2021 / 2022

UK NEQAS FOR BLOOD COAGULATION

General Information for the

Point of Care Testing Programmes

UK NEQAS for Blood Coagulation
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Web site: www.uknegasbc.org

WHAT POINT OF CARE TESTS ARE AVAILABLE THROUGH UK NEQAS BC?

The following tests are available through the UK NEQAS BC EQA programmes

- **INR** testing available for
  - Roche CoaguChek XS series
  - Roche CoaguChek Pro II
  - Siemens Xprecia Stride
  - Abbotts i-STAT

- **D-dimer** testing for
  - Roche Cobas h232
  - Triage

- **Activated Clotting Time** testing for
  - Hemochron **ACT+**
  - Hemochron **ACT-LR**

- **Viscoelastography** for
  - Rotem Delta
  - Rotem Sigma
  - TEG5000
  - TEG6

For any other test of haemostasis performed in the laboratory please refer to our General Information for Laboratory Users.

EXTERNAL QUALITY ASSESSMENT (EQA)

- UK NEQAS BC is an organisation within the NHS and independent from point of care testing (POCT) device manufacturers.
- EQA samples are tested by each centre registered in the programme and results returned to UK NEQAS BC.
- Following analysis a target range is set and each centre's results are scored.
- In this way, your result can be compared with all other centres performing the same test on the same sample.
- This is a retrospective form of quality control; target results are not available until after the testing is performed.

HOW DOES IT WORK?

- UK NEQAS BC distributes test samples through the post with dates of distribution set at the start of each financial year.
- Each centre receives (by post or by courier by arrangement for participants outside the UK) a package of the EQA material with full instructions.
- Samples are provided together with diluent if required per registered device. Samples will have passed homogeneity, stability, and virology testing prior to analysis. See table 1 for sample information.

- The tests are simple to perform but require dedicated time to complete.
- Participants are allowed 17 days to complete the tests for INR, ACT and D-dimer testing and 24 days for Rotem or TEG testing and to return results to UK NEQAS BC.
- Results can be returned through our secure website using a password issued following registration and enrolment.

Table 1

Test	Sample type	Diluent provided	Sample origin
INR	Lyophilised plasma	Yes as separate vial	Human: from patients receiving warfarin
D-dimer(result)	Lyophilised plasma	Yes as separate vial	Human: normal and raised levels of D-dimer
ACT	Lyophilised Whole Blood	Contained in vial	Bovine
Rotem/TEG	Lyophilised plasma	Yes as separate vial	Human: donor plasma Donor plasma containing heparin, Plasma from patients receiving DOACs.

Table 2

Test	Number registered	Number of test samples per pack	Number of test packs per year	What is scored as outwith consensus
INR	4397	2	4	15% deviation above or below the target median
D-dimer (result)	106	1	4	Highest and lowest 10% of results are scored 'outwith' consensus
D-dimer (interpretation)				If an 80% consensus is achieved interpretations are scored. If the user does not agree with the majority interpretation they are scored as "outwith" consensus
ACT	308	2	3	20% deviation above or below the target median
Rotem/TEG	120	1	3	Lower than -33% deviation from target median or >50% above the target median

- Once a survey has closed the results are analysed and a target range (which varies between programmes as shown in Table 2) is set around the median value for results.

- Each individual participant's results are studied and classified as "within consensus" which means within the target acceptable range or "outwith consensus" which means that your result is outside the target acceptable range.
- On completion of result analysis, participants receive an individual report indicating the target acceptable range for the survey, the target median and whether their performance was 'within' or 'outwith' consensus.
- Participants' results and performance details are kept in confidence between UK NEQAS BC and the named individuals identified by the participant number.
- If your results are 'outwith' consensus in 3 consecutive surveys (and/or you fail to return results; see below) you will receive a letter from the Scheme Director bringing this to your attention and offering assistance.
- Reports will be produced within two weeks of the closing date.
- Results received after the closing date will not be included in the analysis and the centres concerned will be considered to be "Non-return: no reason given".

Reports

After analysis, each centre will receive a report, either a paper based report or an email informing the centre that reports are available to be downloaded from our website. It is important to store these documents, but should these be misplaced, copies of the report may be reprinted from each centre's password secure page accessed through the UK NEQAS BC website.

SURVEY DISTRIBUTIONS

Surveys distribution dates are set before the start of the new financial year and a schedule of the planned surveys can be downloaded from our website www.ukneqasbc.org or by request via one of the following methods:

Tel: 0114 267 3300
E-mail: neqas@coageqa.org.uk

REGISTRATION – new participants

- Registration with the programme is made by completion of the registration form, available by contacting UK NEQAS BC by phone: +44 (0)114 267 3300 or email: neqas@coageqa.org.uk.
- **Payment is not required with the registration form, as an invoice will be raised when the registration has been processed**.
- Following registration, you will receive a letter of confirmation, stating your participation number. **This is unique to your centre and should be quoted whenever you need to contact us. You will also receive a unique password allowing access to secure data entry and report pages on the website.**
- Participant details are held in strict confidence and are not shared with any third party. Use of the participant number will assist in maintaining confidentiality in survey correspondence.
- Costs for the year 2021-2022 as shown in Table 3.

Table 3

Test	Cost without VAT	Costs including VAT if applicable
INR	£148	£177.80
D-dimer(result)	£148	£177.80
D-dimer (interpretation)	Included in D-dimer result cost	
ACT	£148	£177.80
Rotem/TEG	£159	£190.80

If you have more than one device

- It is recommended that each device is registered in an EQA programme to individually test and check that reliable results are produced.
- Each device may be cross-referenced with a registration number in the POCT programme enabling a cumulative record to be maintained in the programme.

RE-REGISTRATION – existing participants

In January each year, UK NEQAS BC will send out a re-registration form to the registered person from each centre. This document contains the details we currently hold in our database for your centre and we ask that you check to ensure that these details are correct and to provide us with updated information if necessary. The form also states that a purchase order is required if you wish to continue with your registration for the following financial year. Payment is not required to be returned at this point as an invoice will subsequently be raised.

If you wish to share your results with another centre/person

- Participation in the programme is confidential to your centre and results will not be shared, except in the case of long term issues with performance (see our privacy notice available online at *www.negascoag.org).*
- Should you wish to share your data with another centre, PCT, or a local laboratory, you can share your participant number and password, and this will allow them to view/print reports.

Non-return of survey results

- Registration within the programme carries an obligation to return results.
- Failure to do so will lead to an outwith consensus classification.
- Centres not returning results in 3 consecutive surveys will receive a letter from the Scheme Director indicating performance “persistently outwith consensus”.

UK NEQAS FOR BLOOD COAGULATION WEBSITE

www.ukneqasbc.org

On the website you can find information on our programmes, survey distribution dates, and downloadable files for information and registration documents together with information about educational meetings. There are also photo instructions that show you how to test survey samples.

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: neqas@coageqa.org.uk
Countries outside the UK email: equals@sth.nhs.uk

TROUBLESHOOTING

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. Advice on EQA testing technique and provision of repeat samples to investigate outwith consensus performance is available to all participants. Repeat samples can also be obtained for the duration of a survey if the original samples are lost or spoiled.

COMPLAINTS & APPEALS

We aim to provide a high-quality service to participants, and to ensure participants are satisfied with all aspects of the proficiency testing programmes we run. Any complaint about UK NEQAS for Blood Coagulation will be treated as serious and will be dealt with as soon as possible by the Scheme Director or Scheme Manager.

In the first instance, complaints should be addressed to the Scheme Manager - contact details can be found under Personnel. If the outcome is not to the satisfaction of the participant, referral may be made in the first instance to the Chair of the Steering Committee.

Participants can also appeal against their performance assessment if they feel their results have been scored inappropriately. All appeals will be considered, and participants will be contacted with the outcome of these appeals.

UK NEQAS BC STAFF

Professor I D Walker is 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:

Dr I Jennings	Manager & Deputy Director
Dr C Reilly-Stitt	Deputy Manager
Dr S Kitchen	Scientific Director
Mrs D P Kitchen	Lead scientist for POC programmes
Mrs S Munroe-Peart	Quality Manager & Biomedical Scientist
Mrs L Brown	Biomedical Scientist
Ms A Lowe	Lead scientist for Haemophilia treatment programmes
Mrs J Foster	Office Manager
Mrs J Ogden	EQA Programme Co-ordinator / Deputy Quality Manager
Miss S Shikdar	IT Specialist
Mrs S Burdett	MLA
Mrs C Mather	MLA
Ms H King	Secretary / Receptionist

We are overseen by a Steering Committee which meets twice per year and members are as follows:

Professor H Watson (Chair) Department of Haematology, Aberdeen Royal Infirmary ,Foresterhill, Aberdeen
Dr W Lester (Secretary) Haemophilia Unit, Queen Elizabeth Hospital, Birmingham
Dr E Gray Department of Haematology, National Institute for Biological Standards & Control South Mimms, Herts.
Dr D Harrington Department of Haemostasis & Thrombosis, St Thomas' Hospital, London
Dr A Wood Clinical Haematology, South Tees Hospital
Dr H Lyall Norfolk and Norwich University Hospital NHS Foundation Trust
Dr Gillian Evans East Kent Hospitals Trust, Canterbury
Mr Sean Platton Barts Health NHS Trust, London
Dr R MacLean (Representing UKHCDO) Sheffield Teaching Hospitals, Royal Hallamshire Hospital, Sheffield
Dr R Alikhan (Representing BSH T&H Taskforce) Cardiff and Vale University Health Board
Dr S MacDonald (Representing NQAAP) Cambridge University Hospitals NHS Foundation Trust
Professor I D Walker Director, UK NEQAS BC
Dr I Jennings Manager and Deputy Director, UK NEQAS BC
Dr S Kitchen Scientific Director, UK NEQAS BC
Mrs D P Kitchen Lead scientist for POC programmes, UK NEQAS BC
Mr Chris Reilly-Stitt Deputy Manager UK NEQAS BC
Mrs Anna Lowe Lead scientist for Haemophilia treatment programmes, UK NEQAS BC

General information concerning UK NEQAS BC POC programmes

The proficiency provider is:
UK NEQAS for Blood Coagulation (BC)
3rd Floor, Pegasus House,
463A Glossop Road,
Sheffield S10 2QD, UK
Tel: +44 (0)114 267 3300
E-mail: neqas@coageqa.org.uk
Website: www.ukneqasbc.org

UK NEQAS BC is directed by Professor Isobel Walker and programme manager Dr Ian Jennings.

Sample provided are lyophilised and for Point of care (POC) programmes supplied with a pre measured diluent and disposable pipette.
Lyophilisation of plasma is subcontracted to either Diagnostic Reagents Ltd or HART Biologicals Ltd. Samples for the Hemochron ACT programmes are supplied by Werfen UK Ltd.
All samples have passed homogeneity, virology testing and calcium verification provided by the STH NHS Trust Coagulation, Microbiology (Virology) and Clinical Chemistry Departments respectively. All samples also undergo stability testing for the duration of each survey. Stability testing is subcontracted to the STH NHS Trust Coagulation Department.
The subcontractors are regularly audited (including accreditation status) to confirm competence to provide their services to UK NEQAS BC.

UK NEQAS BC survey reports are posted to the secure online data entry system, accessible only by participant number and unique password with the exception of the Viscoelastography (Rotem and TEG) programmes for which reports are currently paper based. UK NEQAS BC does not share participant information with any third party, except with respect to unresolved performance issues which can be reported to our Steering Committee and if deemed likely to endanger patient safety to the Haematology National Quality Assessment Panel (NQAAP). Please see our privacy policy, available online at www.neqascoag.org . However, as articulated in the Pathology Quality Assurance

Review, participants are encouraged to share their EQA performance data both within and outside of their department.

The standard uncertainty of the median value U_x (1.25xSD/n^0.5) is shown in the tables in the reports for values which are scores. Some programmes have parameters in which data is collected but not scores. This is based on the consensus value from participants and is shown to give an indication of the statistical variation around the median values.

UK NEQAS BC programmes are designed with support from our Steering Committee which meets twice per year.

Individual participant's results, comments on performance, advice on the interpretation of the statistical analysis are covered in participant's individual reports.

APPENDIX

Example of the calculations for the INR median

If the results returned by all participants for one sample were as follows:

2.1, 2.5, 2.3, 2.4, 2.3, 5.8, 2.9, 2.6, 2.0, 2.2, 2.4, 2.6, 2.7, 1.7, 2.4, 2.6, 2.4, 2.5, 2.3, 2.4

- The Median value INR = 2.4
- 15% deviation (either side of 2.4) is 2.0-2.8. This is the target range.
- INR = 2.3 within consensus (deviation from median = -4%)
- INR = 5.8 outwith consensus (deviation from median = 142%)

If your centres results are lower than the median the percentage deviation will be negative whereas if your result is higher than the median the percentage deviation will be positive. The further away your result is from the median value, the higher the percentage deviation will be.

Example of the calculations for the ACT+ median

If the results returned by all participants for one sample were as follows:

460, 408, 450, 439, 446, 435, 446, 435, 454, 436, 437, 424, 325, 437, 431

- The Median value ACT = 437
- 20% deviation (either side of 437) is 350-524. This is the target range.
- ACT = 450 within consensus (deviation from median = 3.0%)
- ACT = 325 outwith consensus (deviation from median = -25.6%)

If your centre's results are lower than the median the percentage deviation will be negative whereas if your result is higher than the median the percentage deviation will be positive. The further away your result is from the median value, the higher the percentage deviation will be.

Example of the calculations for the D-dimer programme

369, 405, 351, 503, 248, 336, 398, 325, 572, 480, 391, 335, 311, 556, 319, 328, 397, 369, 476, 306, 304, 513, 394, 356, 382, 401, 357, 377, 317, 422, 379, 340, 390

These values are ordered from smallest to largest and the 10% further from the median would be outwith consensus. The median value = 377ng/ml FEU.

The acceptable range for this sample is 306-503ng/ml FEU and the value of 248 is outwith consensus, whereas 340 is within consensus.