



Cytogenetic European Quality Assessment (CEQA)

Scheme Organiser:

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PARTICIPANTS' MANUAL 2012

CEQA, John Radcliffe Hospital, Oxford

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1.0 BACKGROUND TO CEQA

In 2005 the Forum of European Cytogenetic EQA providers, assembled under the umbrella of the EuroGentest network, agreed to establish a European EQA Scheme independent of existing or proposed National Schemes. Members of the Forum agreed on a design for the Scheme; set the marking criteria and formed the assessment panel and Steering Committee. Following two successful pilot schemes, undertaken by a small number of invited laboratories in 2006, the CEQA Scheme has been extended to all cytogenetic laboratories within Europe and worldwide.

1.1 THE REMIT OF CEQA

CEQA is a not-for-profit organisation and its objectives are:

- To provide professionally-led and scientifically-based EQAs with an educational objective to help individual laboratories appraise their performance and implement improvements;
- To achieve frequent distributions of multiple specimens, where appropriate, and feedback of results to participants;
- To produce informative and intelligible reports structured to assist interpretation and use by different levels of laboratory staff.

1.2 SCOPE OF THE SCHEME

1.2.1 Assessments

The Scheme assesses the overall quality of diagnostic analysis and interpretation performed by a laboratory using online reference material or, in some cases, 'wet' samples; this is followed by a comparison of the submissions against exemplary results. The Scheme assesses tissue specific performance for constitutional, haemato-oncology and pre-implantation genetic cases.

The Scheme will continue to expand its repertoire to incorporate other methods of assessment or audit.

1.2.2 Scope

CEQA covers Pre- and Postnatal Cytogenetics, Haemato-Oncology Cytogenetics, Preimplantation Genetic Diagnosis (FISH) as well as Microarray/ArrayCGH in collaboration with the European Molecular Quality Network (EMQN). A list of EQAs offered in 2012 can be found under Section 1.3.

1.3 CURRENT EQAs

In 2012 CEQA will offer the following EQAs:

- Postnatal Blood samples;
- Amniotic Fluids;
- CVS;
- Preimplantation Genetic Diagnosis (Blastomere);
- Micorarray (ArrayCGH) in collaboration with EMQN;
- Myeloid Disorders and Acute Leukaemias (AML/ALL/MDS);
- Mature B- and T- cell Neoplasms (LPD/CLL/MM).

Furthermore there will be pilot EQAs for:

- FISH Rapid Aneuploidy testing;

In addition CEQA is collaborating with UK NEQAS for Molecular Genetics on the feasibility of a PGD Array Pilot EQA.

The Scheme currently consists of the online analysis of images by the participating laboratory through the CEQA website. Submissions can be made in Czech, Dutch, English, French, German, Italian and Spanish. (the languages of the current assessors). Assessment of the analysis, report writing and clinical interpretation is carried out by a panel of assessors.

2.0 CEQA INFORMATION

2.1 LOCATION & ADMINISTRATION

The Cytogenetic European Quality Assessment Scheme is based at the Women's Centre, John Radcliffe Hospital in Oxford. The John Radcliffe Hospital is part of the Oxford University Hospitals NHS Trust.

CEQA is administered through the Directorate of Critical Care, Theatres, Diagnostics and Pharmacy within the Trust but is independent from pathology services provided by the Trust. The CEQA Scheme Organiser is the Budget Holder for the Scheme, with financial and administrative services provided by the Finance Department at the Manor House Annexe of the Oxford University Hospitals NHS Trust under Mr Nigel Byng (Finance Manager).

Other support, including IT and domestic arrangements, are provided by the Trust, to whom an annual 'service charge' is paid.

2.2 COMMUNICATIONS AND OFFICE HOURS

The **postal address** is:

CEQA (Cytogenetic European Quality Assessment)
Women's Centre
John Radcliffe Hospital
Headington, OXFORD
OX3 9DU
United Kingdom

Courier services should be given the room number (**Room 2809**) in addition to the address.

The **telephone** number is **+44 (0)1865 220399 (direct line)** staffed on weekdays from 08:00 to 16:00, with voice mail recording out of hours or when staff are not available.

The **FAX** number is **+44 (0) 1865 857632**. The line is available 24 hours a day, 7 days a week.

2.3 WEBSITE

For all queries and contacts, there is an email **mailbox** at bettina.qp@ouh.nhs.uk

In collaboration with EuroGentest and UK NEQAS for Clinical Cytogenetics, CEQA has developed a web based system for registration, electronic submission and transmission of results as well as progress and performance tracking which was launched in Autumn 2007.

The Scheme website address (home page) - www.ceqa-cyto.eu - consists of a public website which gives information such as EQA timetable, contact details, staff and general information about the Scheme as well as performance criteria and composition of the Steering Committee. To access these documents, use the grey menu bar on the Home page.

Once logged in, all registered laboratory participants (maximum 3) can access EQAs and related information, make submissions as well as access the Individual Laboratory Reports (ILR) and summary documents online. The system will also provide a number of certificates (registration, participation, performance) and some statistical information. Only the first and second registered participants can manage their laboratory details – change passwords, contact details and add or delete additional users and purchase EQAs.

Further useful information may be found at www.eurogentest.org which carries general information about the whole EuroGentest network.

2.4 STAFFING

Dr Rosalind Hastings (Clinical Scientist) is the Organiser for the CEQA Scheme. The Scheme is supported by a part time Quality Manager, Bettina Quellhorst-Pawley, a full time Scheme Technical Officer, Cheryl Guiver and a part-time Consultant Cytogeneticist, Rodney Howell.

All staff undergo an annual appraisal. The CEQA office is available for consultation or enquiries during office hours.

The Scheme Organiser is assisted by other colleagues drawn from the ranks of practicing senior clinical cytogeneticists (see **Appendix D**). Steering Committee members as well as assessors are normally experts in their field and in many cases organisers of National Schemes.

2.4.1 Assessors

The assessors are responsible for scrutinising and assessing technical, analytical and interpretive performance in consultation with the Scheme Organiser (see **Appendix D**). Any individual wishing to be an assessor should apply to the Scheme Office by email enclosing a current curriculum vitae in English. Assessors must have at least 6 years experience in cytogenetics and an appropriate national qualification, if applicable. Detailed job and person specifications are available from the Scheme Office. Assessor appointments are for four years for a specific EQA but can be extended for up to four years, if required for succession planning.

2.5 OVERSIGHT AND PROFESSIONAL LINKS

Accountability for the Scheme is set out diagrammatically in **Appendix A**.

The Scheme Organiser receives scientific advice and support from Assessors, the Steering Committee and the PGD Specialist Advisory Group (SAG) comprising of expert professionals in appropriate areas of laboratory work, representatives of professional bodies and fellow Scheme Organisers (**Appendix D**) as well as a Steering Committee. The Steering Committee consists of European Scheme Organisers as well as selected experts in the field (**Appendix D**). The Steering Committee has set the poor performance criteria and deals with any appeals made by participants. Steering Committee appointments are for four years but can be extended for up to four years if required for succession planning.

The Scheme is overseen by the European Society of Human Genetics (ESHG) Genetic Services Quality Committee. Duties of this committee include governance of the European EQA Schemes including CEQA. They also are agreeing genetic persistent poor performance.

The membership and contacts for the Assessors, SAGs, SC and Quality Committee are available in **Appendix D** for any participants who wish to express comments or concerns about the Scheme and its operation (see also Complaints Procedures **Section 2.12**).

The Scheme has informal links with other EQA Schemes such as EMQN (the European Molecular Quality Network) as well as with UK NEQAS for Clinical Cytogenetics and UK NEQAS for Molecular Genetics.

2.6 ACCREDITATION

EQA assesses the performance of laboratories to ascertain the level of service and expertise offered to the patient. In order to ensure that the operation of the Scheme itself meets the highest standards, CEQA is accrediting against ISO17043. This involves detailed analysis and auditing of the scheme design as well as establishing a Quality Management System and annual Quality Objectives. Just like EQA, accreditation is an ongoing process with yearly accreditation visits and audits of the system. The CEQA Scheme Office is expecting its first accreditation visit in the first quarter of 2012.

2.7 PARTICIPATION

All participants of the CEQA Scheme must agree to abide by the Participants Manual. Laboratories must not use any EQA images or cases for any purpose other than education and training.

It is the responsibility of the participant to be aware of the start and closing dates of all EQAs they are currently enrolled for.

2.7.1 Eligibility

CEQA services are open to all public and private sector clinical laboratories serving clinicians and patients throughout Europe and worldwide. Laboratories from other countries will be considered for inclusion on application but acceptance cannot always be guaranteed as preference is given to European participants for the limited participation pilot EQAs. CEQA is also open to research laboratories.

2.7.2 Calendar

A full EQA timetable is published on the CEQA static website in January each year. Participants are alerted to its availability by email.

2.7.3 Registration with CEQA

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 (50***). Login details will be sent by separate email from support@certus-tech.com. Participants should contact the Scheme Office if they have not received their login details within 24 hours of their acceptance email. Registration may take place at any time.

2.7.4 EQA enrolment procedure

Participation in CEQA is deemed to be continuous with online annual renewal and invoicing for EQA and administration fees for each financial year. Full details of the participant's laboratory are collected at registration. Participation begins at the first distribution following receipt of correctly completed online registration forms. Enrolment for specific EQA schemes can occur once the laboratory's registration has been authorised by the Scheme. Laboratories can register throughout the year but EQA enrolment is limited to a set time period (usually January to April of each year). All participants are informed by email once EQA enrolment is available.

2.7.5 Annual registration charges

CEQA 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 either tissue/disease or technique based. As such they are subject to continuous review and may be changed with prior notice. Refunds of EQA enrolment charges are only payable under exceptional circumstances. Laboratories will be invoiced by the Oxford University Hospitals NHS Trust. For 2012 the annual administration fee is £110. All laboratories outside the EU are VAT exempt, all other laboratories will be charged VAT unless they have provided the Scheme Office with their VAT Registration Number.

2.7.6 CEQA laboratory code

The unique five digit laboratory code (50***), 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.

2.7.7 *Withdrawal from EQA*

Any participant wishing to withdraw from an EQA must inform the Scheme Office by e-mail of his intention 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 and will be invoiced in full. Refunds of subscription charges are only payable under exceptional circumstances. (see 'Late EQA Withdrawal Policy' under 'About' 'Scheme Policies' on the home page)

2.7.8 *Reporting of results of EQA exercises*

All participants are expected to submit results promptly within the specified reporting period. Failure to do so may have the consequence of the laboratory receiving a poor performance designation, (see performance criteria, **Appendix E**).

2.7.9 *Online analysis/cost analysis*

The online system allows the participant to choose from a variety of online tests appropriate to the referral criteria. There are often 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 "cost" based on the workload weighting (see Table 1). Once a specific test is selected – e.g. DiGeorge Syndrome – a cost of 7 units is incurred. For any EQA the range of tests available is shown on the screen under the "Tree" function.

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	

2.7.10 *ISCN*

All reports will be marked against the current ISCN nomenclature, ISCN 2009.

2.7.11 *Professional Standards*

All laboratories are assessed against the European Cytogenetic Guidelines (www.biologia.uniba.it/eca/)

2.8 COMMUNICATION

2.8.1 *Annual Report*

An annual report will be produced at the end of the year's assessments. The report includes a general overview of the Scheme operation, summary of the results of the assessments, future pilot EQAs, plans for next year's assessment etc. Where appropriate, the report will also contain an overall analysis of performance (see Individual Laboratory Reports). Copies of this document are available on

the static website. Laboratories should see the EQA Summary Reports and their Individual Laboratory Reports (ILR) for specific EQA information.

2.8.2 Annual Participants' Meeting

The annual meeting, open to all participants, includes presentations concerning the Scheme, general aspects of providing a high quality laboratory service, plans for the future and an opportunity for feedback from participants. All participants are notified of the date and venue in advance. An attendance register and minutes of the meeting are taken. This year's participants' meeting will take place during the ESHG Conference in Nuremberg, Germany in June. Participants will be invited and exact date, time and venue will be communicated to participants by email closer to the date.

2.8.3 Individual laboratory reports

Scheme reports are the main interface with participants, and these are designed to be informative and easy to interpret. Reports contain the following features:

- Tabular summaries of analytical and interpretative scores for the participant;
- Comments on individual reports and their interpretation;
- General comments and conclusions on each aspect of performance.

A summary table of performance scores from all participants as well as all submitted answers are also available in a separate Summary Report.

2.8.4 Report validation and amendment

Results for a specific EQA distribution should be checked to ensure that they are the ones returned by your laboratory. Mistakes can occur if figures are misinterpreted. The Scheme should be informed in writing with a full explanation of the reason for any amendment so that the necessary corrections can be made and a new ILR issued. CEQA undertakes audit of any errors, takes steps to ensure a robust system and keeps records of any actions taken to improve the service. **When communicating with the Scheme, laboratories must use their unique laboratory code at all times.**

2.8.5 Certificates

Participation and performance certificates will be available online after the close of each EQA round. Registration certificates are also available once the enrolment period for each year is closed. Participants are informed by email once the certificates are available to download.

2.8.6 Participants' feedback

CEQA welcomes any feedback from participants concerning the operation of the Scheme, the content of the Participants' Manual, the design and operation of the website, and any other issues. The Scheme Organiser, Quality Manager or any member of the Steering Committee will be pleased to receive your comments.

From time to time the Scheme Office will solicit feedback from the participants through feedback questionnaires. Participants will be sent a link to the relevant questionnaire by email.

2.8.7 Management review

The annual management review is submitted to the Steering Committee and the accreditation body as part of the internal quality management. The review includes participant feedback, a review of the Scheme (including poor performance) and any complaints. As an advisory body the Quality Committee of the European Society for Human Genetics (see also Section 2.5) also requires a copy of the annual management review.

2.8.8 *User manual for the website*

The user manuals for the website are available to all participants on the home page under 'Documents'.

2.9 EQA MATERIALS

The materials distributed are provided for the sole purpose of enabling External Quality Assessment at the participants' laboratory during the current distribution. The images are not for publication and are the copyright of CEQA. However, the images may be used by a participating laboratory for training purposes.

The materials used are independently validated as suitable for EQA assessment, by at least two assessors.

Cases posted on the website are donated by many different laboratories. Abnormalities are verified by assessors to warrant that each EQA exercise is a fair reflection of problems that the diagnostic laboratory may encounter in its routine work. Every effort is made to ensure good quality of images.

Participating laboratories are encouraged to submit any diagnostic cases which would be suitable for EQA. Please contact the Scheme Office before sending the material to discuss if the particular case is appropriate.

2.10 CONFIDENTIALITY

Raw data, scores and performance status are confidential between the individual laboratory and CEQA. The OECD guidelines for Molecular Genetic testing, which are applicable to Cytogenetics, recommend that EQA participation is made public. The Scheme Office will disclose EQA participation (NOT performance) to Orphanet for inclusion in its Quality Assurance (QAU) database and other relevant bodies. This QAU database is a register of genetic laboratories that includes the tests they offer, information on EQA participation and accreditation status.

CEQA reports are copyrighted and may not be copied, distributed, published or used for publicity and promotion in any form without the written consent of the Scheme Organiser on each occasion. However, laboratories may share evidence of EQA participation with individual clients (e.g. GPs, clinicians, pharmaceutical companies) without consultation. Participating laboratories have a responsibility to, as far as possible, ensure confidentiality of their laboratory code and access passwords for the CEQA website.

The unique 5 digit (50***) CEQA laboratory code must not be disclosed to third parties. If you believe your confidentiality has been breached, please contact the Quality Manager (bettina.qp@ouh.nhs.uk) who will arrange for the allocation of a new code and passwords.

2.11 PERFORMANCE CRITERIA

These are criteria by which participating laboratories are assessed (**see Appendix E**). The criteria can be found on the CEQA home page under 'EQA', select 'Marking and Performance Criteria' from the drop down menu. There are separate criteria for constitutional and haemato-oncology cytogenetics as well as for preimplantation genetic diagnosis. Performance criteria have been divided into **two** broad inter-linked categories:

- **Analytical performance:** Scoring of the quality of submitted analyses and written description including ISCN;
- **Interpretative performance:** Scoring of the quality of submitted reports for interpretation of the karyotype/genotype, including clinical advice and follow up studies.

All laboratories are expected to participate in the interpretation part of the EQA. Non-compliance will result in poor performance.

2.11.1 Poor Performance

This is incurred for the following reasons (See performance criteria on website).

- Non-submission;
- Critical analytical error (miss or invent an abnormality);
- Critical interpretation error which affects patient management;
- No interpretation of cytogenetic results.

2.11.2 Persistent Poor Performance

The designation of persistent poor performance is still to be agreed by both the CEQA Steering Committee and the ESHG Quality Committee. It is expected that participants with persistent poor performance will be referred to the ESHG Quality Committee.

2.12 COMPLAINTS PROCEDURE

2.12.1 Appeals

Laboratories usually have 15 working days to appeal any penalty points given in their individual laboratory reports. All appeals must be uploaded onto the CEQA website. An acknowledgement of their receipt will be sent via email. All appeals are reviewed by the Specialist Advisory Group (SAG). **Please note the appeals process may take eight weeks.** Formal notification of the outcome of the appeal will be given to the laboratory by the Scheme. **Any appeals received after the closing date will not be reviewed.**

2.12.2 Formal Complaints

Most complaints received by CEQA consist of minor misunderstandings or problems with Scheme logistics, performance assessment, general Scheme design, website usage or reports. These grievances are usually resolved by telephone or email.

- Participants with continued justified cause for complaint about any aspect of the service should communicate their concerns to the Scheme Organiser in writing;
- If the complaint concerns the conduct of the Scheme Organiser, or you consider that the Scheme Organiser has not addressed your issue, then the deputy Scheme Organiser (**Appendix D**) should be contacted.

Any complaints will be audited by CEQA and a record kept of any action undertaken as a consequence.

3.0 ACKNOWLEDGEMENTS

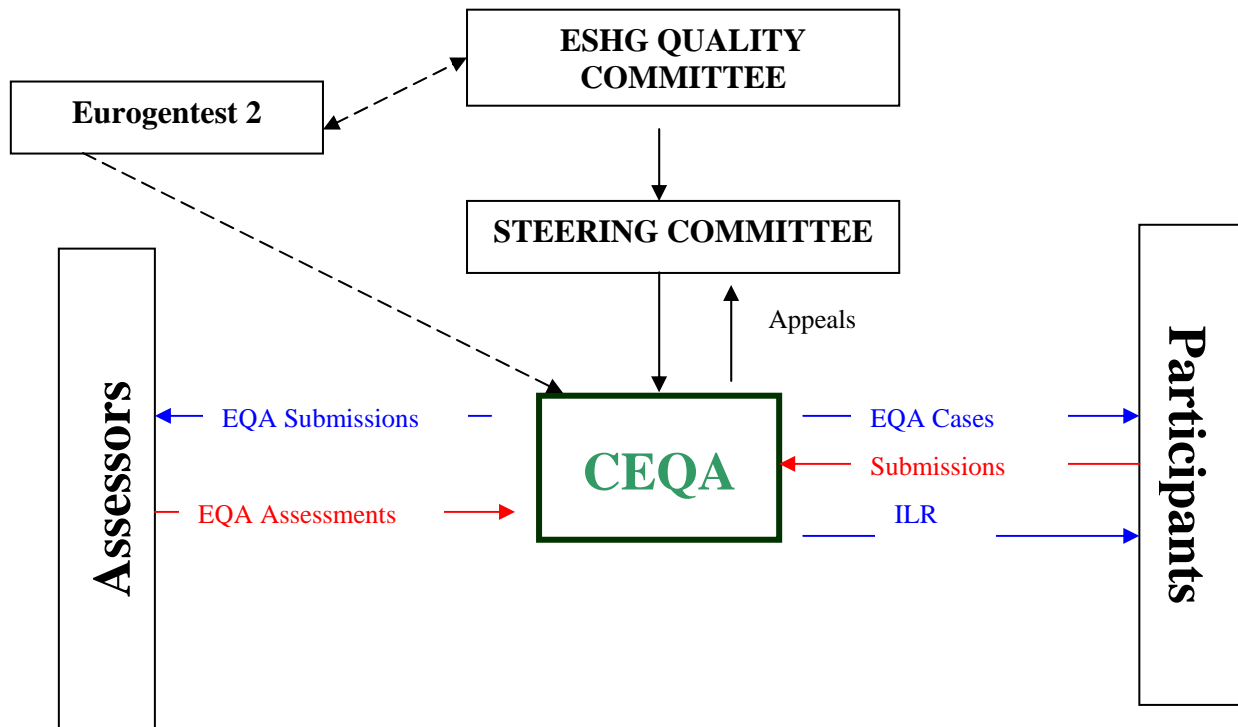
The Scheme relies on the hard work and co-operative efforts of a large number of people including local support staff at Oxford University Hospitals NHS Trust Oxford, Specialist Advisory Groups, Steering Committee, deputy SO and assessors. The Scheme Organiser receives considerable professional support from colleagues without whose professional input the Scheme could not function (see **Appendix D**). 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.

4.0 COPYRIGHT NOTICE

© **Copyright CEQA.** No part of this Manual may be copied, distributed or published in any form without the written permission of the Organiser, CEQA, on each and every occasion. The CEQA logo is also copyright and must not be used on internal laboratory reports.

Appendix A

Overview of the CEQA Organisation and Advisory Structure



Appendix B

The CEQA Code of Practice

Cytogenetic European Quality Assessment (CEQA) was set up in 2005 by the Forum of European EQA Providers under the umbrella of the Eurogentest Network of Excellence. CEQA's aim is to make EQA available to laboratories in countries where no National EQA scheme exists. In addition to this CEQA allows laboratories to submit their results in 12 European languages, making the EQA process more accessible to laboratories that would find it difficult to participate in other international schemes due to language barriers. CEQA also pioneers EQA for rare or innovative tests thereby creating a valuable addition to existing national schemes.

A. Definitions

- A1. Scheme is CEQA.
- A2. The term Organiser means the individual designated to be responsible for the design and direction of the Scheme
- A3. Scheme Participants are laboratories or manufacturers.

B. Scheme Management

- B1. Scheme is not for profit
- B2. Participation in the Scheme shall be open to all laboratories offering a clinical service for analytes or investigations covered by the Scheme.
- B3. The analytes or investigations covered by the Scheme shall be selected on the basis of their clinical relevance.
- B4. The Scheme shall be independent of any manufacturing and marketing interests in equipment and reagents in the field in which they operate. Any interests in the provision of analytical or other services shall be declared.
- B5. The staff involved in directing and operating the Scheme shall be appropriately qualified.
- B6. The Organiser shall monitor those participants failing to maintain acceptable levels of performance.
- B7. The full, realistically calculated costs of operating the Scheme shall be fully recovered from participants' subscriptions. The Scheme shall be non-profit making and any operating surplus shall be reinvested in CEQA.
- B8. Management arrangements shall enable continuity of the EQA service to participants.

C. Scheme Design

- C1. The Scheme's aim shall be to assist laboratories to provide optimal patient care through objective information on laboratory performance (supported by professional advice and assistance where appropriate).
- C2. The Scheme shall enable the detection of inadequate performance by participants. The standard of participants with apparent performance difficulties will be improved by education rather than penalty, as far as possible.
- C3. Material for investigation shall be distributed regularly at an appropriate frequency and in appropriate quantity.
- C4. Evidence shall be available to demonstrate the appropriateness, stability and uniformity (homogeneity) of the material distributed.
- C5. The Scheme shall provide rapid turnaround of results and performance data to participants.
- C6. A "correct" or target result will be presented in conjunction with an appropriate (usually quantitative) evaluation of results presented to allow comparison of individual participants' results with overall results.
- C7. The Scheme shall conform to relevant safety standards and transport regulations.
- C8. Confidentiality of individual participants' results and performance data shall be maintained.
- C9: The CEQA scheme logo is copyright and must not be used by laboratories on their own documents.

Appendix C

Areas of Clinical Cytogenetics covered by CEQA External Quality Assessment Scheme

Constitutional Scheme

The following seven EQAs are currently provided:-

- Amniotic Fluid
- CVS
- Postnatal Blood
- Preimplantation genetic diagnosis of blastomeres
- FISH Rapid Aneuploidy Testing (pilot EQA)
- Microarray/ArrayCGH – in collaboration with EMQN

Haematological Scheme

Consists of two EQAs

- Mature B- and T- cell Neoplasms (LPD/CLL/MM)
- Myeloid Disorders and Acute Leukaemias (AML/CML/ALL/MDS)

Techniques used

The following techniques may be used to establish the result:-

- Cytogenetic analysis
- QF-PCR
- FISH
- MLPA
- Microarray/ArrayCGH

All the results from these techniques are available online, with the exception of microarrays where a DNA sample is distributed and FISH Rapid Aneuploidy where participants receive slides.

Appendix D

CEQA External Quality Assessment Scheme Committees and Oversight

STEERING COMMITTEE MEMBERS

- Oliver Bartsch
- Edith Coonen
- Nicole Dastugue
- Brigitte Faas
- Ros Hastings - Scheme Organiser
- Karsten Held - Chair
- Rodney Howell – Consultant Cytogeneticist
- Bettina Quellhorst-Pawley - Quality Manager
- Marta Rodriguez de Alba - Deputy Scheme Organiser
- Francesc Sole-Ristol
- Joris Vermeesch
- Zuzana Zemanova

Contact Marta Rodriguez de Alba : MRodriguezA@fjd.es

QUALITY COMMITTEE MEMBERS

- Ros Hastings
- Borut Peterlin
- Mireille Claustres
- Els Dequeker
- Brian Fowler
- Claude Giroud
- Viktor Kozich
- Konstantin Miller
- Cor Oosterwijk – EGAN
- Orsetta Zuffardi
- David Barton
- Conny van Ravenwaaij-Arts

Contact Jerome delPicchia at the ESHG: jdp@medacad.org (quoting ESHG Quality Committee)

PGD SAG

- Dr R Hastings – Scheme Organiser CEQA
- Dr Z Deans – Scheme Organiser UK NEEQAS for Molecular Genetics
- Membership t.b.c.

ASSESSORS 2012

Surname	First Name	Country	EQA
Doco	Martine	France	AF
Faas	Brigitte	Holland	AF
Giardino	Daniela	Italy	AF
Held	Karsten	Germany	AF
Novelli	Antonio	Italy	AF
Ramos	Carmen	Spain	AF
Bartsch	Oliver	Germany	Blood
Florida	Giovanna	Italy	Blood
Rodriguez de Alba	Marta	Spain	Blood
Slunga-Tallberg	Anna	Finland	Blood
Sluzas	Vytautas	Lithuania	Blood
Wolstenholme	John	UK	Blood
Gueneri	Silvana	Italy	CVS
Molina Gomes	Denise	France	CVS
Rodriguez de Alba	Marta	Spain	CVS
Stioui	Sabine	Italy	CVS
Wolstenholme	John	UK	CVS
Costa	Dolors	Spain	AML
Dastugue	Nicole	France	AML
Porter	Sarah	Switzerland	AML
Zemanova	Zuzana	Czech Rep	AML
Radford Weiss	Isabelle	France	LPD
TBC			LPD
Sole	Francesc	Spain	LPD
Van den Berg-de Ruiter	Eva	Netherlands	LPD
Coonen	Edith	Holland	PGD Blast
Scriven	Paul	UK	PGD Blast
Barton	David	Ireland	Microarray
Gabriel	Heinz	Germany	Microarray
Pescucci	Chiara	Italy	Microarray
Vermeersch	Joris	Belgium	Microarray
TBC			
Rodriguez de Alba	Marta	Spain	Rapid Aneuploidy
Wolstenholme	John	UK	Rapid Aneuploidy

Ros Hastings, the Scheme Organiser, is involved in all CEQA EQAs

Appendix E

Marking Criteria and Criteria to determine poor performance.

Criteria to determine poor performance.

1. “Critical” Errors Identified In Performance

Errors and omissions are categorised as “critical” if they could have serious clinical consequences, and imply a significant lack of diagnostic skill or scientific knowledge. A zero mark is given (see Marking Criteria below).

One or more critical errors in any EQA round will normally result in a poor performance designation.

The Scheme Organiser will initially contact the head of laboratory by letter when his/her laboratory has a poor performance round, to discuss the performance issue and explain the next steps in the assessment process.

2. “Non-Critical” Errors Identified In Performance

Errors and omissions are categorised as “non-critical” if they are unlikely to have serious clinical consequences, but still imply a lack of diagnostic skill or scientific knowledge.

One or more non-critical errors in any EQA round will **not normally result in a poor performance designation**; although the laboratory’s report will indicate all the errors incurred, and the Scheme Organiser will monitor the extent of non-critical errors between laboratories and rounds to identify those laboratories with recurrent problems. The laboratory can appeal non-critical errors, following the procedure in 2.12.2. Any laboratory that accumulates multiple non-critical errors, or is persistently borderline in its performance, will be reviewed by the Steering Committee, and the Scheme Organiser may write to that laboratory to offer help and advice.

3. Non-Participation

Non-participation in any aspect of the Scheme for which the laboratory offers a service is classed as **poor performance**. Late returns of data or materials not due to postal delay, where no reasonable explanation has been communicated **beforehand** to the Scheme Organiser will also constitute **poor performance** for that distribution and the work will be returned.

4. Non-Compliance

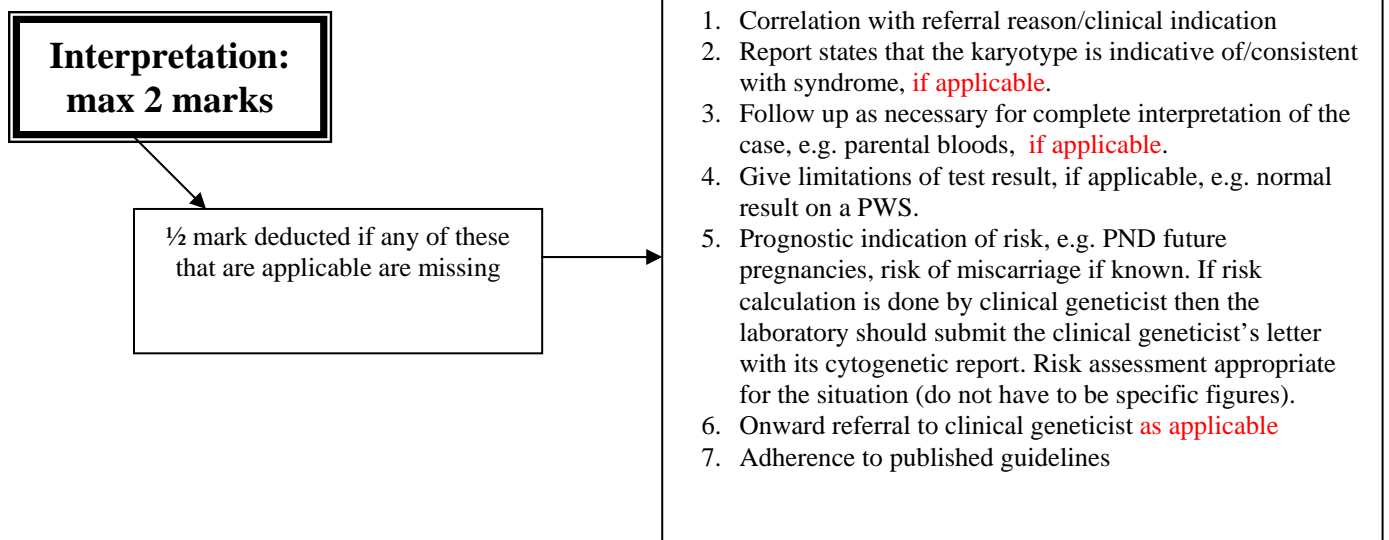
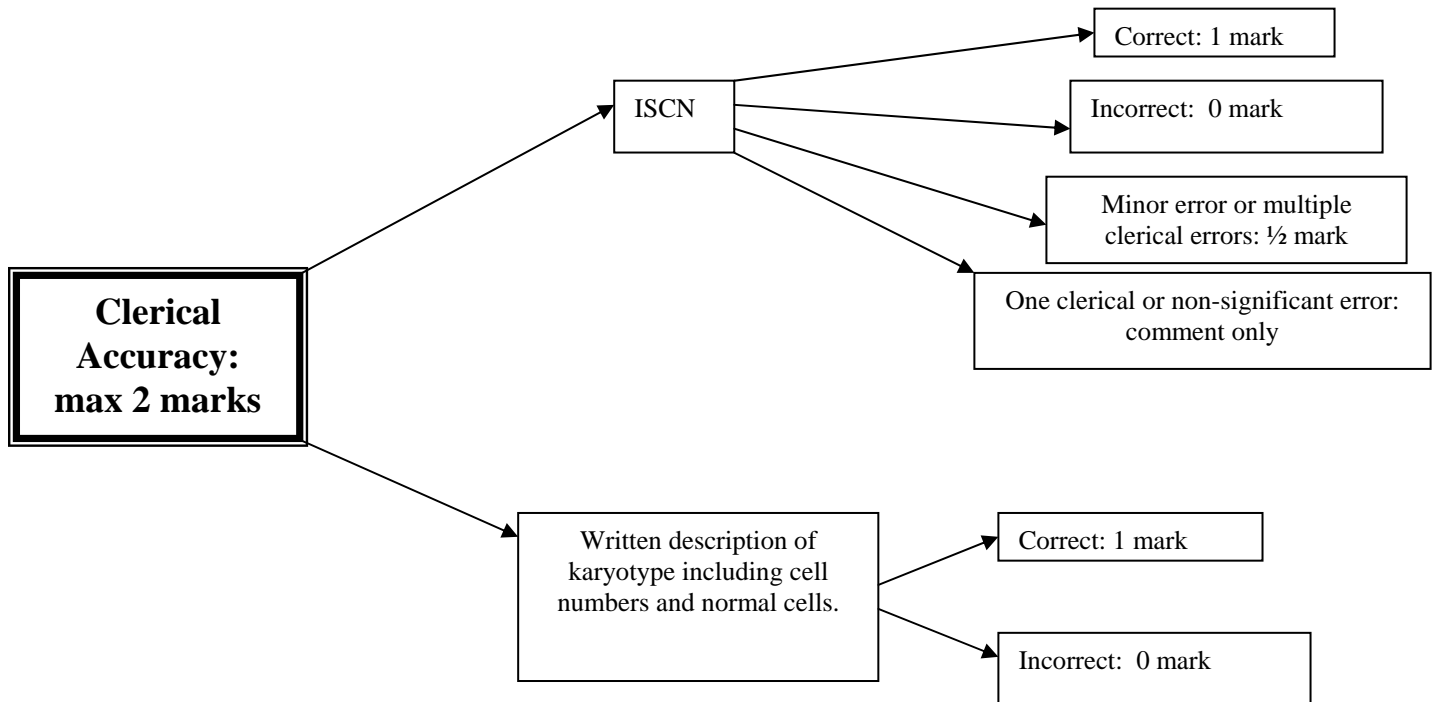
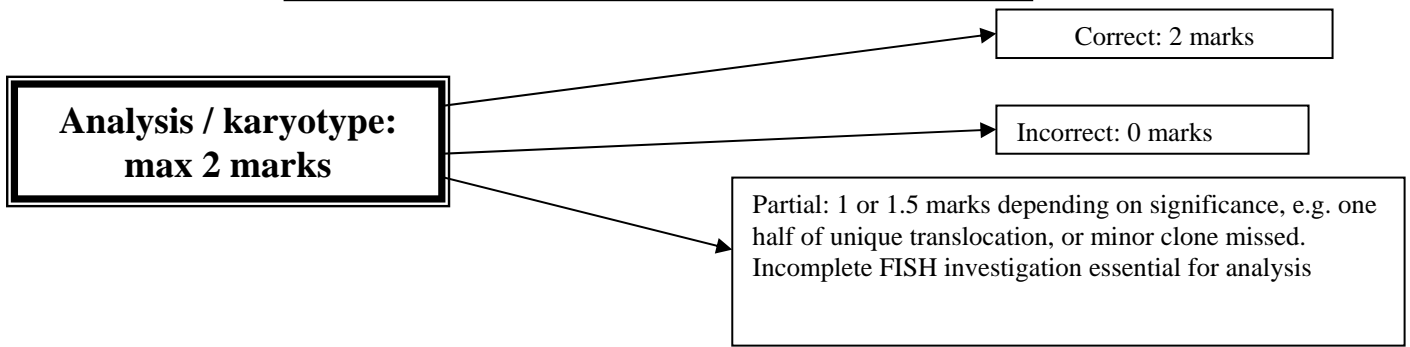
A laboratory will be expected to respond to any recommendations given in its reports. If, after a reasonable period of time it does not act upon such recommendations, that laboratory will lose marks in future EQA rounds.

Three or more warnings for the same omission/oversight within and/or across EQA rounds within a three year rolling period will normally result in a poor performance designation.

5. Definition of Persistent Poor Performance

This is defined as: 1) poor performance in any EQA or combination of EQAs in which the laboratory participates, over 3 or more EQA distributions, within a 3 year rolling period or 2) A poor performance within a year following a previous persistent poor performance categorisation.

Constitutional marking summary



Haem marking summary

**Analysis / karyotype:
max 2 marks**

Correct: 2 marks

Incorrect: 0 marks

Partial: 1 or 1.5 marks depending on significance, e.g. one half of unique translocation, or minor clone missed. Incomplete FISH investigation essential for analysis

**Clerical
Accuracy:
max 2 marks**

ISCN

Correct: 1 mark

Incorrect: 0 mark

Minor error or multiple clerical errors: ½ mark

One clerical or non-significant error: comment only

Written description of karyotype including cell numbers and normal cells.

Correct: 1 mark

Incorrect: 0 mark

**Interpretation:
max 2 marks**

½ mark deducted if any of these that are applicable are missing

1. Consistent with suspected diagnosis
2. Disease(s) category is given in report if a diagnostic case
3. Progression/relapse etc as appropriate
4. Gene involved in standard translocation/rearrangement
5. Follow up necessary for complete interpretation e.g. bloods for constitutional abnormality, samples for molecular analysis etc
6. Limitations of test result, e.g. poor quality, low level tumour infiltration
7. Prognosis
8. Reference if appropriate

PGD marking summary

Each centre will be marked according to the system noted here and sent a report of their individual performance. Each case has a maximum of 6 points available. Points or half points are deducted where the assessors identify omissions or inaccuracies. Points are allocated as follows:

- 2 for analysis
 - Incorrect analysis is usually a critical error and scores 0 points;
 - Partially correct analysis, for example not identifying all the normal embryos, up to two points may be deducted;
 - Insufficient analysis or failure to use supplementary probes, a point may be deducted;
 - Inappropriate use of supplementary tests and too much analysis, a point may be deducted.
- 2 for clerical accuracy
 - Written description, whether normal, abnormal or failed (up to 1 point deducted). Optional to state monosomy/trisomy etc for the individual chromosomes/ chromosome segments;
 - Standardisation of reports according to PGD guidelines or ISO standards;
 - For correct workup.
- 2 for interpretation
 - Errors and omissions with most of the following lose 0.5 points, but allocation of points varies depending on the individual case and the impact of the error on the final outcome

Work-up sheets

- Limitations of test (e.g. not all chromosome abnormalities detected, due to limited or inadequate probes used);
- Follow up, if necessary (e.g. parental samples, samples for molecular analysis);
- Consequences of any unbalanced genotype related to the indication (risk assessment);
- Where appropriate, the infant should be offered genetic counselling at an appropriate age;
- Inappropriate reporting or use of a probe that is polymorphic.

Internal report

- Reporting of all blastomere results
- Clear indication which embryos are considered normal or abnormal;
- Clear indication which embryos are considered transferable/not transferable;

Report to the PGD clinic

- Clear indication which embryos are considered normal or abnormal;
- Clear indication which embryos are considered transferable/not transferable;
- Inappropriate or too directive reporting e.g. strongly recommend PND for normal transferable embryos.