CEQA Cytogenetic European Quality Assessment

FISH EQA in Pre-implantation genetic diagnosis

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External Quality Assessment

- Sometimes referred to as proficiency testing
- An important component of an overall quality management system i.e. quality & competence
- Specific requirement for accreditation
- ISO 15189: 2007
- OECD Guidelines

OECD Guidelines 2007

www.oecd.org/sti/biotechnology

- Recommendations on quality assurance in molecular genetic testing but also valid for other specialist genetic testing
- A number of principles and best practices
  - Promote internationally agreed minimum standards
  - EQA programmes that check the entire examination process including pre- and post-examination procedures
  - Quality policy that includes EQA
  - Implementation of corrective actions

Advantages of EQA

- Comparison between laboratories helps to define good standards (best practice)
- Regular assessment compares laboratory performance against set standards
- Educates participants with the aim of improving the overall service to the user
- Validates service quality
- Helps to build public confidence

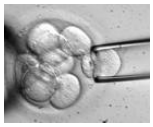
Defining acceptable standards in EQA

- Acceptable standards depend on type of test
- We have to make those standards (= quality) into a numerical score (=quantity)
- Who sets the standards?
- What happens when standards are not met?
- Experience of running EQA - improve standards

EQA aim: Poor performers are educated, not punished

Quality Issues in PGD

- Choice of techniques/probes
- Technical preparation quality
- Accuracy of analysis
- Interpretation of significance of the result
- Information given in the report
- Turn round times (hours/days)
- How does EQA assess this?



Prospective Assessment 2009/2010

EQA scheme distributes the same material to all participants and assesses their returns

- ✓ Allows fair comparison
- ✓ Assessors can agree correct answer to permit consistent marking
- ✓ Online or distribute samples?
- × Online - cannot assess technical ability
- × Participants may give EQA material special priority

Retrospective Assessment 2008 only

Assessment of material from reported cases submitted by participants

- ✓ Examines the real work of the laboratory
- ✓ Easy to set up online
- × Cannot make comparisons between laboratories because submitted cases are different
- × Does not always measure current practice
- × Heavy workload for assessors
- × Technical assessment practical given different probes and filters?

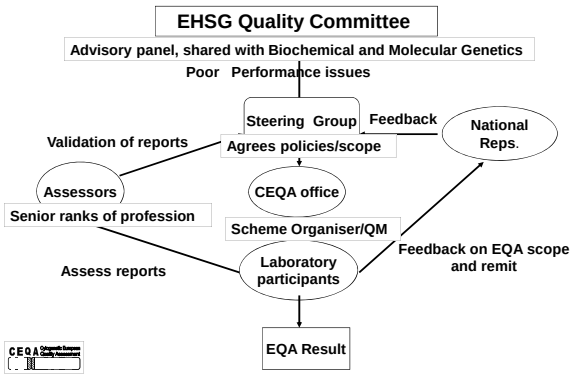
CEQA: Cytogenetics European Quality Assessment

- Set up with funding from EuroGentest 2005 – June 2010
- Constitutional cytogenetic pilot EQA in 2006
- Submission in multiple languages
- 2008 pilots for PGD FISH and leukaemia cytogenetics

CEQA: Cytogenetics European Quality Assessment

- EQAs offered in 2010
- Administration charge: £100 EQA: £200
- Blood
- Amniotic Fluid
- CVS
- PGD FISH (blastomeres and polar bodies)
- Haemato-oncology
- Pilot ArrayCGH (constitutional)

CEQA Structure

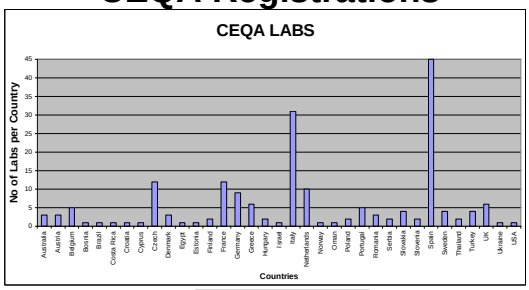


CEQA National Representatives

- One for each EU country
- Provide a link between CEQA and laboratories
- Conduit for communication about CEQA
- Communicate areas where EQA required
- National issues relevant to EQA process
- List available on Eurogentest website

  www.eurogentest.org

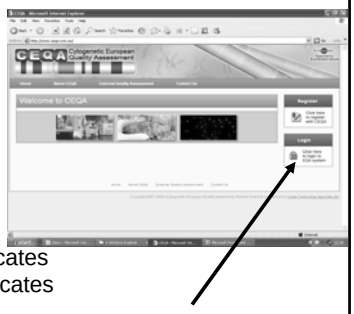
CEQA Registrations



2009
35 countries
189 labs registered
33 for PGD

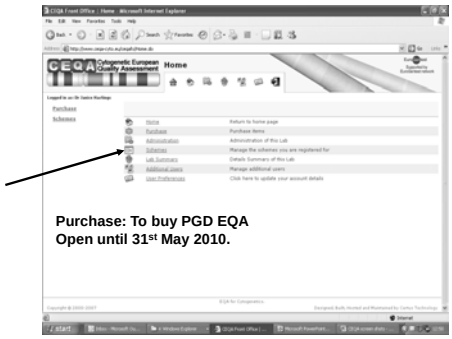
Online EQA

EQA:-
- Open to all labs
- Assess EQA online
- Email alerts



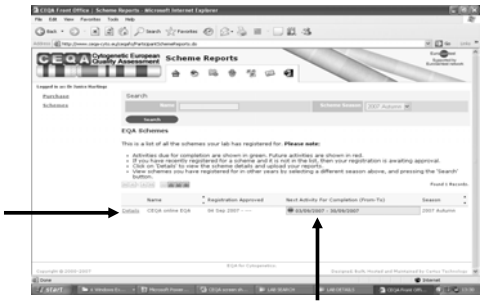
Results:-
- EQA report online
- Summary letter
- Participation certificates
- Performance certificates
- Annual report

Options once logged in

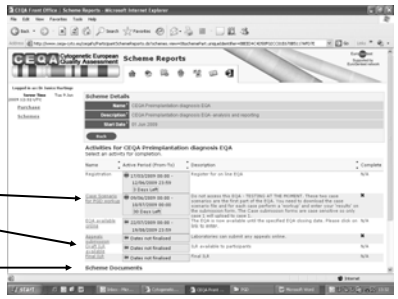


Purchase: To buy PGD EQA
Open until 31st May 2010.

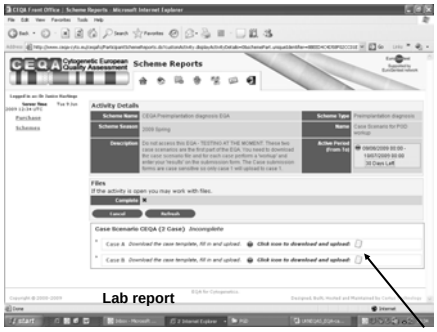
EQA



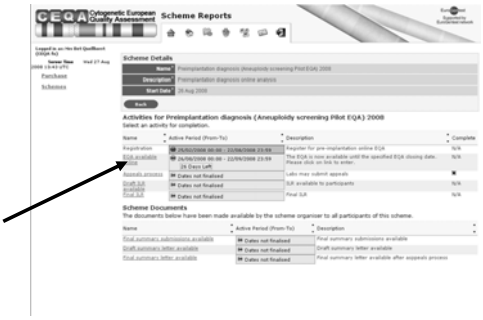
Workup sheets 2009



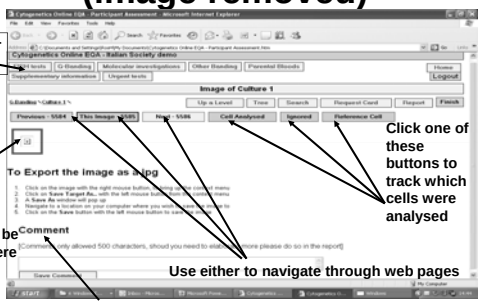
Case Scenario 2009



CEQA online analysis EQA



Enlarged image webpage (image removed)



Menu bar

Enlarged image would normally be visible here

Click one of these buttons to track which cells were analysed

Use either to navigate through web pages

Comments can included - optional.

N.B. Images can be exported into image analysis system

EQA 2009 summary Part A: Work up

- Robertsonian translocation
- Reciprocal translocation
- Feedback

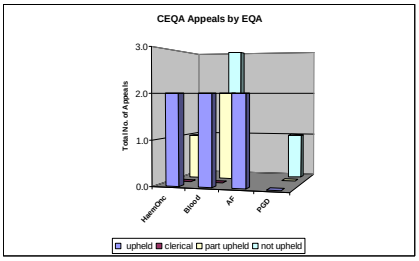
EQA 2009 summary
Part B: Analysis and reporting

- Robertsonian translocation
- Reciprocal translocation
- Feedback

Participation in 2009

- Number Registered
- Number Participating
- Number participating part A & B

Appeals 2009



PGD/PGS 2009

Ros Hastings – CEQA Co-ordinator

Edith Coonen
Joyce Harper
Paul Scriven

CEQA Marking Criteria

The final report must contain information that explains why the investigation is done, what the results are and what the consequences are for the patient

- **Accurate analysis**
- **Written description –** which embryos abnormal/normal/fail etc
- **Interpretation of results -** which embryos transferrable
- **Professional/ISO Standards compliance –** doc control

CEQA Marking Criteria

- Analysis = 3 (correct), 0 (wrong)
- Written description = 3 → Summary = 1; Clerical accuracy = 1; Guidelines followed = 1
- Interpretation = 3 → Up to 6 important components of report: deduct 0.5-1.0 marks for each missing
- Total maximum = 9
- Poor performance if critical error (i.e. 0 score in analysis or interpretation)

Components of interpretation determined by assessors

CEQA Marking Criteria

- Analysis = 3 (correct), 0 (wrong)

Analysis incorrect	= 0
Partially correct	= 1 or 2 points deducted
Inappropriate test	= 1 or 2 points deducted
Insufficient analysis	= 1 point deducted

- Written description = 3

Inappropriate /incomplete work up = 1 point deducted
No mention which embryos were normal/abnormal/fail etc = 1 or 2 points deducted
Not following Professional Guidelines = 1 point deducted

CEQA Marking Criteria

- Interpretation=3

Assessors decide components of interpretation
Deduct 0.5-1.0 marks for component each missing

Workup sheets:
Inappropriate limitation of tests
Inappropriate polymorphic probe used Inappropriate follow up
Inappropriate risk assessment
Internal Report:
Not all embryos reported
No mention whether normal/abnormal/fail etc
No clear indication which embryos should be transferred
External report (to PGD clinic):
No clear indication which embryos are normal/abnormal
No clear indication which embryos should be transferred
Inappropriate directive advice for e.g. PND
Inappropriate follow up requested

Poor Performance

1. Error or omission with potential serious clinical consequence
2. Non-participation
3. Non-compliance: repeated warnings for the same omission or oversight

- Agreed by Steering Committee and assessors
- Laboratory may appeal
- Laboratory issued with a letter and asked what changes have been made

Poor Performance

Examples in PGD may be:

- Incorrect analysis or interpretation of FISH signals
- Incomplete or incorrect interpretation resulting in an incorrect diagnosis/transfer
  - Failure to recognise all the possible chromosome constitutions underlying the FISH signal pattern e.g. normal vs unbalanced translocation segregants

CEQA : 2009

- Individual Laboratory Report with scores
- Summary letter
- Annual report
- Participation AND performance certificates

CEQA -2010

- PGD - 2 parts
  - Part A: workup case scenarios
  - Part B: analysis of embryos
    - Blastomeres and polar bodies
- Future? - ArrayCGH EQA – expand to include PGD

Acknowledgements

Ros Hastings:
CEQA Scheme Organiser,

Bettina Quellhorst-Pawley:
CEQA Quality Manager and Administrator

Assessors
PGD:
Edith Coonen
Joyce Harper
Paul Scriven

Steering Committee
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