CEQAS

Cytogenomic External Quality Assessment Service

CYTOGENETIC EXTERNAL QUALITY ASSESSMENT SERVICE

PARTICIPANTS' MANUAL 2017

CEQAS is part of the UK NEQAS Consortium and is operated by the Oxford University Hospitals NHS Foundation Trust

Level 1, The Women's Centre, John Radcliffe Hospital, Oxford University Hospitals NHS Foundation Trust, Headley Way, Oxford, OX3 9DU, UK

CONTENTS

APPENDICES

1. BACKGROUND OF THE SCHEME

The Cytogenomic External Quality Assessment Service (hereinafter referred to as 'CEQAS' or 'the Scheme') was established in 2014 through the merger of the two largest internationally operating Cytogenetic EQA schemes - Cytogenetic European Quality Assessment (CEQA) and UK NEQAS for Clinical Cytogenetics.

2. SCHEME REMIT:

CEQAS is operated by the Oxford University Hospitals NHS Foundation Trust and is a UKAS accredited proficiency test provider No 7872 CEQAS provides a broad, consistent and sustainable range of relevant EQAs at a reasonable cost to the genetic community worldwide. CEQAS is a not for profit organisation and is a member of the UK NEQAS Consortium.
Details of all EQA Schemes, overseen by UK NEQAS consortium, which may also be relevant to your service are available from the UK NEQAS central office, PO Box 401, Sheffield S5 7YZ, Tel 0114 261 1689.

CEQAS' commitment is

- To provide professionally-led and scientifically-based EQAs with a primarily educational objective;
- To help the laboratory appraise its performance and monitor improvements externally through continuous EQA operation;
- To provide frequent distributions of EQA samples and performance feedback;
- To produce reports which are designed to be clear, informative, intelligible and structured to assist interpretation and use by different levels of laboratory staff;
- To assess technical, analytical and interpretative performance of a laboratory.

CEQAS will continue to:-

- Assess EQA submissions against International and European guidelines;
- Accept submissions in several European languages;
- Recruit assessors from participating countries;
- Work and liaise with international experts;
- Raise awareness in quality issues relating to cytogenomics, pre-implantation genetic diagnosis (PGD) and Genetic Counselling worldwide.

There are many benefits to EQA participation, including.

- Harmonising the quality of diagnostic and/or clinical service;
- Ensuring quality across national borders;
- Ensuring that the provision of genetic counselling is the same for all family members;
- Helping establish continuous quality improvement;
- Identifying imperfect practice and improves quality thus ensuring patient safety.;
- Identifying problems/flaws with diagnostic kits;
- Improving the diagnostic service of laboratories;
- Helping centres to stay up-to-date;
- Educating participants with the aim of improving the overall service to the user;
- Identifying flaws in a laboratories internal quality control, equipment, training etc. - i.e. quality management system (QMS);
- Ensuring uniformity in practices and aiding in the development of services;
- External verification /validation of service quality and building public confidence;
- Having a surveillance role: laboratory's adherence to professional guidelines and international standards;
- Allowing comparison between laboratories may help to refine good laboratory standards and aid in the establishment of best practice guidelines.

3. SCOPE OF THE SCHEME

3.1 Assessments

The Scheme aims to assess the overall quality of diagnostic analysis performed by a laboratory through a combination of web-based EQA and reference material distributions. The Scheme assesses technical, analytical and interpretive disease and syndrome specific performance for constitutional, Preimplantation Genetic Diagnosis, acquired (incl. molecular pathology) genetics. All aspects of the Scheme are under continuous review in collaboration with the CEQAS Scientific Advisory Board.
Suggestions for enhancements to the existing EQAs or development of new EQAs are canvassed from participants through surveys. Unsolicited suggestions are also welcome.

3.2 EQAs offered

A total of 29 EQAs (including pilots and exploratory pilots) will be offered during two EQA seasons (Spring/Autumn). Each EQA season has two or more distribution dates.

A full EQA timetable is included in this manual (**see Appendix D**) and is also available on the website.

3.3 Performance Criteria

Participating laboratories are assessed against set criteria based on EQA specific national and international Guidelines and recommendations **(see Appendix E** and on the **http://www.cegas.org** website home page **).** The criteria can also be found on the CEQAS website under 'Participation'. There are separate criteria for constitutional cytogenetics, acquired cytogenetics, molecular rapid aneuploidy, pre-implantation genetic diagnosis and microarray. All performance criteria have been divided into **three** broad inter-linked categories:

- **Analytical performance**: Scoring of the accuracy of submitted analyses and written description including ISCN.
- **Interpretative performance**: Scoring of the quality of the submitted interpretation of results, including clinical advice and follow up studies.
- **Clerical accuracy:** Scoring the report content and clerical accuracy of submitted reports against guidelines and ISO 15189. The score for clerical accuracy is not included when determining a laboratory's overall performance.

The current performance criteria, including the consequences of poor performance, are given in more detail in **Appendix E** (Select 'Participation' from the main menu).

Unless specifically mentioned in the EQA description all laboratories that offer a diagnostic service (exceptions are manufacturers) are expected to participate in the interpretation part of the EQA. If the interpretation is not carried out by the laboratory then please involve the relevant member of clinical staff in the EQA.

3.4 National Professional Standards

Marks may be deducted under the performance criteria if professional standards are not adhered to. All laboratories will be assessed against the following guidelines unless the laboratory submits information to show that their own national standards or local practices should apply:

- European Cytogenetic Guidelines[1]
- ESHRE Guidelines for clinical preimplantation genetic diagnosis (PGD) and preimplantation genetic screening (PGS)[2]
- ESHG Reporting Guidelines[3]
- ISO 15189[4]

Local policy will be commented on if it is contrary to or discrepant with professional guidelines.

4. EQA MATERIALS

The Scheme receives slides, images (jpeg), fixed cell suspensions, DNA and FFPE tissue for EQA purposes. Material is provided, where possible, by a suitable, accredited laboratory providing a diagnostic service. Images from submitted cases are also captured by the Scheme Office.

All EQA material is validated by at least two assessors prior to being released.

5. PARTICIPATION

All participants of CEQAS must agree to abide by the rules and procedures laid out in this Participants' Manual. Laboratories must not use any EQA images or cases for any purpose other than education and training.

Laboratories are required by accreditation standards (ISO 15189, 17025) to participate in EQA on a regular basis for all aspects of their diagnostic service.

It is the responsibility of the participant to be aware of the start and closing dates of all EQAs they are currently enrolled for, the Scheme Office takes no responsibility for emails not reaching the laboratories. EQA dates can be found on the static website under 'EQA Process' or on the secure website (once logged in) on the specific EQA page.

Participants will be charged for all EQAs in which they are enrolled, regardless of whether they submit results for the EQA or not.

5.1 Eligibility

CEQAS services are designed for public and private sector clinical laboratories/centres serving clinicians or patients. Clinical laboratories, laboratories with purely research or industrial roles, manufacturers of diagnostic instruments and reagents and other laboratories are welcome to participate. Manufacturers may do so on a 'technical and analytical' only basis, i.e. receiving samples and returning results. All laboratories must agree to the current conditions of participation (**Appendix G for non-UK laboratories** and **Appendix F for UK laboratories).**

5.2 Registration

A laboratory must be registered with CEQAS in order to participate in EQA. Registration with CEQAS can take place throughout the year. After a laboratory has registered online the Scheme Office will contact them by email to confirm that their application has been accepted. This email will contain a unique 5 digit laboratory code (8****). Laboratories can register throughout the year, however, registrations received after EQA enrolment is closed will NOT be processed until the beginning of the following calendar year to avoid Annual Administration Fee charges.

The unique five digit laboratory code issued at registration remains associated with the laboratory for the duration of its participation. For identification purposes, this laboratory code MUST be quoted in all correspondence with the Scheme Office. Re-attribution of codes and data can be accommodated, for example where laboratories merge.

Login details will be sent by separate email from support@certus-tech.com. Participants should contact the Scheme Office (ceqas.info@ouh.nhs.uk) if they have not received their login details within 24 hours of their acceptance email.

Laboratories have a maximum of 10 contact facilities, including the Primary and Billing Contact. Participants must ensure that all their contact details, especially delivery and billing details are correct on the system.

5.3 EQA Timetable

A full EQA timetable is published on the CEQAS static website under 'EQA Process' in January each year. Participants are alerted to its availability by email. The Scheme Office reserves the right to change the EQA timetable. The latest version will always be available on the website***. It is the laboratory's responsibility to be aware of all EQA dates relevant to them.***

In the case of changes to the EQA start dates participants enrolled for the EQA in question will be notified by email.

5.4 EQA Enrolment

Enrolment in CEQAS EQAs is available annually between December and the end of February. Participants are alerted by email once EQA enrolment is available online and when enrolment will close.

If participants require a Purchase Order number to be quoted on the invoice they need to add this number online when enrolling or communicate it to the Scheme Office by email at the point of enrolment.

5.5 EQA Charges

CEQAS is a not-for-profit organisation. Annual charges are based on the full costs of providing EQA services and operating the Scheme. The current tariff of charges is EQA based and, as such, subject to continuous review and may be changed without prior notice. Refunds of EQA enrolment charges are only payable under exceptional circumstances and at the Scheme Director's discretion, see 'Late EQA Withdrawal Procedure' on the static website under Participation/Policies.
A late enrolment surcharge is applied to each EQA enrolment made after a specific date. This date is communicated to participants by email and can also be found on the static website under 'Registration' – 'EQA Enrolment'.

An 'Annual Adminstration Fee' of £110 will be added to every invoice.

Laboratories will be invoiced by the Oxford University Hospitals NHS Foundation Trust. Invoices are sent by email between May and July either to the 'Bill payer' or 'Primary Contact' if there is no designated 'Bill Payer' given in the contact details. All laboratories outside the UK (EU and Non-EU) as

well as English NHS laboratories are VAT exempt. All laboratories located in Wales, Scotland and Northern Ireland must give their VAT number otherwise they will be charged VAT.

All Swiss laboratories need to contact CSCQ to obtain the billing details. CSCQ will issue Swiss laboratories with an annual certificate, approved by SMGM, QUALAB and FOPH, for their participation in CEQAS EQAs.

Payment is required no later than 30 days from date of invoice and has to be made regardless of whether or not the participant has submitted results for the EQA in which they are enrolled. The Scheme reserves the right to withhold EQA results as a consequence of non payment. Late payment will incur a 10% surcharge levied by the Oxford University Hospitals NHS Foundation Trust.

EQA charges are quoted in Pound Sterling and Euro (based on an exchange rate of £1 = €1.20 (December 2016). The invoices are made out and must be paid in Pound Sterling, the prevailing exchange rate applies.

5.6 EQA Withdrawal

Any participant wishing to withdraw from an EQA must inform the Scheme Office by e-mail prior to the starting date of the EQA. Any withdrawals not communicated to the Scheme Office or made after the starting date will incur a 'Poor Performance' designation and will still be invoiced in full. Refunds of the respective EQA charges are only payable under exceptional circumstances, the administration fee will always be charged in full. (see 'Late EQA Withdrawal Policy' under Participation/Policies on the static website).

5.7 Online Analysis/Cost Analysis

The online analysis system allows the participant to choose from a variety of online tests appropriate to the referral reason. There are sometimes more tests available online than are required to obtain the correct result. The aim of the online analysis is to mimic the diagnostic process as closely as possible. The Scheme recognises that diagnostic processes vary between laboratories and countries: for example, some laboratories achieve a preliminary CVS result using direct chromosome preparation; others use FISH or QF-PCR or MLPA. All four preliminary CVS tests may be available online but the Scheme would not expect analysis of all four unless a discrepant result had been found.

Each test incurs a 'unit cost' based on the workload weighting (see Table 1). Once a specific test is selected – e.g. for DiGeorge Syndrome a cost of 7 units - is incurred. This function allows the Scheme Office to monitor which 'tests' have been accessed by the lab as part of their analysis. The 'unit cost' does not represent a penalty nor an additional cost to the laboratory. Incurrence of excessively high 'unit cost' may be commented upon but not penalised.

Table 1: Cost weightings

Sample/technique	Website Unit Cost	Comments
Blood	10	
Amniotic Fluid	13	
CVS	14	
CVS +direct	21	
Solid Tissue	14	
Haematology	25	
Tumour	30	
Simple FISH	7	Microdeletion, wcp
Intermediate FISH	30	Octochrome
Complex FISH	50	Telomere screening, M-FISH
Aneuploidy screening (FISH)	11	
Breakage syndromes	15	
MLPA	50	
QF-PCR	13	

5.8 ISCN

All reports will be marked against the current ISCN (2016) nomenclature.

5.9 Reporting of Results

Participants are expected to submit results promptly within the specified reporting period. Non

submission of results may lead to the laboratory receiving a 'Poor Performance' designation, (see performance criteria**, Appendix E**).

Submissions can be made in a number of languages. The following languages are offered on a regular basis (with the exception of the MRA, PGD, Microarray and Clinical Genetics EQAs). More information about which language options are available for a given EQA can be found in the EQA Instructions.

- English
- French
- German
- Italian
- Spanish

6. PERFORMANCE PROBLEMS

6.1 Poor Performance

This is incurred for the following reasons and applies to all laboratories (See performance criteria on website).

- Non-submission;
- Critical analytical error (incorrect analysis);
- Critical interpretation error which adversely affects patient management;
- No interpretation of the results.

Laboratories that have received a poor performance will be asked to complete and submit a Root Cause Analysis Form.

6.2 Persistent Poor Performance

Participating laboratories that have received a persistent poor performance (two poor performances in any category – i.e. constitutional/Haematology etc. – over three or more distributions of material within a 36 months rolling period. OR A poor performance within one year following a previous persistent poor performance designation) will receive notification of their persistent poor performance from the SAG via the Scheme Office and will be referred to their national regulatory body where applicable (i.e. NQAAP – UK and FOPH -Switzerland).

When a persistent poor performance referral is made to a regulatory body, the identity of the laboratory will be made known. Acceptable performance criteria and action taken on poor performers is described in **Appendix E**. The performance criteria documents can be found on the website **http://www.ceqas.org/** (Select 'EQA' from the grey menu bar link).

6.3 Appeals

Laboratories usually have 10 working days to appeal any penalty points/comments given in their Individual Laboratory Reports starting from the date the original ILR is published) . Laboratories wishing to appeal must download the appeals form from the website, complete it and re-upload it prior to the appeals deadline given on the website. ***Any appeals received after the closing date will not be reviewed.*** No appeals are accepted for pilot EQAs but comments by participants are welcome and can be communicated to the Scheme Office by email.

All appeals are reviewed by the relevant SAG. **Please note the appeals process may take six to eight weeks**. Formal notification of the outcome of the appeal will be given to the laboratory by the Scheme. The decision of the SAG is final. If the appeal is successful an amended ILR will be issued.

6.4 Disqualification

If the Scheme Office has reason to suspect collusion between laboratories, the laboratories in question will be contacted by the Scheme Office and their submissions for this EQA will not be marked. The respective ILRs would state that the laboratory was found colluding with another laboratory. The Scheme Office reserves the right to disqualify any participating laboratory from future EQAs if there is evidence of falsification of results or collusion with another participating laboratory.

7. COMMUNICATION

7.1 Annual Report

An Annual Report is produced at the end of the annual assessment round. A copy of the current document is available on the 'Scheme Reports' page on the secure Participants' website. Just click the button 'Documents' and then follow the online instructions. The report includes a general overview of the Scheme, summaries of the pilot EQAs undertaken during the year, plans for next years' assessment etc. Where appropriate the report will also contain a summary of the EQA results (see

also Summary Reports distributed with the Individual Laboratory Report). Laboratories are notified by email once the Annual Report is available and are given instructions on how to access it.

7.2 Annual Participants' Meeting

Participants' meetings will be held annually at the ESHG, ECA and ESHRE (PGD EQAs only) conferences. All participants are notified of the meeting and agenda in advance. An attendance register is taken and all presentations given will be available on the website under 'Documents'. The meetings will review the previous year's EQAs and there will be opportunity for open discussions. EQA results for the first round – if available - may also be given during the meeting.

7.3 Individual Laboratory Reports (ILRs)

ILRs give the result, score and performance designation for each EQA (no performance designation for Pilot EQAs) a They are designed to be informative and easy to interpret. Reports share the following features:

- The submitted ISCN result and expected result in ISCN (online analysis EQA only) for each case;
- Analytical and interpretative scores;
- Educational comments on the submitted individual reports (some may incur a deduction of marks);
- General comments, recommendations and performance status.

In addition to the ILRs, laboratories receive an EQA Summary Report which includes the performance score distributions and specific details relating to the EQA.

Pilot and exploratory pilot EQAs, are marked and scored but no performance status is given.

7.4 Result validation and amendment

Results for any EQA distribution should be checked to ensure that they correspond to your submission. If there are discrepancies, the Scheme should be informed immediately so that the necessary corrections can be made and a new report issued.

Laboratories MUST quote their unique five digit laboratory code in all communication with the Scheme Office.

7.5 Certificates

Separate participation and performance certificates are made available online on the Scheme Report page, select the button 'Certificates' and follow the online instructions. Participants will be notified once the certificates have been released. Participants requiring proof of participation/performance for accreditation purposes prior to the release of the certificates should contact the Scheme Office (ceqas.info@ouh.nhs.uk).

7.6 Laboratory Feedback

Occasionally laboratories will be invited to complete online questionnaires when specific information is required by the Scheme Office**. Results of these surveys will be made available to participants.**

7.7 Complaints

Minor misunderstandings or problems with specimens and reports, can usually be resolved over the telephone or by email (ceqas.info@ouh.nhs.uk).

Formal complaints need to be made in writing (email or letter) and will, where possible, be dealt with within 14 days of receipt. If outside bodies need to be involved in resolving the complaint then the originating laboratory will be informed of the delay and will be kept informed of the progress

All formal written complaints are discussed with the relevant Specialist Advisory Group (SAG) or Scientific Advisory Board and the Scheme Director will reply to the complainant. The Chair of the relevant SAG or Scientific Advisory Board will respond to any complaints sent directly to them. Addresses for the SAG chairs and the Chair of the Scientific Advisory Board are available from the Scheme Office to any participants who wish to express comments or concerns about the Scheme and its operation.

7.8 Unresolved complaints

If difficulties persist, then participants with continued justified cause for complaint about any aspect of the service should communicate their concerns in writing to the Chair of the relevant SAG - though a preliminary telephone call may be helpful in clarifying the issue and establishing the requisite action.

- Where the complaint is about Scheme logistics, or a matter related to performance assessment and EQA design, it is more appropriate to contact the Scheme Director;
- If the complaint concerns the conduct of the Scheme Director, Deputy Scheme Directors or Quality Manager, then the OUH Operational Services Manager for Pathology and Laboratories should be contacted;
- Complaints are logged, and the action taken recorded and audited;
- If the complaint concerns the conduct of the SAG or Scientific Advisory Board, the respective Chair should be contacted;
- If contacting the Specialist Advisory Group does not deliver satisfactory results, the Chair of the Scientific Advisory Board should be contacted;
- If the issue concerns a persistent poor performance designation, the Chair of the NQAAP (UK) or relevant national bodies may also be contacted;
- Where lack of compliance with ISO 17043 standards is suspected by the complainant, the Chief Executive of UKAS may be contacted;
- Where the UK NEQAS Consortium code of practice itself is the issue of concern, the Chair of the UK NEQAS Executive is appropriate.

In all cases, CEQAS staff will provide the names and addresses of the appropriate individuals.

8. MANUALS AND GUIDES

There are a number of user guides available on the static website under http://www.ceqas.org/user-manuals to assist participants in navigating the different aspects of the online system.

8.1 Website User Guide

A user guide for navigating the Participant Website is available to download on the static website under Participation/User Manuals.

8.2 Online EQA User Guide

A user guide describing the process of the online EQA is available to download from the website under Participation/User Manuals.

9. LOCATION & ADMINISTRATION

CEQAS is based at the Women's Centre, John Radcliffe Hospital in Oxford. The John Radcliffe Hospital is part of the Oxford University Hospitals NHS Foundation Trust.

CEQAS is administered through the Directorate of Clinical Support Services Division within the Trust but is independent from pathology services provided by the Trust.

Financial administrative services for the Scheme are provided by the Finance Department OUH Finance Department, Third Floor, Unipart House Business Centre, Garsington Road, Oxford. OX4 6LN The Scheme Director is the budget holder for the Scheme and obtains advice and support from the Directorate Finance Manager.

The Scheme's IT support, as well as all other service costs are covered by the hosting agreement with the Oxford University Hospitals NHS Foundation Trust.

Postal address:

CEQAS
Level 1, Women's Centre
John Radcliffe Hospital
Oxford University Hospitals NHS Foundation Trust
OXFORD, OX3 9DU
U.K.

Courier services should be given the room number (Room 1410) in addition to the postal address.

Telephone
The office is staffed on weekdays from 0800 to 1600. To help us deal with your query efficiently, please select as follows:

Quality Management/general queries	+44 (0)1865 220399
Invoices/Repeat samples	+44 (0)1865 220545
Scientific/Scheme Management	+44 (0)1865 220324
Scientific/Scheme Management	+44 (0(1865 857644

:
Voice mail recordings can be left outside office hours and during official holidays.

Email **cegas.info@ouh.nhs.uk**

Website **http://www.cegas.org**

This website consists of a static website (public) and a secure website (participants only).

- The static website gives information such as EQA timetable, contact details, staff and general information about the Scheme as well as performance criteria and composition of the SAGs and Scientific Advisory Board.
- The secure website (after logging in) allows all registered participants to access EQAs and related information, make submissions as well as access the Individual Laboratory Reports (ILR) and summary documents online.

The primary laboratory contact can manage their laboratory details – change address and contact details, add or delete additional users and purchase EQAs. Every laboratory has a 'staff quota' of 10 which the Primary Contact can allocate.

If the Primary Contact changes please contact the Scheme Office giving the name and email address of the new Primary Contact so that the developers can make the necessary changes to the account.

If you require a new password, please contact the Scheme Office (**cegas.info@ouh.nhs.uk**).

10. STAFFING

10.1 Scheme

Dr Rosalind Hastings (Clinical Scientist) is the Scheme Director (SD) for the Scheme. **Dr Katrina Rack** (Clinical Scientist) is the Deputy Scheme Director for acquired disorders. **Mrs Bettina Quellhorst-Pawley** is the full time Quality Manager, **Mrs Cheryl Guiver** is the Scheme Technical Officer. All staff are subject to annual appraisal. A member of staff is usually available in the office for consultation or enquiries during office hours.

10.2 Assessors

Assessors are senior members of the profession with extensive experience of reporting complex results and are usually recruited by advertisement **(for list see Appendix C)**. Appointments are for four years initially and can be extended by mutual agreement. Assessors' laboratories are expected to participate in the EQAs they are assessing but their laboratories are are not charged for the EQA, however, assessors should not be involved with their laboratory's report for the EQA they are assessing.

Assessors are involved in the design of the EQA to ensure that it reflects clinical case scenarios and also help to establish marking criteria. The assessors are responsible for scrutinising and assessing technical, analytical and interpretive performance in consultation with the Scheme Director, relevant Deputy Scheme Director and Specialist Advisory Group **(see Appendix C)**. Any individual wishing to be an assessor should contact the Scheme Director who will be pleased to discuss details.

11. OVERSIGHT and PROFESSIONAL LINKS

Accountability for the Scheme is set out diagrammatically in **Appendix A.** The Scheme complies with the UK NEQAS Consortium code of practice (**Appendix B**).

All EQA providers are required to seek advice from a Scientific Advisory Board and Specialist Advisory Groups, comprising of expert professionals in appropriate areas of laboratory work, representatives of professional bodies and fellow organisers (**Appendix C**).

11.1 Scientific Advisory Board

The Scheme has its own Scientific Advisory Board, chaired by Dr Lorraine Gaunt (Manchester) which provides scientific support to the Scheme Director. The Scientific Advisory Board consists of the Chairs of the different Specialist Advisory Groups, invited experts, the Scheme Director, Deputy Scheme Directors and the Quality Manager. The Board meets once a year.

11.2 Scientific Advisory Groups (SAG)

The Specialist Advisory Groups advise the Scheme Director on the overall design, operation and scientific content of the EQAs, appropriateness of the investigations surveyed, the nature of the specimens distributed as well as on the number and frequency of specimen distribution. The SAGs consists of representatives from all relevant assessor teams (e.g. Amniotic Fluid, CVS etc for the Prenatal SAG) as well as the Scheme Director, the relevant Deputy Scheme Director and the Quality Manager. The SAGs also review participants' submissions that have received a poor performance and review appeals. The Chairs of the SAGs are members of the Scientific Advisory Board.

11.3 NQAAP and other national regulatory bodies

The Scheme Director reports to the chair of the National Quality Assurance Advisory Panel (NQAAP) for Genetics which is responsible for monitoring performance standards in UK laboratories and to . If applicable, the Scheme Director reports to the relevant national regulatory bodies in other countries.

On request of the Swiss Society of Medical Genetics (SSMG), CEQAS has a collaboration agreement with CSCQ (Centre Suisse de Contrôle de Qualité) who distribute EQA samples for CEQAS and administer the EQA payment for the laboratories. CSCQ will issue Swiss laboratories with an annual certificate, approved by SMGM, QUALAB and FOPH, for their participation in CEQAS EQAs, CSCQ will pass on information about poor performance to FOPH.

Anonymised Poor Performance data is also shared with the ESHG-Eurogentest Quality Subcommittee.

The Scheme is currently recognised by the Joint Working Group for Quality Assurance (JWG) according to criteria developed for all EQA providers **(Appendix F)**.

11.4 Professional Links

The Scheme collaborates with other EQA schemes such as the UK NEQAS for Molecular Genetics and EMQN (European Molecular Quality Network). In addition, CEQAS has links with other National Cytogenetic Schemes. The Scheme also has informal links with the ACGS (Association for Clinical Genetic Sciences), ECA (European Cytogeneticists Association), ESHG (European Society of Human Genetics) and ESHRE (European Society of Human Reproduction and Embryology).

12. CONFIDENTIALITY

Laboratories must not disclose their CEQAS participant codes to third parties. Raw data and performance scores are confidential between the individual laboratory and CEQAS staff.

Participation information on whether a laboratory participates in CEQAS or a specific EQA will be disclosed to Orphanet database and other EQA related bodies. The unique laboratory code, raw data or performance will not be disclosed to these bodies. A laboratory can specifically request that the participation information is not disclosed; this request has to be made to the Scheme Director in writing.

Performance scores (and some other relevant raw data) may be shared with the relevant national regulatory body where applicable under defined circumstances (**see Appendix E and F**) as part of the routine reporting of persistent poor performance. When a laboratory is referred to NQAAP the identity of the laboratory will be disclosed to the panel.

CEQAS offers a number of EQAs in collaboration with other EQA providers, namely EMQN and UK NEQAS for Molecular Genetics. In order to maintain performance monitoring for laboratories potentially alternately registering with either of these providers, the identity of laboratories with poor performance and persistent poor performance may be shared between the Scheme Directors if applicable.

Performance scores, in anonymised form, may be shared with local management, accrediting bodies, and suppliers of equipment and reagents where appropriate and necessary, ***but only with the participant's explicit permission***.

If deemed appropriate by the Scheme Directors, participation and performance data may be shared with collaborating EQA providers (EMQN, UK NEQAS for Molecular Genetics) in order to prevent 'Scheme Hopping' due to Poor Performance.

13. ACCREDITATION

CEQAS is operated by the Oxford University Hospitals NHS Foundation Trust and is a UKAS accredited proficiency test provider No 7872. Further information about the scope of accreditation and the EQA Standard (ISO17043) can be obtained from UKAS at 21-47 High Street, Feltham, Middlesex, TW13 4UN, Tel: (020) 8917 8400, Fax: (020) 8917 8500 website **http://www.ukas.com.**

14. PARTICIPANTS MANUAL

14.1 Feedback

This Manual has been made as comprehensive as possible, but it is appreciated that revision may be required to reflect changes and/or progress. Participants are invited to make comments and suggestions, so that amendments may be made for the next edition. This also applies to the websites where much of the information contained in this manual can also be found.

14.2 Copies

This manual is provided free of charge for the individual use of the Scheme participants and professional expert groups.

15. COPYRIGHT NOTICE.

CEQAS logo – The CEQAS logo is copyright. It must not be used on laboratory documents, promotional material or websites without the written consent of the Scheme Office.
© Copyright CEQAS

Images CEQAS images, reports and documents are copyright and may not be copied, distributed, published or used for publicity and promotion in any form without the written consent of the Scheme Director on each and every occasion, though performance data may be shared with individual clients (e.g. GPs, clinicians, pharmaceutical companies) without consultation.

Participants' Manual - No part of this participants' manual may be copied, distributed or published in any form without the written permission of the CEQAS Scheme Director on each and every occasion.
© Copyright CEQAS

16. ACKNOWLEDGEMENTS

The Scheme relies on the hard work and cooperative efforts of a large number of people including local support staff at Oxford University Hospitals NHS Foundation Trust, the Scientific Advisory Board, the Specialist Advisory Groups, and all assessors. The Scheme Director receives considerable professional support from colleagues without whose professional input the Scheme could not function (**see Appendix C**). The continued loyalty of all participants, which has enabled us to develop and expand to meet the challenges of the new EQA environment, is also acknowledged.

17. TECHNICAL (IT) REQUIREMENTS

All CEQAS software works optimally with Google Chrome although Firefox and Internet Explorer 9 may also be used (some reduced functionality). Earlier versions of Internet Explorer are NOT supported.

18. REFERENCES

All links and references given in this manual were correct at the time of publication

1. European Cytogenetic Guidelines for Constitutional, Acquired and Tumour http://www.e-c-a.eu/en/GUIDELINES.html

2. ESHRE Guidelines for clinical preimplantation genetic diagnosis (PGD) and preimplantation genetic screening (PGS): http://humrep.oxfordjournals.org/cgi/content/full/20/1/35

3. ESHG Reporting Guidelines http://www.nature.com/ejhg/journal/v22/n2/full/ejhg2013125a.html

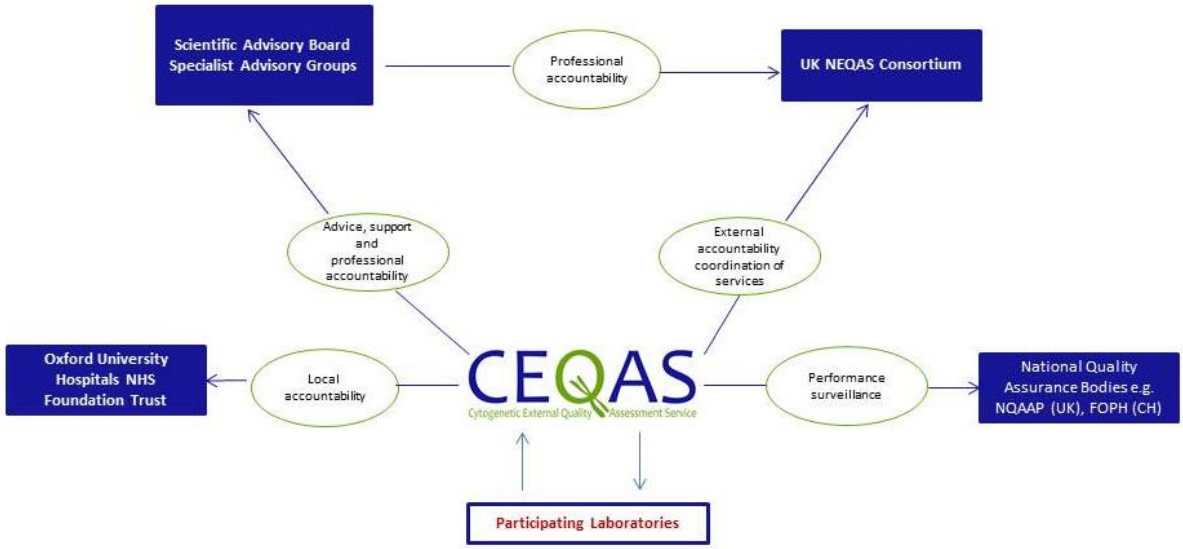
4. ISO 15189:2012. Medical laboratories – requirements for quality and competence.

Appendix A

Overview of the UK NEQAS Consortium Organisation

UK National External Quality Assessment Service Consortium:

- A charitable company limited by guarantee (charity registration number: 1044013; company registration number: 3012351)
- Company membership (guarantor) open to those Schemes entitled to use the name UK NEQAS
- Executive elected from and by the membership
- UK NEQAS pilot schemes may enjoy associate membership
- The CEQAS Scientific Advisory Board and Specialist Advisory Groups are professionally accountable to the UK NEQAS Consortium,
- CEQAS has external accountability and co-ordination of services to the Consortium.
- The consortium publishes Codes of Practice for member schemes on their website (see **Appendix B**)



Appendix B: UK NEQAS Consortium Document

The UK NEQAS Code of Practice for member schemes

DATED 18 October 2013

1. Defined Terms

1.1 "**Company"** means the legal entity known as United Kingdom National External Quality Assessment Service – a company limited by guarantee and a registered UK Charity.

1.2 **"Executive Committee"** means those directors the company have appointed to perform the duties of the executive committee as defined in the memorandum and articles of the association of the company.

1.3 **"Members"** are defined as EQA Schemes or groups of EQA Schemes which have been accepted for membership of the Company as represented through the members Scheme or Unit Organiser/Director

1.4 **"Organiser"** means the individual designated by the executive committee as being responsible for the design and direction of the member Scheme and accountable to the executive committee for its compliance with the UK NEQAS Code of Practice. The term 'Director' may be used by member Schemes to mean Organiser if this is their tradition, provided that there is no confusion in understanding. For example, the distinction must be clear between the Director (head of service) of a department which hosts a Scheme, and the designated Director (= Organiser) of the member Scheme, if they are separate individuals.

1.5 The Rules shall be binding on all members of the Company. No Rule shall be inconsistent with, or shall affect or repeal anything contained, in the articles and in the event of any conflict or ambiguity between the articles and these Rules, the articles shall prevail.

1.6 The Executive Committee is accountable to the members for implementation of the strategy of the organization, as agreed by the members at General Meetings.

1.7 Directors of the Executive Committee are responsible for complying with all UK Company Law and UK Charity Law, as both directors and trustees of the Company.

1.8 Scheme Participants may be individuals, laboratories or other service providers.

1.9 The Executive Committee directors are responsible for ensuring that all Members of the Company adhere and comply with this Codes of Practice, and any other Rules as made by the Executive Committee from time to time in accordance with article 33 of the articles of association and the memorandum and articles of association of the Company.

1.10 This Code of Practice applies to all Members. Entry into Membership of the Company is conditional upon the complete and absolute adherence to these codes and any other subsequent Rules made by the Company.

2. Purpose of the Code

2.1 This Code of Practice governs the behaviour of and provides guidance to Members, the Company, and Directors on the Executive Committee as to best practice and standards and governs the conduct of behaviour between the parties.

2.2 This code operates and is applicable in relation to Members and the Executive Committee.

2.3 In examining an individual's or Member's behaviour against this Code, account shall also be taken of the company's articles and memorandum of association.

2.4 This Code should be read in conjunction with guidance issued from Companies House and the Charity Commission that covers the statutory responsibilities of the directors on the executive committee as company directors and charity trustees.

2.5 All Members shall receive a copy of this Code and the Memorandum and articles of the company upon admission as a Member of the Company.

2.6 An undertaking to abide by this Code is mandatory to all members, Scheme Directors and Directors on the Executive Committee. It operates as a contract between the Company and its members.

2.7 This Code may be reviewed, to ensure its effectiveness; and compatibility with the ethos of the Company and symmetry, adherence and compatibility to the company's memorandum and articles of association.

3. Membership Procedures

3.1 Schemes shall be admitted to membership of the Company when approved by the Executive Committee in accordance with the articles of association of the Company.

3.2 Applications for membership shall be made to the Executive Committee on an approved application form available from the Company Secretary and submitted in accordance with the articles of association. The application shall be accompanied by a signed statement from the Organiser that the Scheme(s) complies with the Code of Practice.

3.3 Pilot Schemes shall be admitted as Associates in accordance with the memorandum and articles of association and will comply with all relevant conditions of this Code of Practice, including clause 6.3 where a subscription is charged.

3.4 The Executive Committee can in its absolute discretion decline to admit to Membership any Applicant that fails to fulfil the criteria for the objects of the memorandum and articles of association, and this Code of Practice.

3.5 Only those Schemes that are admitted to full membership or have associate status shall be entitled to use the service mark "UK NEQAS" and associated logo. Use of the UK NEQAS service mark and logo by member Schemes and third parties is regulated and governed by the attached Appendix 1.

3.6 A Scheme that fails to comply with this Code of Practice shall be reminded by the Executive Committee of its obligation as a member of the Company and be required to rectify the non-compliance. In the event that a Scheme still fails to comply with this Code of Practice, the Executive Committee will prepare a written case for that Scheme to cease to be a member of the Company, and be entitled to follow the procedure with regard to the termination of membership as detailed at article 4 of the Company's articles of association.

3.7 For a breach by a Member of this Code of Practice the Member shall be offered three months in which to prepare a written case for remaining as a member of the Company. The documents shall be circulated to all members, who will determine, by a majority vote of the Company in General Meeting, whether the member should be expelled from the Company, provided that any member to be so expelled shall also have the opportunity to make representation to the meeting at which the decision is to be made, in accordance with article 6 of the Company's articles of association.

3.8 Any decision to expel a member shall have immediate effect. Membership is not transferable, and all such rights and privileges shall cease upon the Member ceasing to be such.

3.9 A Member will be declined and expelled from Membership if it carries out activities of a profit-making nature which includes, but is not limited to declaring a dividend, bonus or otherwise making profit. Any operating surplus will be reinvested.

4. Member Scheme Management

4.1. The Scheme shall be open to all UK providers offering a clinical service for investigations covered by the Scheme. Other participants may be accepted by agreement with the Scheme Director.

4.2. The investigations covered by the Scheme shall be selected on the basis of their clinical relevance.

4.3. Schemes shall be independent of any manufacturing and marketing interests in equipment and reagents in the field in which they operate, and any interests in the provision of analytical or other services shall be declared.

4.4. The staff involved in directing and operating the Scheme shall be appropriately qualified to the required professional standard and proof of such qualifications should be provided.

4.5. The conditions of participation for UK providers of direct or indirect clinical service shall be those currently defined by the Joint Working Group for Quality Assurance.

4.6. The Scheme Director shall liaise with a UK NEQAS Steering Committee and/or Specialist Advisory Group comprising appropriate experts, participants and clinical advisers approved by the Executive Committee

4.7. Minutes and lists of attendees at Steering Committee/Specialist Advisory Group Meetings shall be copied to the Company's office.

4.8. The Scheme Director shall monitor those participants failing to maintain acceptable levels of performance. The Scheme Director shall be responsible for presenting reports as required to the appropriate division's National Quality Assurance Advisory Panel (NQAAP) which is recognised by the Joint Working Group for Quality Assurance.

4.9. The full, realistically calculated costs of operating the Scheme shall be fully recovered from participants' subscriptions.

4.10. Schemes shall be non profit making and in no circumstances shall operate on a profit making basis to benefit individuals, shareholders, guarantors or host organisations. Any operating surplus shall be reinvested in the Schemes.

4.11. The Scheme Director shall ensure that all Schemes comply with this Code of Practice and the Memorandum and Articles of Association including reporting any profit making activity to the Executive Committee.

4.12. Management arrangements shall enable continuity of the EQA service to participants.

5. Member Scheme Design

5.1. The Scheme's aim shall be to promote optimal patient care by facilitating the availability of reliable laboratory investigations, through provision of objective information on participant performance and professional advice and assistance where appropriate.

5.2. Schemes shall enable the detection of inadequate performance by participants. Participants with apparent performance difficulties should be encouraged to improve by education rather than penalty.

5.3. Material for investigation shall be distributed regularly at an appropriate frequency and in appropriate numbers, guided by advice from Steering Committee or Specialist Advisory Group.

5.4. Evidence shall be available to demonstrate the appropriateness, stability and uniformity (homogeneity) of the material distributed.

5.5. The Scheme shall provide rapid turnaround of results and performance data to participants.

5.6. Target results should be identified and an appropriate (usually quantitative) evaluation of results be presented to allow comparison of individual participants' results with overall results.

5.7. Report format should ensure the following;

5.7.1 The unique Participant Identifier Code is clearly stated on all individual reports

5.7.2 The performance scores are clearly stated on all participant reports (UK and non UK)

5.7.3 The performance criteria for each analyte/scheme are clearly stated or shown within the report or point to a website reference

5.8. The Scheme shall conform to relevant safely standards and transport regulations.

5.9. Confidentiality of individual participants' results and performance data shall be maintained except under circumstances specified in the Joint Working Group for Quality Assurance Conditions of Participation for UK clinical laboratories.

6. Obligations and Responsibilities of Member Schemes and their Scheme Directors

6.1. Scheme Directors shall keep the Company informed of changes in Schemes' details and activities and a Register of all members shall be kept at the Company's registered office in accordance with the Articles.

6.2. Scheme Directors will have reporting and filing duties which shall include the completion of an Annual Return and mid year update as required. Changes to scheme details and other information for publication (eg enhancement of services and notice of participants meetings) shall be made promptly to the Company and these amendments checked by Schemes after publication.

6.3. Financial returns including annual accounts shall be submitted as required to the Executive Committee. These shall be in a standard format and validated by appropriate supporting documentation indicating agreement and acknowledgement by the budget holder. Scheme Directors shall disclose all sources of UK NEQAS Scheme incomes. In addition, any additional income which supports the viability of the Scheme shall also be stated.

6.4. The Scheme shall share a common participant identification code with other UK NEQASs and co-operate fully with the development and maintenance of the unified participant identification code database. Information in the data base shall not be used by member schemes to the detriment of other member schemes.

6.5. The Scheme shall contribute to the operating costs of the Company's Office and the costs of the services provided by the Office, as determined by the Association and determined by the Executive Committee.

6.6. The Scheme Director shall uphold, support and promote the underlying principles of the Company as embodied in the memorandum, articles of association and Code of Practice (Rules). . Scheme Directors shall play a full part in ensuring that the Company is a harmonised, participant-responsible service and shall not damage the reputation of the Company as a whole through inappropriate action or inaction.

6.7. Scheme Directors shall achieve appropriate accreditation for their Schemes.

6.8. All aspects of the work of a member Scheme shall be open to audit conducted by or on behalf of the Company. The purpose of any such audit shall be to assess the management of the Scheme in its ability to provide a service that complies with the stated aims as stated in the memorandum, articles of association and Code of Practice of the Company.

6.9. Where Organisers of member Schemes also operate other services including non-member Schemes, other than pilot Schemes intending to be full Members, the other services shall be financially independent of the member schemes.

6.10. Organisers and staff of member Schemes and members of Steering Committees or Specialist Advisory Groups shall neither operate nor advise any EQA schemes which are in direct competition with member Schemes.

6.11 In the event of a scheme developed/provided in collaboration between two or more members/divisions, results data for all participants will be combined and presented to participants, as a minimum on an annual basis. Combined performance data will be presented to the relevant National Quality Assurance Advisory Panel(s).

6.12 The Organiser of the Scheme shall ensure that the Scheme is carried out in a non profit making capacity and shall communicate this ethos across all stakeholders of the Scheme

6.13 The Organiser of the Scheme shall ensure that all Personnel of their Scheme are aware that they can be expelled from membership of the Company if they operate the Scheme in a profit making manner.

Appendix C
Scheme Oversight and Associated Professional Bodies

Scientific Advisory Board

Name	SAG	Location
Dr Lorraine Gaunt	Chair	Manchester
Prof Karsten Held	Clinician/Deputy Chair	Hamburg
Dr Ros Hastings	Scheme Director	Oxford
Dr Katrina Rack	Deputy Scheme Director Haematology/Oncology	Oxford
Vacancy	Deputy Scheme Director	Oxford
Mrs Bettina Quellhorst-Pawley	Quality Manager	Oxford
Dr Heleen Schuring-Blom	Prenatal Constitutional	Utrecht
Dr Anna Slunga-Tallberg	Postnatal Constitutional	Helsinki
Dr Pamela Renwick	PGD	London
Mr Eddy Maher	MRA	Edinburgh
Mrs Eva van den Berg de Ruiter	Haematology	Groningen
Mr David Betts	Oncology	Dublin
Dr Sandi Deans	Scheme Director UK NEQAS for Molecular Genetics	Edinburgh
Dr Conny van Ravenswaaij-Arts	Genetic Counselling	Groningen
Dr Jonathan Waters	Chair of NQAAP/HGTA	London
TBC	Clinical Geneticist	

Address Scientific Advisory Board Chair:
Dr Lorraine Gaunt
Regional Cytogenetics Unit - Genetic Medicine (6th Floor)
St Mary's Hospital
Oxford Road
Manchester
M13 9WL

CEQAS Scientific Advisory Groups

Prenatal Constitutional

Name	Location
Heleen Schuring **(Chair)**	Utrecht
Martine Doco	Reims
Daniela Giardino	Milan
Silvana Guerneri	Milan
Richard Hall	London
Ros Hastings	Oxford
Karsten Held	Hamburg
Luca Lovrecic	Ljubljana
Sian Morgan	Cardiff
Bettina Quellhorst-Pawley	Oxford
Katrina Rack	Oxford
Ingrid Simonic	Cambridge
Heather Ward	Manchester

Postnatal Constitutional

Name	Location
Anna Slunga-Tallberg (**Chair)**	Helsinki
Laura Berardini	Rome
Nicole de Leeuw	Nijmegen
Caroline Devlin	Oxford
Andrew Green	Dublin
Ros Hastings	Oxford
Ron Hochstenbach	Utrecht
Bettina Quellhorst-Pawley	Oxford
Katrina Rack	Oxford
Kath Smith	Sheffield

Preimplantation Genetic Diagnosis (PGD)

Name	Location
Pamela Renwick **Chair)**	London
Tina Buchholz	Munich
Edith Coonen	Maastricht
Sandi Deans	Edinburgh
Francesco Fiorentino	Rome
Veerle Goossens	Grimbergen
Gary Harton	Boston
Ros Hastings	Oxford
Miroslav Hornak	Brno
Farrah Khawaja	Edinburgh
Céline Moutou	Strasbourg
Pamela Renwick	London
Martine de Ryke	Brussels
Markus Stumm	Berlin
Jan Traeger-Synodinos	Athens
Dagan Wells	Oxford

Rapid Prenatal (formerly MRA)

Name	Location
Erik Sistermans **(Chair)**	Amsterdam
Stephanie Allen	Brimingham
Lyn Chitty	London
Sandi Deans	Edinburgh
Jerry Evans	Newcastle
Lorraine Gaunt	Manchester
Ros Hastings	Oxford
Lucy Jenkins	London
Farrah Khawaja	Edinburgh
Kathy Mann	London
Simon Patton	Manchester
Katrina Rack	Oxford
Helene Schlecht	Manchester
Heleen Schuring-Blom	Utrecht
Ingrid Simonic	Cambridge

Haematology

Name	Location
Eva van den Berg de Ruiter **(Chair)**	Groningen
Berna Beverloo	Rotterdam
Blanca Espinet	Barcelona
Nicola Foot	London
Claudia Haferlach	Munich
Ros Hastings	Oxford
Isabelle Luquet	Toulouse
Kate Martin	Nottingham
Sheila O'Connor	Leeds
Katrina Rack	Oxford
Bettina Quellhorst-Pawley	Oxford
Sabine Stiou	Milan
Polly Talley	Sheffield
Zuzana Zemanova	Prague

Oncology

Name	Location
David Betts **(Chair)**	Dublin
Olaf Ansorge	Oxford
Patrick Buckley	Dublin
Steve Chatters	London
Sandi Deans	Edinburgh
Ros Hastings	Oxford
Anna Kelsey	Manchester
Thomas Kerr	Glasgow
Avril Morris	Glasgow
Bettina Quellhorst-Pawley	Oxford
Katrina Rack	Oxford
Paul Roberts	Leeds
Bauke Ylstra	Amsterdam

The names of the relevant assessors are given in the Summary Report for each EQA. A list of all CEQAS assessors is available from the Scheme Office on demand.

Assessors' term of office is 4 years with the option to extend for a further 4 years if required for succession planning. The Scheme Director is involved in all EQA rounds.

UK laboratories are subject to performance surveillance under JWG conditions as defined by the Genetics NQAAP. This Scheme is therefore required to provide information on persistent poor performance designation to the Genetics NQAAP. Acceptable performance criteria to reflect the needs of a clinical diagnostic service are agreed by the Genetics NQAAP after consultation with the Scheme Director and ratification by the relevant SAG. Special procedures are used to identify those laboratories which have breached these limits on a set number of occasions within the cumulative reporting period.

On request of the Swiss Society of Medical Genetics (SSMG), CEQAS has a collaboration agreement with CSCQ (Centre Suisse de Contrôle de Qualité) who distribute EQA samples for CEQAS and administer the EQA payment for the laboratories. CSCQ will issue Swiss laboratories with an annual certificate, approved by SMGM, QUALAB and FOPH, for their participation in CEQAS EQAs, CSCQ will pass on information about poor performance to FOPH.

National Quality Assurance Advisory Panel (NQAAP) for Genetics

Name	Role	Affiliation
Dr Jonathan Waters	Chair	JWG
Dr Fiona Coyne		ACGS
Dr Sandi Deans	By invitation	Molecular Genetics Scheme Director
Mr Jerry Hancock	By invitation	
Dr Ros Hastings	By invitation	CEQAS Scheme Director
Dr Kathy Mann		ACGS
Dr Jane Moorhead	By invitation	
Dr Simon Patton	By invitation	EMQN Scheme Director
Mr Paul Roberts		ACGS
Dr Gill Rumsby		ACB
Mr Stu Scott	By invitation	

Address NQAAP Chair:
Dr Jonathan Waters
Regional Cytogenetics Laboratory, North East Thames Regional Genetics Service
Great Ormond St Hospital NHS Trust
Level 5, Barclay House, 37 Queen Square
London
WC1N 3BH
United Kingdom

Appendix D
EQAs offered by CEQAS in 2017

CEQAS Cytogenetic External Quality Assessment Service

EQA Timetable 2017

Spring EQAs	Type	EQA open	EQA close	Part 2 close
Amniotic Fluid	OL	03/04/2017	05/05/2017	
Bloods - Postnatal	OL	03/04/2017	05/05/2017	
Chorionic Villus - CVS	OL	03/04/2017	05/05/2017	
Mature B&T cell Neoplasms (G-banded only)	OL	03/04/2017	05/05/2017	
Mature B&T cell Neoplasms (FISH only for CLL and lyphoproliferative disorders)	FC	03/04/2017	05/05/2017	
Lymphoma Pilot EQA	FFPE	03/04/2017	05/05/2017	
Myeloid - AML/MDS/CML	OL	03/04/2017	05/05/2017	
PGD Blastomere (FISH)	OL	03/04/2017	05/05/2017	16/06/2017
Constitutional Microarray Analysis - Postnatal [1]	DNA	08/05/2017	23/06/2017	
Prenatal micorarray	DNA	08/05/2017	23/06/2017	
Acquired (CLL) Microarray	DNA	08/05/2017	23/06/2017	
Myeloma	FC/OL	08/05/2017	23/06/2017	
Sperm FISH	FC	08/05/2017	23/06/2017	
ALL - Acute lymphoblastic leukaemia	OL	22/05/2017	23/06/2017	

Autumn EQAs	Type	EQA open	EQA close	Part 2 close
MRA - Molecular Rapid Aeuploidy (QF-PCR/MLPA/BoBs) [2]	DNA	04/09/2017	30/09/2017	
Rapid Aneuploidy FISH	FC	04/09/2017	30/09/2017	
PGD Polar Body Array [2]	DNA	04/09/2017	30/09/2017	
PGD Blastomere/Trophectoderm array/NGS for aneuploidy [2]	DNA	04/09/2017	30/09/2017	
PGD Blastomere/Trophectoderm array/NGS for rearrangement [2]	DNA	04/09/2017	30/09/2017	
NIPT Exploratory Pilot [1][2]	cff DNA	04/09/2017	30/09/2017	
Products of Conception/Fetal Tissue G-banded	OL	11/09/2017	10/10/2017	
Products of Conception/Fetal Tissue (Array/MLPA/QF-PCR/NGS)	DNA	11/09/2017	10/10/2017	
Breakage Syndrome Exploratory Pilot	TBC	11/09/2017	10/10/2017	
CNS Tumours (formerly Adult Molecular Neuropathology)	FFPE	11/09/2017	10/10/2017	
Sarcoma [2]	FFPE	11/09/2017	10/10/2017	
Neuroblastoma Pilot	TBC	11/09/2017	10/10/2017	
Renal/Hepato Tumour Pilot	TBC	11/09/2017	10/10/2017	
Clinical Genetics Educational EQA - Cardiovascular	Online	16/10/2017	01/12/2017	
Clinical Genetics Educational EQA - Dysmorphology	Online	16/10/2017	01/12/2017	
Clinical Genetics Educational EQA - Monogenic Disorders	Online	16/10/2017	01/12/2017	
Clinical Genetics Educational EQA - Oncology	Online	16/10/2017	01/12/2017	
Clinical Genetics Educational EQA - to be announced	Online	16/10/2017	01/12/2017	

FC = Fixed Cell Suspension

[1] EQA offered in collaboration with EMQN
[2] EQAs offered in collaboration with UK NEQAS for Molecular Genetics (NB. There may be an educational case for MRA only)

FC = Fixed Cell Suspension
Participation may be limited for pilot EQAs
*in collaboration with EMQN
** in collaboration with UK NEQAS for Molecular Genetics

The following types of EQA may be involved:-

1. **Online EQA** involves the online analysis and interpretation of two or three cases. The online EQA enables you to select appropriate additional tests (e.g. FISH) if required for the reporting of the case (analytical and interpretive proficiency assessed). All cases are validated by at least two assessors prior to release.
2. **EQA samples (Sample, DNA, FFPE)** involves the distribution of DNA, fixed cell suspension samples or FFPE slides for analysis and interpretation of two or three cases (technical, analytical and interpretive proficiency assessed). All samples are validated by at least two assessors prior to dispatch.
3. **Sequential EQA** involves the online analysis and interpretation of one genetic counselling case scenario. Each stage has to be completed before the next stage can be accessed. All cases are validated by at least two assessors prior to release.
4.

Documents required for each EQA type.

All documentation must be anonymised with laboratory and staff names obscured**.**

1. **Online EQA:-** reports must be uploaded to the website as pdf documents .
2. **Validated Samples:-** reports must be uploaded to the website as pdf documents .
3. **Sequential EQAs:-** reports are entered directly into a 'report field' online

Appendix E

Performance Criteria for

Constitutional
Haematology-oncology
MRA Microarray
PGD

Background to Performance Scoring in Cytogenetics

The following Performance Criteria are applied:

- CEQAS Constitutional Performance Criteria v1.1 2016
- **https://www.ceqas.org/sites/default/files/CEQAS%20Constitutional%20%20criteria%20v1.1%202016.pdf CEQAS**
- Haematology Performance Criteria v1.1 2016 **https://www.ceqas.org/sites/default/files/CEQAS%20Haematology%20criteria%20v1.1%202016.pdf**
- CEQAS Microarray Performance Criteria v1.1 2016 **https://www.ceqas.org/sites/default/files/CEQAS%20Microarray%20%20criteria%20v1.1%202016.pdf**
- CEQAS Preimplantation Genetic Diagnosis Performance Criteria v1.1 2016 **https://www.ceqas.org/sites/default/files/CEQAS%20PGDI%20criteria%20v1.1%202016%20%20approved%20by%20NQAAP.pdf**
- CEQAS and UK NEQAS for Molecular Genetics MRA Performance Criteria v2 2015 **https://www.ceqas.org/sites/default/files/CEQAS-MolGen%20MRA%20Criteria-V5.0.pdf**

Laboratory performance surveillance and assessment by CEQAS is regarded by the profession as an essential component of quality assurance of the clinical cytogenetics service. External quality assessment facilitates optimal patient care by encouraging the availability of timely and reliable laboratory investigations and professional advice.

CEQAS maintains the principle of assessment by professional consensus, and supports the general philosophy of the UK NEQAS consortium schemes to improve standards by education and peer group review rather than by penalty wherever possible. Performance criteria provide benchmarks which allow comparison of laboratories against national guidelines. Satisfactory performance reassures clinical colleagues, other professionals, and the public about the standard of work in laboratories.

In order to comply with UKAS accreditation standards for External Quality Assessment Schemes (ISO 17043), it is necessary to define the criteria for acceptable performance. CEQAS has developed a scoring system such that substandard performance in any criterion can be converted into a numerical score. This is considered essential to allow objective comparisons to be made between participant laboratories and against absolute standards. Furthermore, in order to protect the interests of patients, appropriate strategies for dealing with poor performance have to be clearly defined.

A laboratory with persistent poor performance, as defined in the performance scoring document, will be referred to the relevant advisory panel, which has executive responsibility for maintaining satisfactory standards of work in laboratories in the respective country. Such a referral, for any aspect of its service, could have adverse implications for a laboratory for Accreditation. It is clearly important, therefore, that only those laboratories consistently providing an unacceptably low standard of service are identified as being persistent poor performers.

Past performance of laboratories would suggest that the referral of a laboratory to an advisory panel will be a relatively infrequent event.

Where no advisory panel exists, laboratories with persistent poor performance, as defined in the performance scoring document, will be ratified by the Scientific Advisory Board. It is however, the responsibility of the laboratory to inform the relevant authorities of a persistent poor performance designation.

The performance criteria can be found on the website (http://www.ceqas.org) under ‘Participation’.

Appendix F

Joint Working Group (JWG) Conditions of Participation by UK Clinical Laboratories in External Quality Assessment Schemes

CONDITIONS OF PARTICIPATION BY UK CLINICAL LABORATORIES IN EXTERNAL QUALITY ASSESSMENT SCHEMES

Joint Working Group for Quality Assurance : Conditions of EQA Scheme Participation

The Joint Working Group for Quality Assurance (JWG) is a multidisciplinary group accountable to the Royal College of Pathologists for the oversight of performance in external quality assurance schemes (EQA) in the UK. Membership consists of the Chairmen of the National Quality Assurance Advisory Panels (NQAAPs), and representatives from the Institute of Biomedical Sciences, the Independent Healthcare Sector, the Department of Health and CPA (UK) Ltd.

1. The Head of a laboratory is responsible for registering the laboratory with an appropriate accredited EQA scheme.

2. The laboratory should be registered with available EQA schemes to cover all the tests that the laboratory performs as a clinical service.

3. EQA samples must be treated in exactly the same way as clinical samples. If this is not possible because of the use of non-routine material for the EQA (such as photographs) they should still be given as near to routine treatment as possible.

4. Changes in the test methodology of the laboratory should be notified in writing to the appropriate Scheme Director and should be reflected in the EQA schemes with which the laboratory is registered.

5. Samples, reports and routine correspondence may be addressed to a named deputy, but correspondence from Organisers and NQAAPs concerning persistent poor performance (red – see point 8.) will be sent directly to the Head of the laboratory or, in the case of the independent healthcare sector, the Hospital Executive Director.

6. The EQA code number and name of the laboratory and the assessment of individual laboratory performance are confidential to the participant and will not be released by Scheme Directors without the written permission of the Head of the laboratory to any third party other than the Chairman and members of the appropriate NQAAP and the Chairman and members of the JWG. The identity of a participant (name of laboratory and Head of Department) and the tests and EQA schemes for which that laboratory is registered (but not details of performance) may also be released by the Scheme Director on request to the Health Authority, Hospital Trust/Private Company in which the laboratory is situated after a written request has been received.

7. NQAAP may, with the written permission of the Head of a laboratory, correspond with the Authority responsible for the laboratory, about deficiencies in staff or equipment which, in the opinion of the NQAAP members, prevent the laboratory from maintaining a satisfactory standard.

8. Laboratories' EQA performance will be graded using a traffic light system; green will indicate no concerns, amber poor performance, red persistent poor performance, with black being reserved for the tiny number of cases that cannot be managed by the Organiser or NQAAP and that have to be referred to the JWG. The criteria for poor performance (amber) and persistent poor performance (red) are proposed by the EQA scheme Steering Committee in consultation with the EQA Provider/Scheme Director and approved by the relevant NQAAP.

9. When a laboratory shows poor (amber) performance the Organiser will generally make contact with the participant in accordance with the Scheme Standard Operating Procedure for poor performance. Within 2 weeks of a laboratory being identified as a persistent poor performer (red), the Organiser will notify the Chairman of the appropriate NQAAP together with a resume of remedial action taken or proposed. The identity of a persistently poor performing laboratory (red)

will be made available to members of the NQAAP and JWG. The NQAAP Chairman should agree in writing any remedial action to be taken and the timescale and responsibility for carrying this out; if appropriate, this letter will be copied to accreditation/regulatory bodies such as CPA (UK) Ltd, UKAS and HFEA who may arrange an urgent visit to the laboratory. Advice is offered to the Head of the Laboratory in writing or, if appropriate, a visit to the Laboratory from a NQAAP member or appropriate agreed expert may be arranged.

10. If persistent poor performance remains unresolved (black), the NQAAP Chairman will submit a report to the Chairman of the JWG giving details of the problem, its causes and the reasons for failure to achieve improvement. The Chairman of the JWG will consider the report and, if appropriate, seek specialist advice from a panel of experts from the appropriate professional bodies to advise him/her on this matter. The Chairman of the JWG will be empowered to arrange a site meeting of this panel of experts with the Head of the Department concerned. If such supportive action fails to resolve the problems and, with the agreement of the panel of experts, the Chairman of the JWG will inform the Chief Executive Officer, or nearest equivalent within the organisation of the Trust or Institution, of the problem, the steps which have been taken to rectify it and, if it has been identified, the cause of the problem. The Chairman of the JWG also has direct access and responsibility to the Professional Standards Unit of the Royal College of Pathologists. Should these measures fail to resolve the issues, the laboratory will be referred to the Care Quality Commission for further action.

11. Problems relating to EQA Schemes, including complaints from participating laboratories, which cannot be resolved by the appropriate Organiser, Steering Committee or NQAAP, will be referred to the Chairman of the JWG.

Joint Working Group for Quality Assurance in Pathology, August 2010.

Appendix G
CEQAS
Conditions of Participation
in
External Quality Assessment

CONDITIONS OF PARTICIPATION

1. The Head of the laboratory will be responsible for registering the laboratory with the Scheme Director as a participant in the appropriate EQA (EQAs) and must indicate which of the tests available within the Scheme the laboratory performs and for which it should be registered.

2. The laboratory should be registered with available EQA to cover all the tests that the laboratory performs as a clinical service. Any changes in the laboratory's requirements in this respect must be notified in writing to the Scheme Director.

3. Samples, reports and routine correspondence may be addressed to a named Deputy, but correspondence from Scheme Director and Specialist Advisory Group (SAG) concerning poor performance or unsatisfactory return rates, will be sent directly to the Primary contact i.e. Head of the laboratory.

4. EQA samples must be treated in the same way as clinical samples. If this is not possible because of the use of non-routine material for the EQA (such as images) they should still be given as near to routine treatment as possible.

5. Changes in the test methodology of the laboratory should be notified in writing to the Scheme Director and should be reflected in the EQAs for which the laboratory is registered.

6. The EQA code number of the laboratory and the assessment of individual performance is confidential to the participant and will not be released by Scheme Director to any third party, *other than* the Chair and members of the Scientific Advisory Board (the Board) and in specified circumstances the Chair of the accrediting body, without the written permission of the Head of the laboratory. The identity of a participant (name of laboratory and Head of Department) and the tests and EQAs for which that laboratory is registered (but *not* details of performance) may also be released by the Scheme Director on request to the Health Authority, Hospital Trust/Private Company in which the laboratory is situated after a written request has been received (see section 12).

7. This Scheme has criteria for unsatisfactory performance agreed by the Genetics NQAAP (UK National Quality Assurance Advisory Panel). When a laboratory shows unsatisfactory performance or fails to return results, the Scheme Director will generally make informal contact with the participant. If performance fails to improve, the Scheme Director will notify the Chairman of the Specialist Advisory Group. Advice is then offered to the Head of the laboratory by contact in writing.

7.1 On request of the Swiss Society of Medical Genetics (SSMG), CEQAS has a collaboration agreement with CSCQ (Centre Suisse de Contrôle de Qualité) who distribute EQA samples for CEQAS and administer the EQA payment for the laboratories. CSCQ will issue Swiss laboratories with an annual certificate, approved by SMGM, QUALAB and FOPH, for their participation in CEQAS EQAs, CSCQ will pass on information about poor performance to FOPH.

8. Problems relating to EQAs, including complaints from participating laboratories, which cannot be resolved by the Scheme Director or Specialist Advisory Group will be referred to the Board.

9. All reports, and the data they contain, issued by the Scheme Director are copyright and may not be published in any form without the permission of the Scheme Director on each and every occasion.