Still room for improvement : an update of the ESP KRAS EQA scheme

Marjolijn Ligtenberg
Most slides obtained from
Prof. dr. E. Dequeker
UZ-K.U.Leuven, Belgium

Role of Scheme organizers*

- Inventarisation of adequat FFPE material:
  - Type of mutation (similar among schemes)
  - Sufficient material
  - ≥ 30% tumor cells after microdissection

- Preparation and distribution of slides:
  - 3 slides consecutive unstained slides/lab
  - Highest and lowest slide should be comparable
  - One or two spare sets
  - Last set of three slides > reference lab

* Participated successful in a pilot scheme

Role of reference lab (Nijmegen/Leuven)

- Check results of subscheme organisers labs
- Compare quality of tissues selection among schemes:
  - % tumor cells
  - Quality of isolated DNA
- Compare detectability of mutations
- Find explanation for discrepancies (e.g. case of heterogeneous tumor)

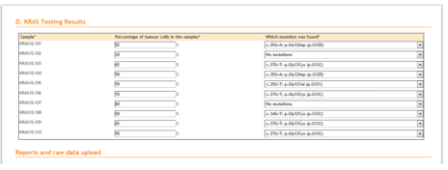
Role of Coordination centre Leuven

- Coordination role between all scheme organizers and participants
- Responsible for the harmonization of the samples
- Responsible for all communications
- Responsible for the website and electronic submission form
- Data collection of the results, draft first report and overview of results
- Logintudional research on performance

Information submitted by the laboratory to the European QA coordinator

Tabular reporting form (electronic data submission)
- which mutations were tested
- which method was used
- % tumor cells and genotype results
- general information of the lab

Raw data of the lab results and the reports sent to treating physian of the first 3 samples



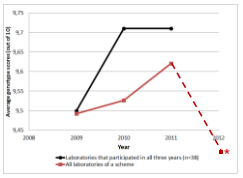
Data-analysis

- **Results have to be submitted within 10 workdays**
  - Mutation analysis of the samples
  - Analysis of tumor percentage
  - Written reports of the first 3 samples
  - Raw data
  - List with general questions

Genotyping results

Number of laboratories and countries for each year

Scheme	Number of labs	Number of countries	% of labs reported all genotypes correctly
2009	61	9	69
2010	76	14	67
2011	124	17	72
2012	105	26	75 *



Average genotype scores on 10 samples over the years

Numerical scoring system
- 1 point correct genotype or in case mutation was not screened and identified as wild type
- 0 points incorrect genotype
- 0 points in case of technical failure in samples of unambiguous quality

Genotyping results Dutch labs

All laboratories

Scheme	Number of labs	% of labs reported all genotypes correctly
2009	61	69
2010	76	67
2011	124	72
2012	105	75

Dutch laboratories

Number of labs	% of labs reported all genotypes correctly	Average genotyping score
14	79	9,8
16	56	9,1
19	89	9,9
22	54 *	9,4 *

* Preliminary data

Listing on the website

All labs with > 90% genotype score are listed on:

http://kras.eqascheme.org/info/public/eqa/previous_participants.xhtml

Dutch laboratories

Scheme	Number of labs	% of labs reported all genotypes correctly	Average genotyping score	On website
2009	14	79	9,8	14 (100%)
2010	16	56	9,1	14 (88%)
2011	19	89	9,9	18 (95%)
2012	22	54 *	9,4 *	20 (91%) *

* Preliminary data

Evaluation of the reports

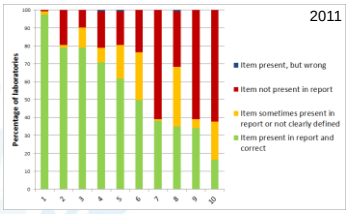
Scores of important criteria in written reports sent by the participants.

Analysis of the reports was based on:

- *ISO 15189:2007*
- *Guideline document CAP regarding reporting of molecular results (Gulley ML, et al Clinical laboratory reports in molecular pathology. Arch Pathol Lab Med. 2007 Jun;131(6):852-863).*

Evaluation of diagnostic reports

Requested are (mock) **reports as sent to treating physician**

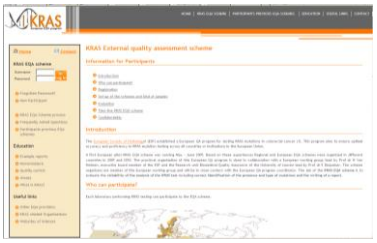


1. Test results given
2. % of tumour in the sample
3. Methods used
4. Patient name
5. Nature of the sample
6. Reason for testing
7. Interpretation of the case
8. Name and address of the requesting service
9. Sensitivity of the method
10. Patient history

Conclusion

- The ESP KRAS EQA schemes **highlight the need for continuing EQA** in this field
- EQA scheme assesses not only the laboratory's **ability to obtain accurate, reliable results**, but also **the ability to safely interpret the results** and ensure that the referring clinician has the correct information.
- The **contents of the reports clearly need to improve**.

More information on the website
http://kras.eqascheme.org



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first meeting on external quality assurance in molecular pathology

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MEETING REPORT

Guideline on the requirements of external quality assessment programs in molecular pathology

J. Han van Krieken · Nicola Normanno · Fiona Blackhall · Elke Boone · Gerardo Botti · Fatima Carneiro · Ilhan Celik · Fortunato Ciardiello · Ian A. Cree · Zandra C. Deans · Anders Edsjö · Patricia J. T. A. Groenen · Outi Kamarainen · Hans H. Kreipe · Marjolijn J. L. Ligtenberg · Antonio Marchetti · Samuel Murray · Frank J. M. Opdam · Scott D. Patterson · Simon Patton · Carmine Pinto · Etienne Rouleau · Ed Schuuring · Silke Sterck · Miquel Taron · Sabine Tejpar · Wim Timens · Erik Thunnissen · Peter M. van de Ven · Albert G. Siebers · Elisabeth Dequeker

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Medical and technical expert
H Van krieken and M Ligtenberg, Nijmegen, The Netherlands

Scheme organisers
G Hofler, Austria, P Vandenberghe, Belgium, G De Hertogh, Belgium, K de Sticker, Denmark, E Rouleua, France, A Jung, Germany, G Vassalis, Greece, J Machado, Portugal, F Lopez-Rios, Spain, A Edjso, Sweden, M Ligtenberg, The Netherlands

Scheme co-ordinator and assistants co-ordinator
E Dequeker, S Sterck, L Tembuyser
Biomedical Quality research Unit KU Leuven, Belgium

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The participating laboratories