CEQA Cytogenetic European Quality Assessment

EQA in the Quality Management of pre-implantation FISH 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 www.iso.org
- OECD Guidelines

OECD Guidelines 2007

www.oecd.org/sti/biotechnology

- Recommendations on quality assurance in molecular genetic testing but also valid for other specialist testing
- A number of principles and best practices
  - Promote internationally agreed minimum standards
  - Facilitate mutual recognition of quality frameworks
  - Increase public confidence in governance
  - 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

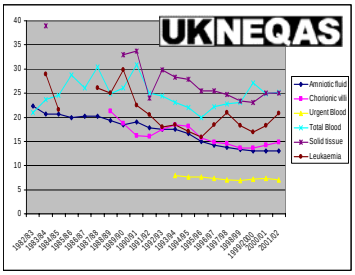
Defining acceptable standards

- 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?

Poor performers are educated, not punished

Impact of Cytogenetic EQA in UK Laboratories over 20 years

- ↑ banding quality
- ↑ 'pick up' rate
- ↓ ISCN errors
- ↑ interpretation
- ↓ report times



Overall- accuracy of report content

Quality issues

- Choice of tests
- Technical preparation quality
- Accuracy of analysis
- Interpretation of significance of the result
- Information given in the report
- Turn round times (hours/days)

Prospective assessment

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
- × Impractical to distribute samples for PGD for FISH
- × Therefore cannot assess technical ability
- × Participants may give EQA material special priority

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Retrospective assessment

Assessment of material from reported cases submitted by participants

- ✓ Examines the real work of the laboratory
- ✓ Easy to set up by mail or online
- × Cannot make comparisons between laboratories because submitted cases are different
- × Does not always measure current practice
- × Heavy workload for assessors

CEQA Cytogenetic European Quality Assessment

CEQA: Cytogenetics European Quality Assessment

- Set up with funding from EuroGentest in 2005
- Internet EQA based on system used by UK NEQAS
- Blood and amniotic fluid pilots in 2006
- Submission in multiple languages
- Assessors drawn from various EU countries
- 2008 PGD FISH and leukaemia cytogenetics pilots

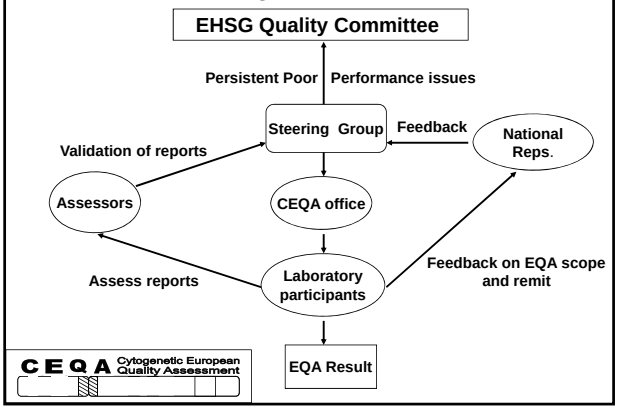
CEQA: Cytogenetics European Quality Assessment

EuroGentest is an EU-funded Network of Excellence looking at all aspects of genetic testing - Quality Management, Information Databases, Public Health, New Technologies and Education. Through a series of initiatives EuroGentest encourages the harmonization of standards and practice

Structure of CEQA EQA Scheme

- Scheme Organiser
- Steering Committee agrees policies/scope
- Assessors invited from senior ranks of the profession
- ESHG Quality Committee acts as the advisory panel, shared with Molecular Genetics, monitors persistent poor performance

CEQA Structure

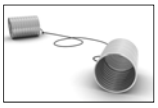


CEQA National Representatives

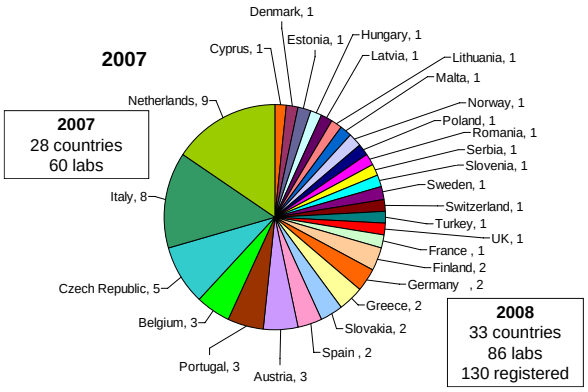
- Provide a link between CEQA and laboratories
- Conduit for communication about CEQA
- Communicate areas where EQA required
- National issues relevant to EQA process
- List available on EuroGentest website

www.eurogentest.org

CEQA Cytogenetic European Quality Assessment



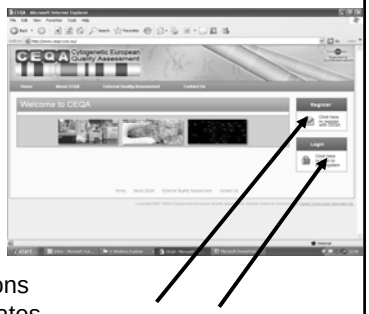
CEQA Registrations



Internet EQA analysis

- Password controlled access
- Referral form
- Set of jpeg images can be imported to image analysis system
- Software can calculate cost based on number of tests viewed
- Report text entered by participant
- Exit password finalises submitted report: must be completed before deadline

On line EQA



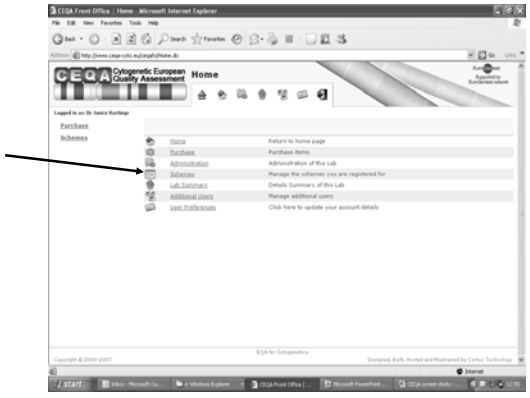
EQA:-

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

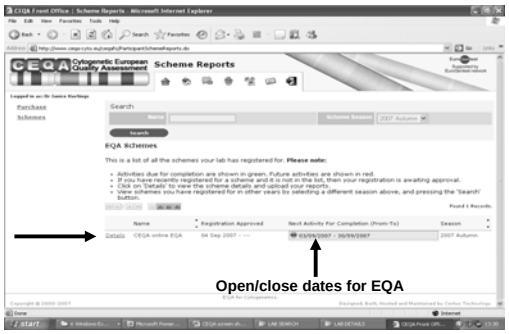
Results:-

- EQA report online
- Summary letter
- Summary submissions
- Participation certificates

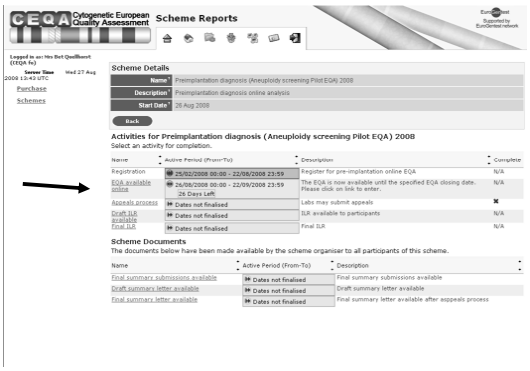
Options once logged in



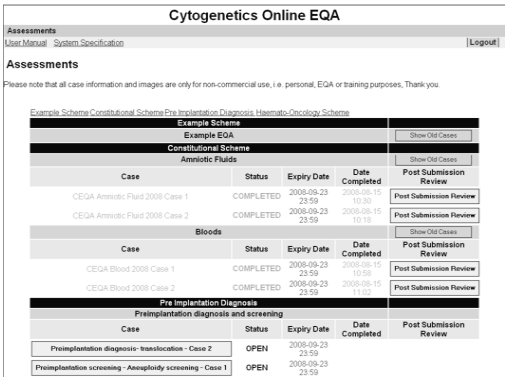
EQA



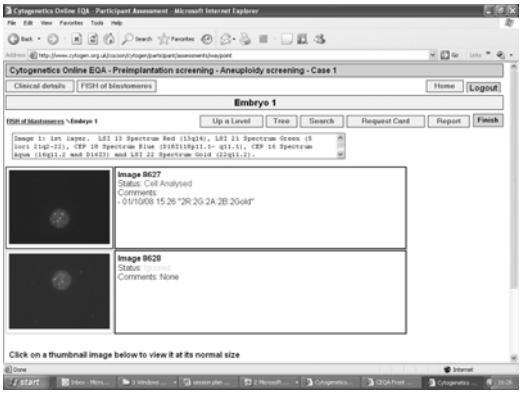
CEQA Online Analysis EQA



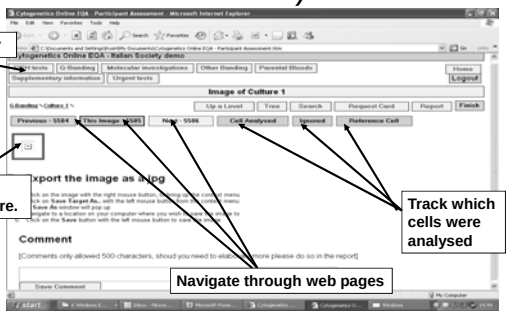
CEQA Online analysis EQA:



CEQA Online EQA



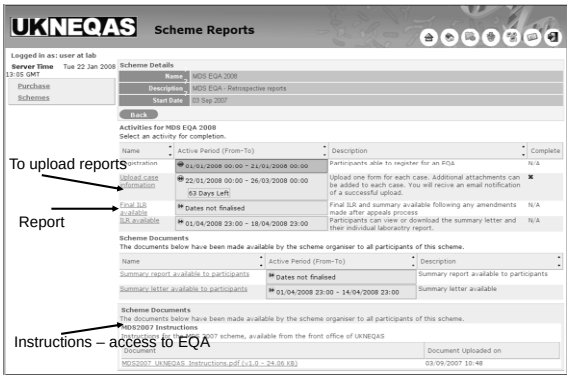
Enlarged image web page (image removed)



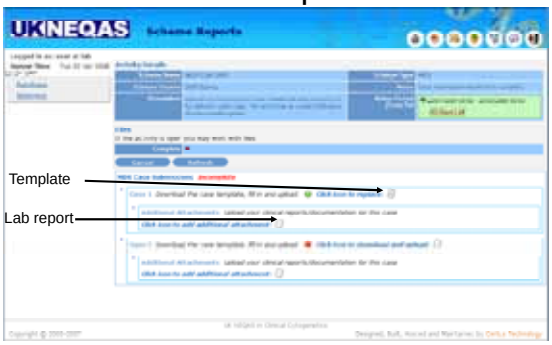
N.B. Images can be exported into image analysis system

Comments can be included

Retrospective - UK NEQAS example



Retrospective - UK NEQAS example



CEQA marking scheme

- Analysis = 3 (correct), 0 (wrong)
- Written description = 3 → ISCN or summary = 1; Text of report = 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 <7

Components of interpretation determined by assessors

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 extra EQA cases and/or confirm that action has been taken to improve quality management

Examples of Poor Performance

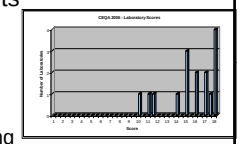
- Incorrect interpretation of FISH signals
- Incomplete interpretation resulting in an incorrect diagnosis
- ➢ Failure to recognise all the possible chromosome constitutions underlying the FISH signal pattern e.g. normal vs unbalanced translocation segregants
- ➢ Inappropriate FISH probes used (Retrospective)

Persistent Poor Performance

- Failure to improve performance results in referral to Quality Committee (ESHG)
- Failure to respond to advice from Quality Committee potentially results in reporting of laboratory to governing bodies
- Could lead to loss of accreditation – dependant on accreditation body

CEQA PGD Pilot: Participants will receive

- Individual Laboratory Report
- Summary of all submitted reports



- Summary letter
- ➢ Histogram of scores for benchmarking
- ➢ Check list for content of exemplary report
- ➢ Recommendations for incorporation into Best Practice Guidelines

CEQA PGD Scheme

- Registration fee £50
- EQA fee pilot £75
- 25 labs participated, one PGD case, one PGS case
- 2 non-submissions
- Results will be reported online
- Summary letter
- Summary of submitted reports (online analysis only)
- Participation certificates
- Performance certificates

web: www.ceqa-cyto.eu/ **email: eurogentest@orh.nhs.uk**

Assessors

Ros Hastings – CEQA & UK NEQAS Co-ordinator

Joyce Harper (PGD)

Sjoerd Repping (PGS)

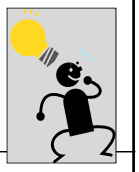
Paul Scriven (PGD)

Alan Thornhill (PGS)

Joris Vermeesch (BE)
Heinz Gabriel (DE)

CEQA - Future Developments

- Expansion of EQAs available?
- Submission of images – technical EQA
- Accreditation of CEQA Scheme
- Steering Committee remit & membership



Future EuroGentest Vision

CEQA and National Schemes dovetail to give every laboratory in Europe and beyond access to the widest possible range of EQAs

Acknowledgements

Ros Hastings:
Scheme Organiser,
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Administrator and Quality Manager,
UK NEQAS and CEQA

Assessors

Steering Committee

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