) |
| Mrs K A Stott | Assistant Clerical Officer-(EQUALS BC) |

STEERING COMMITTEE MEMBERS

The organisation receives advice from a Steering Committee. Current members of the Steering Committee are as follows:

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| Professor H Watson (Chair) | Department of Haematology, Aberdeen Royal Infirmary, Foresterhill, Aberdeen |
| Dr E Gray | Department of Haematology, National Institute for Biological Standards & Control, South Mimms, Herts. |
| Dr D Harrington | Department of Haemostasis & Thrombosis, St Thomas's Hospital, London |
| Dr I Jennings | UK NEQAS for Blood Coagulation, 3 rd Floor Pegasus House, 463A Glossop Road, Sheffield |
| Mrs D P Kitchen (Secretary) | UK NEQAS for Blood Coagulation, 3 rd Floor Pegasus House, 463A Glossop Road, Sheffield |
| Dr S Kitchen | Coagulation Laboratory, Sheffield Teaching Hospitals, Royal Hallamshire Hospital, Sheffield. |
| Professor I D Walker (Director) | UK NEQAS for Blood Coagulation, 3 rd Floor Pegasus House, 463A Glossop Road, Sheffield |
| Ms A Riddell | Haemophilia Centre, Royal Free Hospital, London |
| Dr W Lester | Haemophilia Unit, Queen Elizabeth Hospital, Birmingham |
| Dr Angela Wood | Clinical Haematology, South Tees Hospital |
| Mr T A L Woods (Manager & Deputy Director) | UK NEQAS for Blood Coagulation, 3 rd Floor Pegasus House, 463A Glossop Road, Sheffield |