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

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Most slides obtained from
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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
- Logitudinal 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 physician 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:

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of labs</th>
<th>Number of countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>61</td>
<td>69</td>
</tr>
<tr>
<td>2010</td>
<td>76</td>
<td>14</td>
</tr>
<tr>
<td>2011</td>
<td>124</td>
<td>17</td>
</tr>
<tr>
<td>2012</td>
<td>105</td>
<td>26</td>
</tr>
</tbody>
</table>

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

Average genotype scores on 10 samples over the years:

<table>
<thead>
<tr>
<th>Year</th>
<th>Scheme</th>
<th>Number of labs</th>
<th>% of labs reported all genotypes correctly</th>
<th>Average genotyping score</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
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* 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

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<td>14</td>
<td>73</td>
<td></td>
<td>9.8</td>
</tr>
<tr>
<td>2010</td>
<td>16</td>
<td>56</td>
<td></td>
<td>9.1</td>
</tr>
<tr>
<td>2011</td>
<td>19</td>
<td>89</td>
<td></td>
<td>9.9</td>
</tr>
<tr>
<td>2012</td>
<td>22</td>
<td>54 *</td>
<td></td>
<td>9.4 *</td>
</tr>
</tbody>
</table>

* 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

Evaluation of diagnostic reports

Requested are (mock) reports as sent to treating physician

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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.
Acknowledgement

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

Scheme organisers
G Heffer, Austria, P Vanderhem, Belgium, G De Hertogh, Belgium, K de Sticker, Denmark, E Rouleau, France, A Jung, Germany, G Vassalis, Greece, J Machado, Portugal, F López-Rios, Spain, A Edsjö, 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

ESP for administrative support

The participating laboratories

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