UK NEQAS
Blood Coagulation

UK NEQAS FOR BLOOD COAGULATION

General Information for the

Point of Care Testing Programmes

2023 / 2024

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WHICH 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 (*XS, XS Plus, XS Pro, INRange*)
  - Roche CoaguChek Pro II
  - Siemens Xprecia Stride
  - Abbott i-STAT1
  - LumiraDX

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

- **Activated Clotting Time** testing for
  - Hemochron Signature Elite, GEM Hemochron 100 **ACT+**
  - Hemochron Signature Elite, GEM Hemochron 100 **ACT-LR**

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

For any other test of haemostasis performed in the laboratory please refer to our Participation Manual & General Information Laboratory Programmes 2023/24

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 programmes 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 ranges 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 (April 1st – March 31st).
- Each centre receives a package of the EQA material with full instructions (by post or by courier by arrangement for participants outside the UK).

- 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 and return results to UK NEQAS BC for INR, ACT and D-dimer testing and 24 days for Rotem or TEG testing
- Results must be returned through our secure website using a password issued following registration and enrolment.

Table 1. Sample type and origin for Point of Care programmes.

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

- Once a survey has closed the results are analysed and a target acceptable range is set around the median value for results (see Table 2 for programme specific details).
- Each individual participant's results are studied and classified as "within consensus" which means the result is within the target acceptable range **or** "outwith consensus" which means the result is outside the target acceptable range.
- On completion of result analysis, participants receive an individual report indicating the target median, the target acceptable range for the survey, and whether their performance was 'within' or 'outwith' consensus.
- 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 are produced within ten working days 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" and will be scored as outwith consensus".

Table 2: Performance analysis for Point of Care test results.

Test	Number registered	Number of test samples per pack	Number of test packs per year	What is scored as outwith consensus
INR	4198	1	4	% deviation: a result more than 15% deviation above or below the target median (ie, outside the target range)
D-dimer (result)*	97	1	4	Z scores: (a way of viewing how far away a result is from the median result, taking into account the standard deviation). A z-score of >+/-2 is considered outwith consensus, with a 'warning' flag; if the z-score is >+/-3, this is considered outwith consensus with an 'action required' flag.
ACT	426	1	3	% deviation: a result more than 20% deviation above or below the target median
Rotem/TEG Rotem Sigma/ TEG6	161	1	3	% deviation: A result more than -33% deviation below the target median or more than 50% above the target median

* For the D-Dimer programme, we also invite centres to provide an interpretation based on their result and a clinical scenario including pre-test probability (Well's) score. Performance is assessed as follows: If 80% or more of the results state the same interpretation, this is considered to have reached consensus and the interpretations are scored. If the users' interpretation does not agree with the majority interpretation they are scored as 'outwith' consensus, if they do agree they will be 'within consensus'.

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 reports may be reprinted from the UK NEQAS BC website.

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 accessed via our secure online database using personal email and password details. 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/

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.uknegasbc.org or by request via one of the following methods:
Tel: 0114 267 3300
E-mail: negas@coagega.org.uk

REGISTRATION – new centres

- For new centres wishing to join the programme an application needs to be completed via our website. Once an account is established the registrant can purchase the programmes they wish via our online web basket system.
- **Payment is not required when registering as an invoice will be raised when the registration has been processed**.
- Following registration your centre will be allocated a registration number . **This is unique to your centre and should be quoted whenever you need to contact us. The named person that has set up the registration will set up their own password and then add other staff members who will also then set their own passwords.**
- Registration details are held in strict confidence and are not shared with any third party. Use of the registration number will assist in maintaining confidentiality in survey correspondence.
- Costs for the year 2023-2024 as shown in Table 3.

REGISTRATION – additional devices

- Centres that are already registered with devices but wish to add further devices can add devices to the system and then purchase these via the web basket.

Table 3

Test	Annual participation fee (excluding VAT)
INR	£159
D-dimer(result)	£164
D-dimer (interpretation)	Included in D-dimer result cost
ACT	£164
Rotem/TEG	£177

Pro-rata fees will be applied for centres joining a programme part way through the financial year.

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.
- Registration fee discounts may be applied for multiple registrations at the same site.

RE-REGISTRATION – existing participants

In January each year, UK NEQAS BC will send out a reminder to register for the coming financial year. Centres enrol in the system for a 1 year period and once that year has expired so does the registration therefore users need to enrol for the year starting on 1st April during the period January – end of March. We will send regular reminders to encourage users to complete this registration. 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

- Registration in the programme is confidential to your centre and results will not be shared by UK NEQAS BC, except in the case of long term issues with performance (see our privacy notice available online at *www.neqascoag.org).*
- Should you wish to share your data with another centre, PCT, or a local laboratory, you can add these as staff members and allow them access to the results and reports without giving them full access to the account.

Non-return of survey results

- Registration within the programme carries an obligation to return results for each survey distribution.
- 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.uknegasbc.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@coagega.org.uk
Countries outside the UK email: equals@coag.org.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

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	Specialist Biomedical Scientist
Ms A Williams	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	Medical Laboratory Assistant
Mrs C Mather	Medical Laboratory Assistant
Ms T Withington	Medical Laboratory Assistant
Ms H King	Secretary / Receptionist

UK NEQAS BC programmes are designed with support from our Steering Committee which meets twice per year and members are as follows:-

Dr W Lester (Chair) Haemophilia Unit, Queen Elizabeth Hospital, Birmingham
Mr Chris Reilly-Stitt (Secretary) Deputy Manager UK NEQAS BC
Ms Helen Wilmott Department of Haematology, National Institute for Biological Standards & Control South Mimms, Herts.
Dr A Wood Clinical Haematology, South Tees Hospital
Dr H Lyall Norfolk and Norwich University Hospital NHS Foundation Trust

Dr G Evans East Kent Hospitals Trust, Canterbury
Mr S Platton Barts Health NHS Trust, London
Dr P Baker (Representing BSH T&H Taskforce) Oxford University Hospitals NHS FT
Dr S MacDonald (Representing NQAAP) Cambridge University Hospitals NHS Foundation Trust
Dr M Sutherland Genomics Diagnostic Laboratory, Manchester Centre for Genomic Medicine, St. Mary's Hospital, Manchester
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
Mrs A Williams 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.uknegasbc.org

Samples 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 sourced from 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 or tested in house by the UK NEQAS BC team. 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 user name and individuals password with the exception of the Viscoelastography (Rotem and TEG) programmes for which reports are currently paper based, however it is planned to more this programme to the web based system this year.. 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.

Individual registrants' results, comments on performance, advice on the interpretation of the statistical analysis are covered in 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 scored using z scores which take into account the median value , the standard deviation and the number of results submitted.. The median value = 377ng/ml FEU.

The acceptable range for this sample is 304-480ng/ml FEU and the value of 248 is outwith consensus with a z score of -2.28 which is a warning flag. The value of 572 is outwith consensus with a z score of 3.67 which is outwith consensus with an action required flag and the value of 340 is within consensus (z score of -0.59)..