



Cytogenetic European Quality Assessment (CEQA)

Scheme Co-ordinator:

Ros Hastings
Women's Centre
John Radcliffe Hospital NHS Trust
Headington
OXFORD
OX3 9DU
United Kingdom

PARTICIPANTS' MANUAL 2009

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 that it would be desirable to establish a European EQA Scheme independent of existing or proposed National Schemes. Members of the Forum agreed on a design for the Scheme; setting the marking criteria, forming the assessment panel and the Steering Committee. Following two successful pilot schemes, undertaken by a small number of invited laboratories in 2006, the CEQA Scheme has been extended to laboratories worldwide with preference given to those in Europe.

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, 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. In 2009 EQA will be available for postnatal blood samples, prenatal amniotic fluids and haemato-oncology; as well as preimplantation diagnosis. Furthermore there will be a micorarray (ArrayCGH) pilot EQA in collaboration with EMQN.

1.1 THE REMIT OF CEQA

The objectives of CEQA 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.

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).

2.2 COMMUNICATIONS

The **postal address** is:

CEQA (Cytogenetics 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 09:00 to 17:00, 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. All fax traffic is logged to enable tracing of receipt of documents and coloured paper is used to distinguish documents received by fax from those received by post.

Systems and facilities are under development for the electronic transmission of results for those laboratories with appropriate computer and modem equipment.

The Scheme website address is www.ceqa-cyto.eu and further useful information may be found at www.eurogentest.org which carries general information about the whole EuroGentest network.

For all queries and contacts, there is an email **mailbox** at eurogentest@orh.nhs.uk

2.3 STAFFING

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

All staff members are subject to annual appraisal. The Co-ordinator is usually available in the office for consultation or enquiries during the week. At other times messages may be left on voice mail.

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

2.3.1 Assessors

The Scheme Co-ordinator is assisted by colleagues drawn from the ranks of practicing senior Clinical Cytogeneticists and Scheme Organisers from many European countries who act as assessors and Steering Committee members (Appendix D). Assessors are members of an appropriate National Genetic Society, have responsibility for reporting cytogenetic results and are senior members of the profession.

Any individual wishing to be considered as an assessor should contact the Co-ordinator who will be pleased to discuss details.

2.4 OVERSIGHT and PROFESSIONAL LINKS

The European Society of Human Genetics (ESHG) has recently formed a 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.

As of 2009 the CEQA Scheme will be overseen by a Steering Committee consisting of European Scheme Organisers as well as selected experts in the field (Appendix D). The Steering Committee will set the poor performance criteria and deal with any appeals made by participants. Participants with persistent poor performance will be referred to the ESHG Quality Committee.

Suggestions from participants for improvements or development of new EQA schemes are welcome.

2.5 ACCREDITATION

The CEQA Scheme is working towards accreditation with UKAS (UK Accreditation Service) in 2010.

2.6 SCOPE OF THE SCHEME

The Scheme assesses the overall quality of diagnostic analysis and interpretation performed by a laboratory using online reference material; this is followed by a comparison of the submissions against

exemplary results agreed by the Steering Committee and assessors. The Scheme may extend in future to incorporate other methods of assessment or audit.

The **performance criteria** against which submissions are marked and the level at which poor performance is attributed are given in **Appendix E**. Performance criteria comprise two categories, **analytical performance** and **interpretative performance**. The performance criteria are not exhaustive and assessors and Steering Committee may penalise for an incorrect analysis or interpretation not covered by these criteria.

2.7 PARTICIPATION

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 be guaranteed as preference is given to European participants. CEQA is also open to research laboratories.

2.7.2 Calendar

Participation in the scheme is deemed to be continuous with online annual renewal and invoicing for registration fees for each financial year. Participation may begin at any time during the year but enrolment for EQA is limited to a Spring and Autumn timetable. Full details of the participant's laboratory are collected at registration.

2.7.3 Enrolment procedure

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. Enrolment may take place at any time but not all EQAs will be available if the enrolment is made late in the EQA calendar.

2.7.4 CEQA laboratory code

On registration, each participant is given a unique CEQA laboratory code which remains associated with that participant. Re-attribution of codes and data can be accomplished, for example where laboratories merge. All codes have five digits beginning with 50.

2.7.5 Annual registration

Annual registration and EQA enrolment charges are based on the full costs of providing EQA services and operating the Scheme. 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.

2.7.6 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 charged in full.

2.7.7 Use of reference material

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.

2.7.8 Validation of EQA material

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

2.7.9 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**).

2.7.10 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	

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, discussion of the results of the assessments, summaries of pilot schemes undertaken, plans for next year’s assessment etc. Where appropriate, the report will also contain an overall analysis of performance and a summary of laboratory reports (see Individual Laboratory Reports). Copies of this document are available upon request.

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 the 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. The first participants’ meeting will take place during the ECA conference in 2009 on 4th July from 12.45-13.45pm.

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.

- A summary table of performance scores from all participants.
- General Comments and Conclusions on each aspect of performance.

2.8.4 Report validation and amendment

When you receive a report, please check the results to ensure that they match the submissions made by your laboratory. CEQA should be informed immediately of any errors so that the necessary corrections can be made and a new report 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.

2.8.5 Complaints procedure

Most complaints received by CEQA consist of minor misunderstandings or problems with website usage or reports that 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.
- Where the complaint is about scheme logistics, or a matter related to performance assessment and scheme design, also contact the Scheme Co-ordinator.
- 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 Steering Committee (**Appendix D**) should be contacted.

Complaints are audited by CEQA regularly and a record kept of any actions undertaken as a consequence.

2.8.6 Appeals

Laboratories have 15 working days to appeal any penalty points given in their individual laboratory reports. All appeals must be sent by email or post. An acknowledgement of their receipt will be sent via email. All appeals are reviewed by assessors and 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.**

2.8.7 Participation certificates

Participation and/or performance certificates will be available online. Separate participation and performance certificates will be available after the Autumn EQA round individual laboratory reports are available. Registration certificates are also available once the registration period for each year is closed.

2.8.8 Laboratory Feedback

Feedback questionnaires are sent out after each EQA round. These forms give laboratories an opportunity to feed back to the Scheme on what went well and also with suggestions for further improvements. Occasionally additional questionnaires may be sent out when specific information is required.

2.8.9 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 part of their oversight of CEQA, the Quality Committee of the European Society for Human Genetics (see Section 2.4) requires a copy of the annual Management Review.

2.8.10. User manual for the website

A user manual for the website is available to all participants and is sent once registered for the UKNEQAS scheme.

2.9 MATERIALS

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 excellent quality of images.

2.10 CONFIDENTIALITY

Raw data, scores and performance status are confidential between the individual laboratory and CEQA. Participation (and some relevant raw data) may be shared with relevant bodies under defined circumstances as part of the action taken to address persistent poor performance, but only with the participant's explicit permission. 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. 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. However, evidence of EQA participation may be shared with individual clients (e.g. GPs, clinicians, pharmaceutical companies) without consultation. CEQA participant codes (Laboratory Numbers) must not be disclosed to third parties. If you believe your confidentiality has been breached, please contact the Scheme Co-ordinator who will arrange for the allocation of a new code and passwords.

Participating laboratories have a responsibility to, as far as possible, ensure confidentiality of their code number and access passwords for the CEQA website.

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 Oxford, Assessors and Steering Committee to the Scheme. The Co-ordinator receives considerable professional support from colleagues, without whose input the scheme could not function. 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 by e-mail 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 B

The CEQA Code of Practice

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 may be laboratories or individuals.

B. Scheme Management

B1. Participation in the Scheme shall be open to all European laboratories offering a clinical service for analytes or investigations covered by the Scheme.

B2. The analytes or investigations covered by the Scheme shall be selected on the basis of their clinical relevance.

B3. 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.

B4. The staff involved in directing and operating the Scheme shall be appropriately qualified.

B5. The Co-ordinator shall monitor those participants failing to maintain acceptable levels of performance.

B6. 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.

B7. 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**
- **Blood**
- **Preimplantation diagnosis of blastocysts**
- **Microarray – in collaboration with EMQN (pilot)**

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
- Lymphomas

Techniques used

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

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

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

QUALITY COMMITTEE MEMBERS

Ros Hastings – CEQA (Chair)
Jacques Beckmann – ESHG Board
Mireille Claustres – Diagnostic Laboratory
Els Dequeker – CF Network
Rob Elles – EMQN
Peter Farndon – Clinical Geneticist & UKGTN
Brian Fowler – ERNDIM
Claude Giroud – EDMA (industry)
Viktor Kozich – SSIEM and ERNDIM Board
Lidia Larizza – ECA Board representative
Cor Oosterwijk – EGAN (patient group)
Orsetta Zuffardi – Genetic Research Community
David Barton – Expert in Reference Materials

STEERING COMMITTEE MEMBERS

- Francesc Sole-Ristol (Oncology Assessor)
- Nicole Dastugue (Oncology Assessor)
- Zuzana Zemanova (Oncology Assessor)
- Brigitte Faas (Constitutional Assessor)
- Karsten Held (Constitutional Assessor)
- Rodney Howell (Constitutional Assessor)
- Joris Vermeesch (Expert Micorarrays)
- Joyce Harper (Expert Preimplantation Diagnosis)
- Kalle Simola (Clinical Geneticist)
- Ros Hastings (Scheme Co-ordinator)
- Bettina Quellhorst-Pawley (Quality Manager)
- Expert in Clinical Oncology - to be appointed

ASSESSORS

Constitutional – Prenatal

Karsten Held
Brigitte Faas
Carmen Ramos
Martine Doco-Fenzy
Ros Hastings
Rod Howell

Haemato-Oncology

Francesc Sole-Ristol
Zuzana Zemanova
Nicole Dastugue
Reiner Siebert
Isabelle Radford-Weiss
Ros Hastings
Rod Howell

Constitutional – Postnatal

Rod Howell
Giovanna Florida
Oliver Bartsch
Marta Rodriguez de Alba
Ros Hastings

Preimplantation Diagnosis

Alan Thornhill
Joyce Harper
Edith Coonen
Ros Hastings

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, offering support and explaining 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 2.8.6. 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 (proposal)

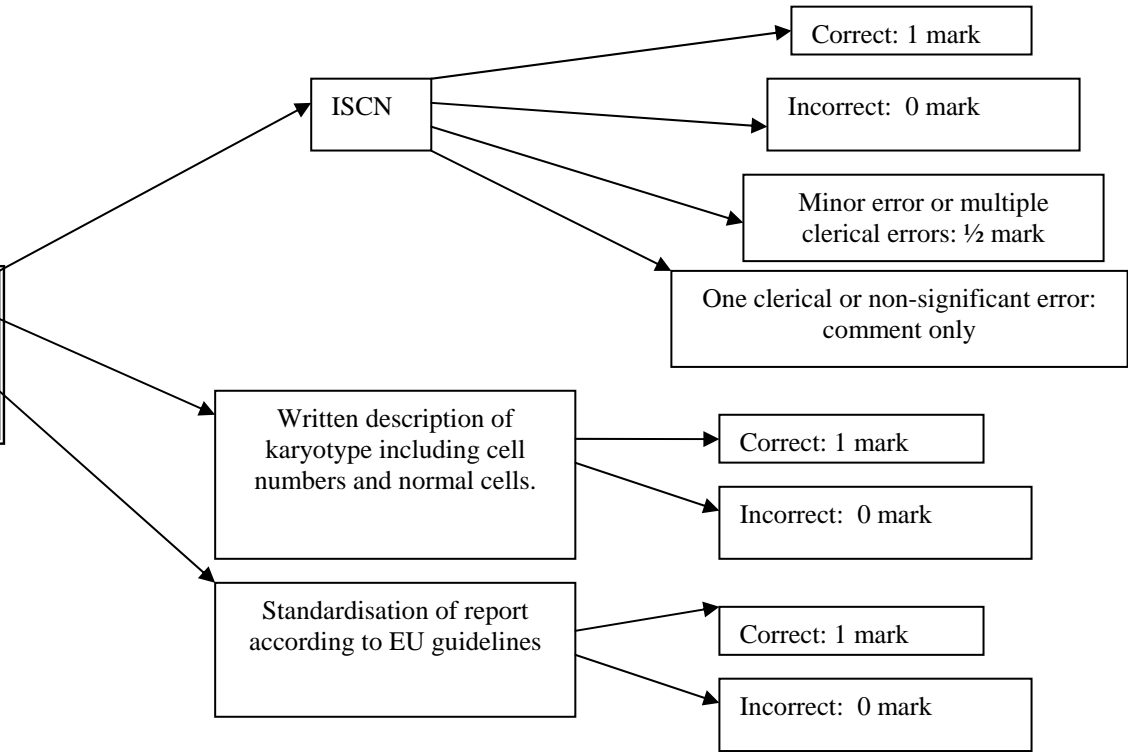
This is defined as: 1) poor performance in any EQA or combination of EQAs in which the laboratory participates, over 3 or more EQA distributions, within a 3 year rolling period or 2) A poor performance within a year following a previous persistent poor performance categorisation.

CEQA constitutional marking

Analysis / karyotype: max 3 marks

- Correct: 3 marks
- Incorrect: 0 marks
- Partial: 1 or 2 marks depending on significance, e.g. one half of unique translocation, or minor clone missed. Incomplete FISH investigation essential for analysis

Written description: max 3 marks

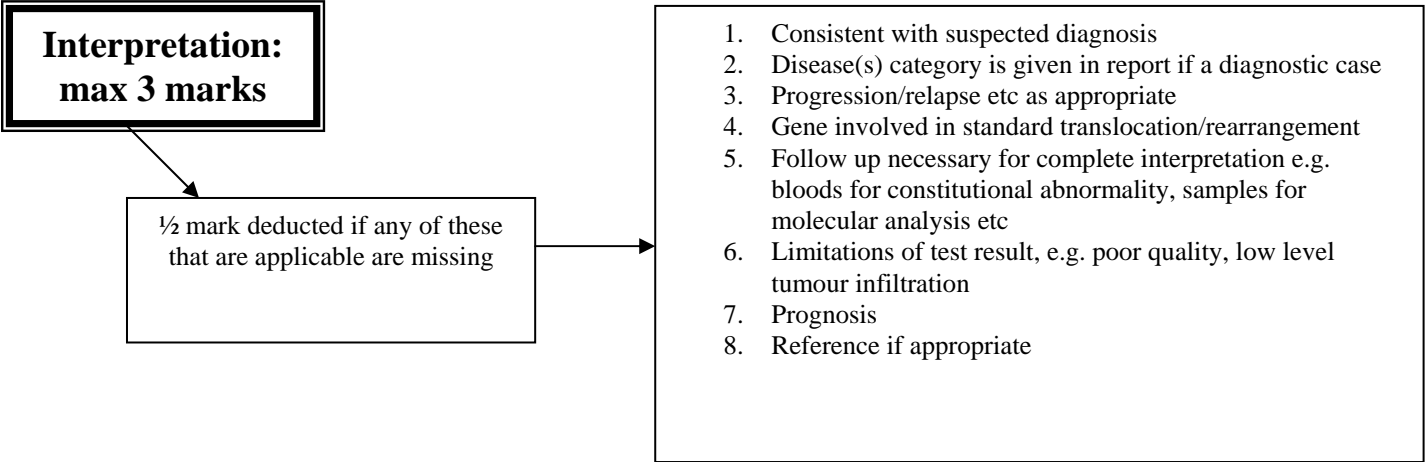
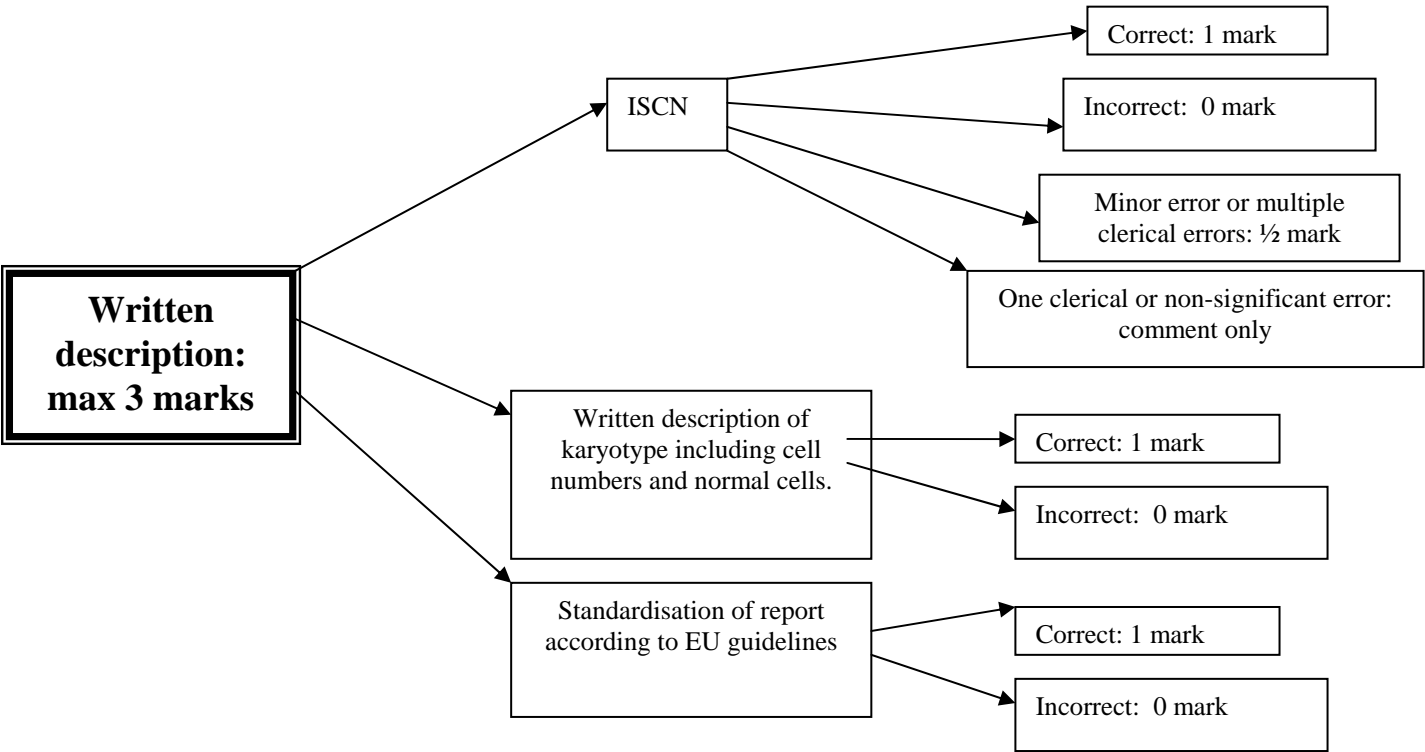
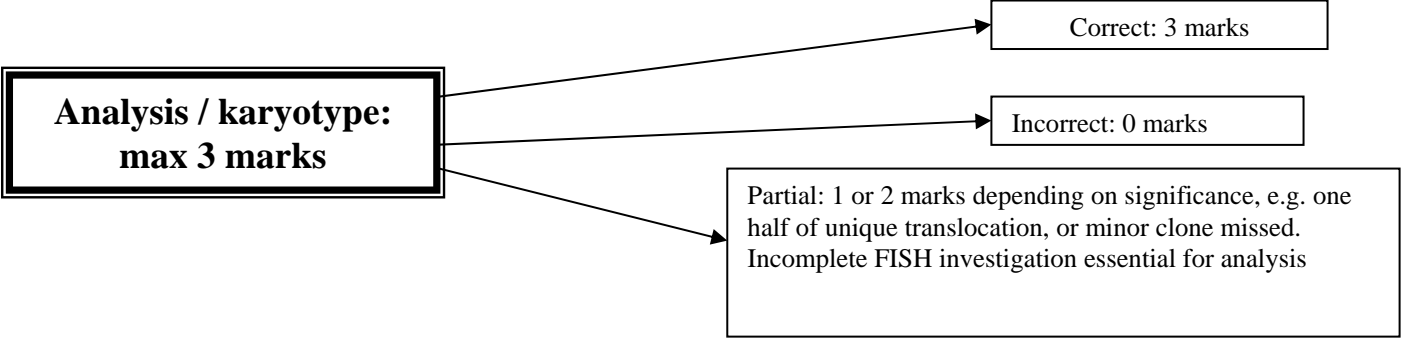


Interpretation: max 3 marks

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

1. Correlation with referral reason/clinical indication
2. Report states that the karyotype is indicative of/consistent with syndrome, **if applicable**.
3. Follow up as necessary for complete interpretation of the case, e.g. parental bloods, **if applicable**.
4. Give limitations of test result, if applicable, e.g. normal result on a PWS.
5. Prognostic indication of risk, e.g. PND future pregnancies, risk of miscarriage if known. If risk calculation is done by clinical geneticist then the laboratory should submit the clinical geneticist's letter with its cytogenetic report. Risk assessment appropriate for the situation (do not have to be specific figures).
6. Onward referral to clinical geneticist **as applicable**
7. Adherence to published guidelines

CEQA haem marking summary



CEQA PGD proposed marking summary

This is for discussion at the next ESHRE meeting on June 27th. It may be subject to further modification as the EQA evolves.

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.