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# EuroGentest e-news

## Good news

We can go to Vienna in good spirit since hard work by the management group over the last few months appears to be bearing fruit. We have applied for a six-month extension to EuroGentest which would give us time to exploit the other opportunities to continue key activities that have recently become apparent. There is no doubt now that the Commission recognizes the value of our work. They see that our drive to increase accreditation and promote quality schemes mirrors the trend in all medical fields not just genetics in Europe and this is the only way to ensure patients have confidence in the services they are being offered. Similarly they value our pioneering work in charting patient rights across the community and providing patient education materials. Furthermore, both they and industry are coming to the conclusion that the validation framework we are providing is the key to accelerating access to new tests and treatments for patients. Finally the Commission has also acknowledged that our partner Orphanet is the prime source of information on rare disorders for EU citizens. I hope to have more news at Vienna where you can all help by continuing to spread the message about EuroGentest and signing up more of your colleagues to CEQA, our Quality Symposium and other initiatives.



## EuroGentest in Vienna

Visit our joint stand with OrphaNet and ESHG.  
This year's activities include

Accreditation for beginners, 22-23rd May - for labs at the start of the process of implementation of a quality management system (places still available). [More.](#)

Fulfilling the requirements of ISO 15189 for management review, IQC and EQA, 22-23rd May - learn how to do management review by debate in small groups. [More.](#)

Case studies on QA and QC issues in genetic testing labs, 24th May - A 2-hour roundtable session discussing concrete, everyday solutions. [More.](#)

Innovative Technologies in Genome Diagnostics, 25th May - satellite meeting running from Genome wide SNP array diagnostics to MAQ. [More.](#)



## More new patient leaflets

Unit 6 has developed a new set of patient information leaflets. The four titles added to the series are:

### EuroGentest proposes only Accredited Labs Should Be Allowed to Use Laboratory-Developed Assays

The EU Directive on In Vitro Diagnostic Devices (the IVD Directive) places obligations on the manufacturers of diagnostic test kits or devices to ensure that all devices are safe and effective. Compliance with the Directive is indicated by the "CE mark" on the device or packaging.

At present, clinical laboratories are exempt from the obligations of the IVD Directive if they manufacture and use diagnostic test kits within their own health institution. While this exemption is important to allow for specialist testing that is not commercially viable it potentially allows tests which have not been properly manufactured or validated to be used in clinical diagnostics. The IVD Directive is currently being revised. Unit 1 of EuroGentest has developed a proposal that the exemption for laboratory-developed assays should in future only be available to laboratories which are accredited to EN ISO 15189 or equivalent. Accredited laboratories have a comprehensive quality system in place, including the validation of all assays used. Restriction of the exemption to accredited laboratories would, we believe, make an important contribution to patient safety.

The detailed proposal is open for comments and can be viewed [here](#). All comments or enquiries to David Barton

### 1st EuroGentest Quality and Laboratory Management Symposium creating a stir

Why are quality issues never given the prominence they deserve at international conferences was question that spurred Els Dequeker to organize the first EuroGentest Quality Symposium June 18-19 in Leuven. The response has been superb and Els and her team have managed to assemble a first class speaker line up of experts from across Europe and further afield. Topics include:

- An accreditor's view
- Maintaining QMS and document control
- IT support for QMS
- EQA and ISO 17043
- The working of ILAC, EA and national accreditation bodies

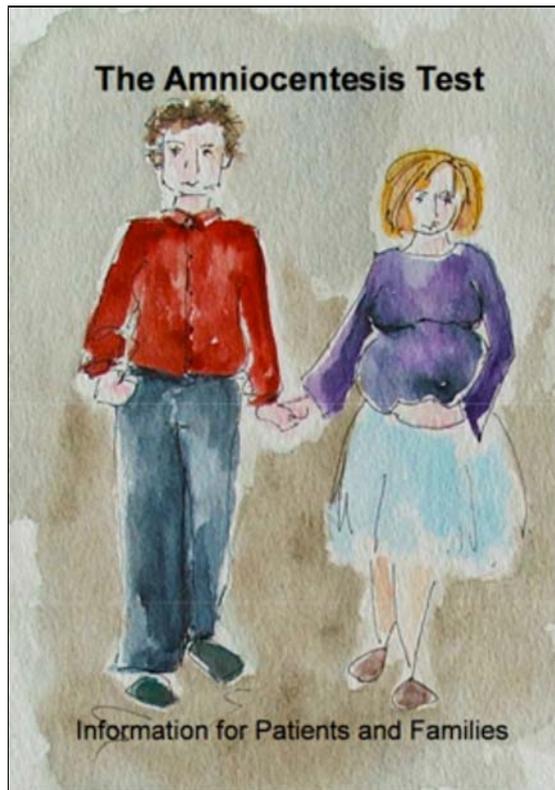
The winner of the EuroGentest Laboratory Quality Award will also be announced. [More information here](#)

- **Carrier Testing**
- **Predictive Testing**
- **Predictive Testing for Inherited Cancer**
- **What Happens in a Genetics Laboratory?**

Download English versions [here](#)

They will be translated over the coming months and uploaded onto the appropriate pages.

For further information please contact [celine@gig.org.uk](mailto:celine@gig.org.uk)



### NEW - First Workshop on accreditation for beginners in French

Atelier d'initiation - Accréditation dans les laboratoires de génétique en français.

It will be a mammoth task, but the necessary next step in our quality mission - to provide advice in community languages. The workshop will be held 22-23 September 2009 in Paris, France in collaboration with l'Agence de la biomédecine. [Registration here](#).

### CEQA goes from strength to strength



Cytogenetic European Quality Assessment (CEQA) is now entering its fourth year of operation. Since the first pilot round in 2006, offering two constitutional cases (AF and Blood) to 18 invited laboratories it has gone from strength to strength. Participation numbers doubled for the second pilot round in 2007. In 2008, 86 laboratories participated in the first full EQAs (AF and Postnatal Bloods) as well as two pilot EQAs (Preimplantation Diagnosis and Haemato-oncology). Overall performance was satisfactory with some poor performances being identified. Last year also saw the introduction of charges for the constitutional EQAs, a step that, thankfully, did not adversely affect registration and participation.

In 2009 CEQA has expanded its repertoire even further, adding a Microarray (arrayCGH) Pilot EQA in collaboration with EMQN. CEQA registration so far stands at 164 with one month to go before the start of the first EQA round. This year also sees the improvement of the governance structure of the Scheme with the introduction of a Steering Committee. This committee is composed of European EQA Providers as well as invited experts and will meet for the first time in October during the assessors' meeting in Berlin. This committee will set the performance criteria for the EQAs, deal with appeals and complaints and refer persistent poor performance to the ESHG Quality Committee.

For the first time this year CEQA will be represented with a stand at both the ESHG conference and the ECA conference. Through our network of National Representatives we have informed cytogenetic laboratories in 28 countries of our presence at those meetings and hope to "spread the word" of Cytogenetic Quality Assessment in Europe during our time in Vienna and Stockholm. [More information here](#)

### Genetic test validation workshop – Bologna, October 26-27

With an ever increasing number of tests appearing, the need for validation has never been more important. This workshop provides an introduction to the requirements of ISO 15189 and practical ways of meeting them. [Register here](#)

**EuroGentest**  
**Harmonizing genetic testing**  
**across Europe**

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