



Cytogenetic European Quality Assessment (CEQA)

Scheme Co-ordinator:

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PARTICIPANTS' MANUAL 2010

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 CURRENT EQAs

In 2010 CEQA will offer the following EQAs: Postnatal Blood samples, Prenatal Amniotic Fluids and Haemato-Oncology; as well as Preimplantation Genetic Diagnosis (Blastomere). Furthermore there will be Pilot EQAs for CVS and Preimplantation Genetic Diagnosis (Polar Body) as well as a Micorarray (ArrayCGH) pilot EQA in collaboration with EMQN.

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, Finnish, French, German, Italian, Polish, Russian, Spanish and Swedish (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 Radcliffe Hospitals Trust.

CEQA is administered through the Directorate of Laboratory Medicine and Clinical Sciences within the Trust but is independent from pathology services provided by the Trust. The CEQA Scheme Co-ordinator 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 Radcliffe 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

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.

For all queries and contacts, there is an email **mailbox** at bettina.qp@orh.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 is www.ceqa-cyto.eu and 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

2.3 STAFFING

Dr Rosalind Hastings (Clinical Scientist) is the Co-ordinator for the CEQA Scheme. The Scheme is supported by a part time Quality Manager, Bettina Quellhorst-Pawley, and a part-time Consultant Cytogeneticist, Rodney Howell.

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

The Scheme Co-ordinator 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.

2.3.1 Assessors

The assessors are responsible for scrutinising and assessing technical, analytical and interpretive performance in consultation with the Scheme Co-ordinator and Steering Committee (**see Appendix D**). Any individual wishing to be an assessor should apply to the Scheme Office by email enclosing a current CV 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 but can be extended for up to two further periods, each of two years if required for succession planning.

2.4 OVERSIGHT and PROFESSIONAL LINKS

The European Society of Human Genetics (ESHG) has recently formed a Genetic Services Quality Committee. Duties of this committee will include governance of the European EQA Schemes including CEQA. They will also advise on defining persistent poor performance.

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

EQA providers are required to seek advice from and report to specialist Steering Committees and Advisory Panels, comprising of expert professionals in appropriate areas of laboratory work, representatives of professional bodies and fellow scheme organisers (**Appendix D**). CEQA has its own Steering Committee (SC) which advises and provides support to the Scheme Co-ordinator. The Steering Committee consisting 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. Participants with persistent poor performance will be referred to the ESHG Quality Committee. Steering Committee appointments are for four years but can be extended for up to two further periods, each of two years if required for succession planning.

The membership and contacts for the 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 2.8.5**).

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

2.5 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 working towards accreditation against ISO17043. The process of accreditation 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 to achieve accredited status by 2011..

2.6 SCOPE OF THE SCHEME

2.6.1 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 and haemato-oncology cases.

The Scheme may extend in future to incorporate other methods of assessment or audit.

2.6.2 Scope

CEQA covers constitutional and haematological Cytogenetics as well as Molecular Genetics. This includes Pre- and Postnatal Cytogenetics, Haemato-Oncology Cytogenetics, Preimplantation Genetic Diagnosis (FISH) as well as Microarray/Array CGH. A list of EQAs offered in 2010 can be found under Section 1.2.

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.

2.7.1 Eligibility

CEQA services are open to all public and private sector clinical laboratories serving clinicians and patients throughout Europe. 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 February each year. Participants are alerted to its availability by email.

2.7.3 Registration with CEQA

After 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 12 hours of their acceptance email. Registration may take place at any time.

2.7.4 EQA enrolment procedure

Participation in the scheme is deemed to be continuous with online annual renewal and invoicing for registration 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. EQA enrolment is limited to a set time period (usually February to May of each year). All participants are informed by email once EQA enrolment is available.

2.7.5 Annual registration charges

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 Radcliffe Hospitals NHS Trust. For 2010 the annual administration fee is £100. All laboratories outside the EU are VAT exempt.

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.

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 upon request. Laboratories should see the EQA Summary Letters and their Individual Laboratory Reports (ILR) for specific EQA information on the EQA.

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 will be taken. This year’s participants’ meeting will take place during the ESHG Conference in Gothenburg, Sweden, on Sunday, 13th June at 11:30. Participants have already been invited. Further details will be communicated to all participants 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 Letter.

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 should use their unique laboratory code at all times.**

2.8.5 Certificates

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

2.8.6 Laboratory Feedback

Suggestions from participants for improvements or development of new EQA schemes are welcome. Feedback questionnaires are available online after each EQA round, participants will be sent a link to the relevant questionnaire by email. These forms give laboratories an opportunity to feed back to the Scheme on what went well and also invites suggestions for further improvements. Occasionally additional questionnaires may be sent out when specific information is required.

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 2.4) 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 'External Quality Assessment', select 'Online EQA' from the drop down menu.

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. 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 (QuA) database and other relevant bodies. This QuA 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 Co-ordinator 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 code number 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 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 website under "Performance Criteria". 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, including clinical advice and follow up studies.

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

Acceptable performance criteria and action taken on poor performers is described in **Appendix E**. The performance criteria documents can be found the website home page <http://www.ccneqas.org.uk/> (Select 'Scheme' from the grey menu bar link).

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 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 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 Co-ordinator in writing.
- If the complaint concerns the conduct of the Scheme Co-ordinator, or you consider that the Scheme Co-ordinator has not addressed your issue, then the Deputy Scheme Co-ordinator (**Appendix D**) should be contacted.

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

2.12.2 Appeals

Laboratories 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 Steering Committee. **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.**

3.0 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 Co-ordinator, Quality Manager or any member of the Steering Committee will be pleased to receive your comments.

4.0 ACKNOWLEDGEMENTS

The Scheme relies on the hard work and co-operative efforts of a large number of people including local support staff at John Radcliffe Hospital, Oxford, Steering Committee, Deputy SO and assessors. The Scheme Co-ordinator 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.

5.0 THE PARTICIPANTS MANUAL: INFORMATION

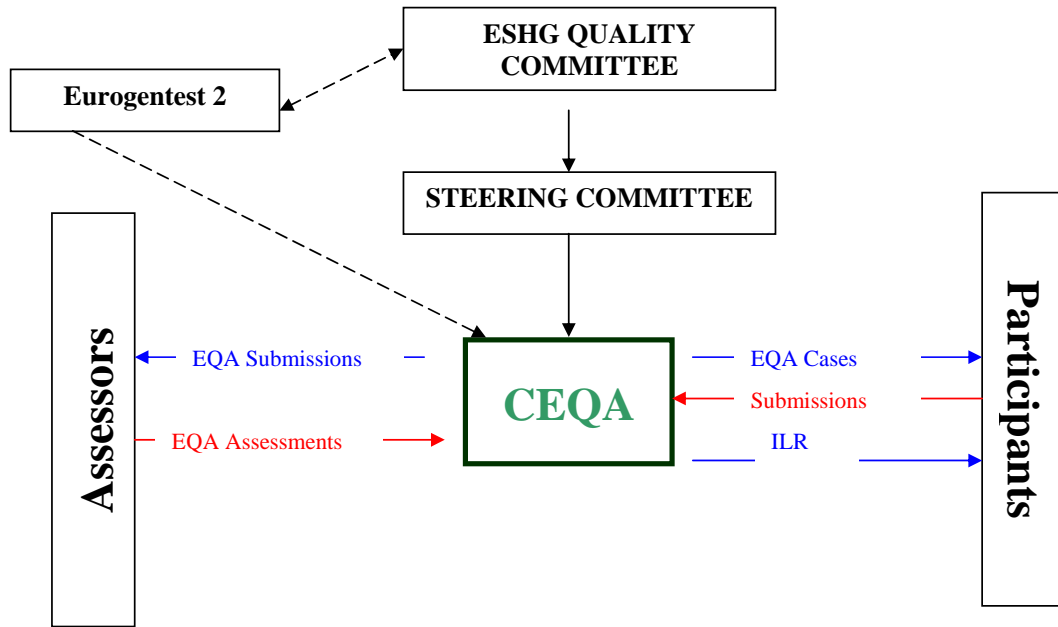
This Manual is provided free of charge to CEQA participants, and professional expert groups. It is also available through the CEQA website **www.ceqa-cyto.eu**

6.0 COPYRIGHT NOTICE

© **Copyright CEQA**. No part of this Manual may be copied, distributed or published in any form without the written permission of the Co-ordinator, CEQA, on each and every occasion.

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 Co-ordinator 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 Co-ordinator 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.

Appendix C

Areas of Clinical Cytogenetics covered by CEQA External Quality Assessment Scheme

Constitutional Scheme

The following four EQAs are currently provided:-

- **Amniotic Fluid**
- **Postnatal Blood**
- **Preimplantation Genetic Diagnosis of blastomeres**
- **Preimplantation Genetic Diagnosis of polar body**
- **Microarray/ArrayCGH – in collaboration with EMQN (pilot EQA)**
- **CVS (pilot EQA)**

Haematological Scheme

Consists of one EQA with 2 leukaemic blood or marrow cases from either:-

- Acute Myeloid Leukaemias (AML), or
- Acute Lymphoid Leukaemias (ALL), or
- Lymphoproliferative disease

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.

Appendix D

CEQA External Quality Assessment Scheme Committees and Oversight

STEERING COMMITTEE MEMBERS

- Nicole Dastugue
- Brigitte Faas
- Ros Hastings - Scheme Co-ordinator
- Joyce Harper
- Karsten Held
- Rodney Howell
- Bettina Quellhorst-Pawley - Quality Manager
- Marta Rodriguez de Alba - Deputy Scheme Co-ordinator
- Kalle Simola
- 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
Rob Elles
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)

ASSESSORS

Surname	First Name	Country	EQA	
Doco	Martine	France	AF	Formatted Table
Faas	Brigitte	Holland	AF	Formatted: Centered
Giardino	Daniela	Italy	AF	Formatted: Centered
Held	Karsten	Germany	AF	Formatted: Centered
Novelli	Antonio	Italy	AF	Formatted: Centered
Ramos	Carmen	Spain	AF	Formatted: Centered
Bartsch	Oliver	Germany	Blood	Formatted: Centered
Florida	Giovanna	Italy	Blood	Formatted: Centered
Howell	Rod	UK	Blood	Formatted: Centered
Rodriguez de Alba	Marta	Spain	Blood	Formatted: Centered
Simola	Kalle	Finland	Blood	Formatted: Centered
Slunga-Tallberg	Anna	Finland	Blood	Formatted: Centered
Gueneri	Silvana	Italy	CVS	Formatted: Centered
Molina Gomes	Denise	France	CVS	Formatted: Centered
Stioui	Sabine	Italy	CVS	Formatted: Centered
Calasanz	Mari Jose	Spain	Haem	Formatted: Centered
Dastugue	Nicole	France	Haem	Formatted: Centered
Howell	Rod	UK	Haem	Formatted: Centered
Porter	Sarah	Switzerland	Haem	Formatted: Centered
Radford Weiss	Isabelle	France	Haem	Formatted: Centered
Siebert	Reiner	Germany	Haem	Formatted: Centered
Sole	Francesc	Spain	Haem	Formatted: Centered
van den Berg-de Ruitter	Eva	Netherlands	Haem	Formatted: Centered
Zemanova	Zuzana	Czech Rep	Haem	Formatted: Centered
Gabriel	Heinz	Germany	Microarray	Formatted: Centered
Vermeersch	Joris	Belgium	Microarray	Formatted: Centered
Coonen	Edith	Holland	PGD Blast	Formatted: Centered
Scriven	Paul	UK	PGD Blast	Formatted: Centered
Bucholz	Tina	Germany	PGD PB	Formatted: Centered

Ros Hastings, the Scheme Co-ordinator, 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 Co-ordinator 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 Co-ordinator 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 Co-ordinator 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 Co-ordinator will also constitute **poor performance** for that distribution and the work will be returned.

4. Non-Compliance

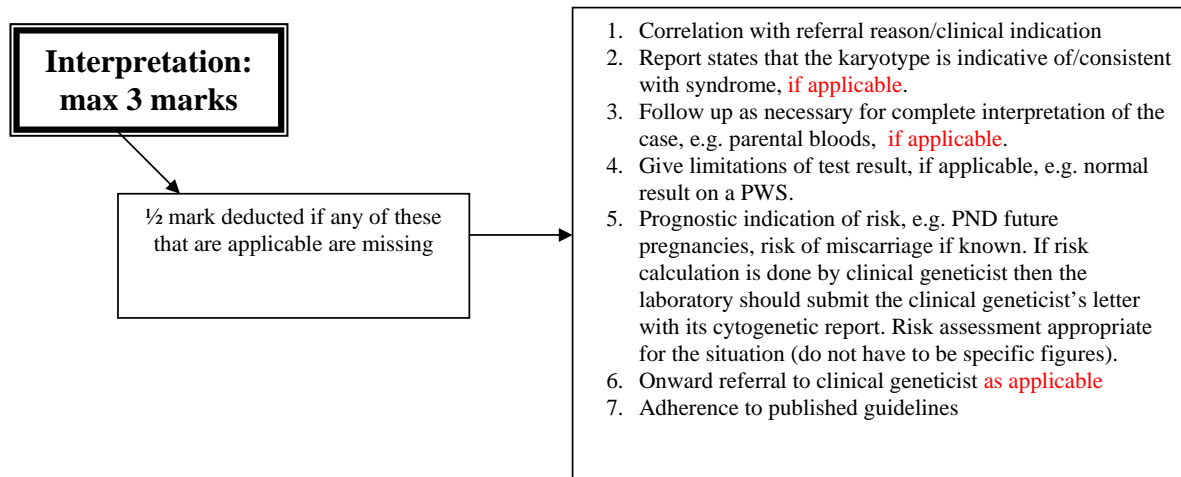
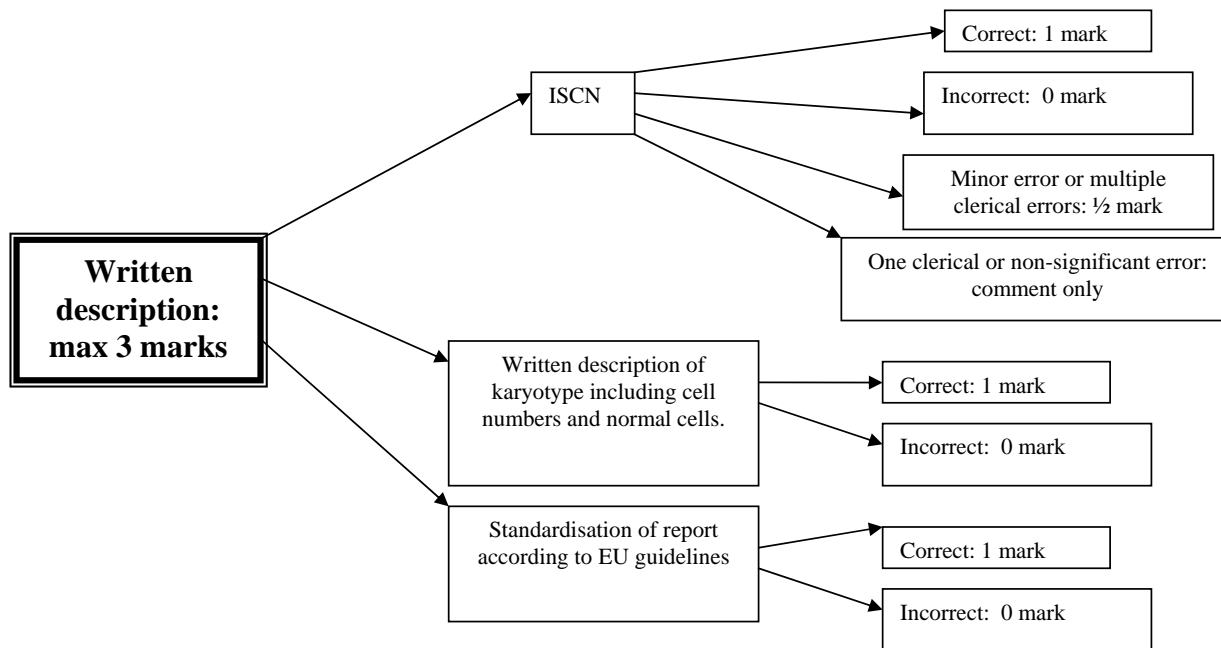
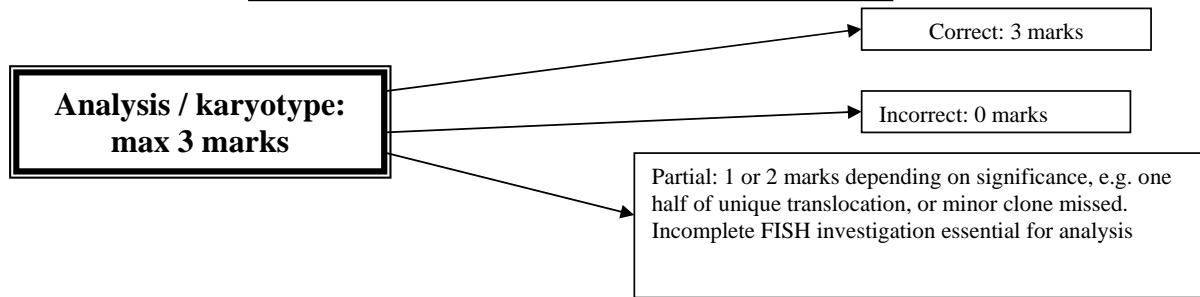
A laboratory will be expected to respond to any recommendations given in its reports. If, after a reasonable period of time it does not act upon such recommendations, that laboratory will lose marks in future EQA rounds.

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.

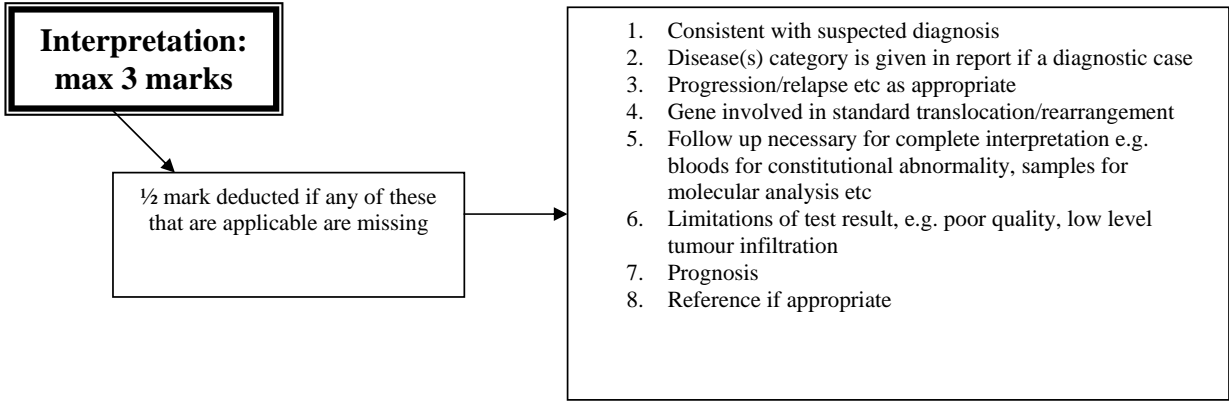
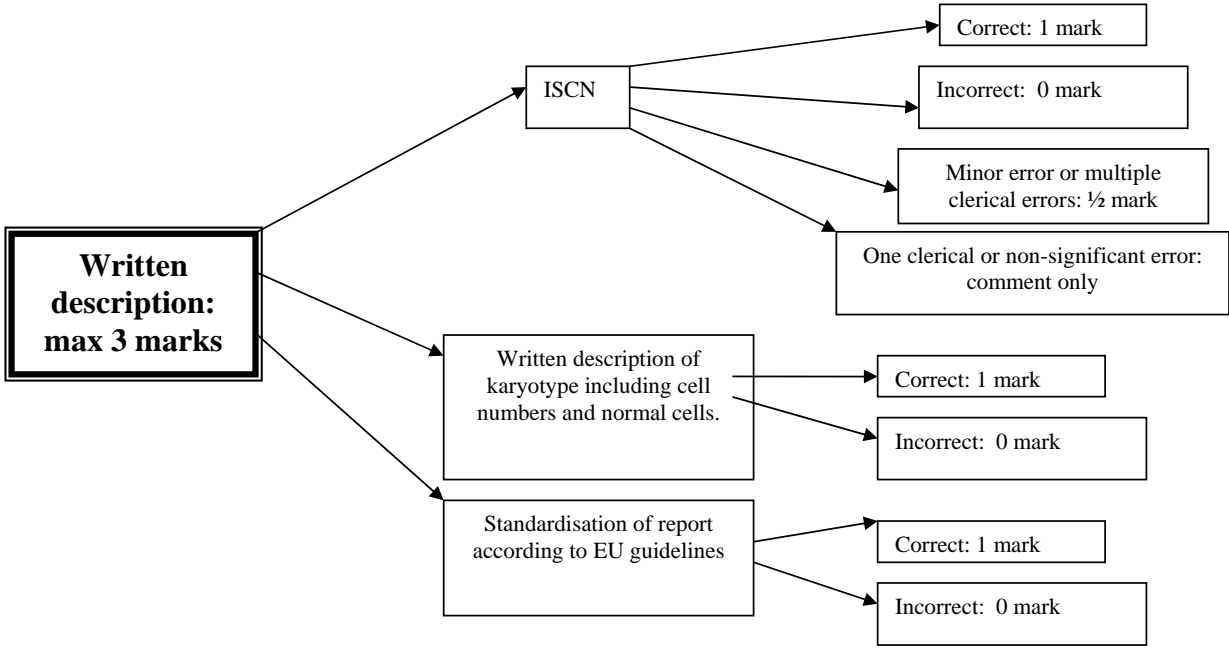
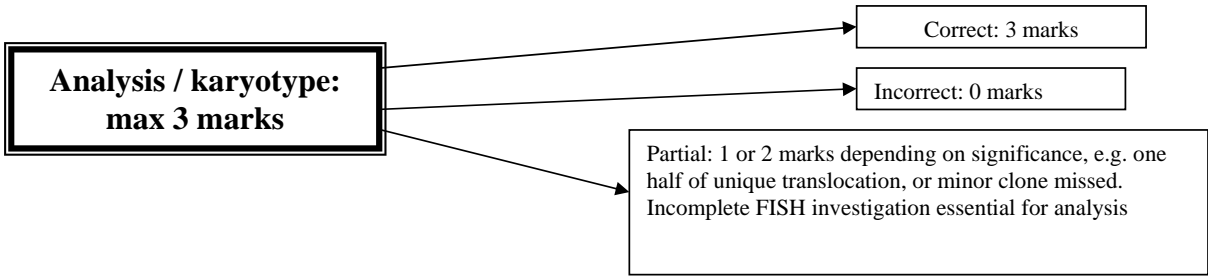
5. Definition of Persistent Poor Performance (proposal)

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



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 9 points available. Points or half points are deducted where the assessors identify omissions or inaccuracies. Points are allocated as follows:

- 3 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.
- 3 for written description/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.
- 3 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.