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

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Most slides obtained from Prof. dr. E. Dequeker
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Role of Scheme organizers*
- Inventarisation of adequate 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 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>
<th>% of labs reported all genotypes correctly</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>51</td>
<td>9</td>
<td>69</td>
</tr>
<tr>
<td>2010</td>
<td>76</td>
<td>14</td>
<td>67</td>
</tr>
<tr>
<td>2011</td>
<td>104</td>
<td>17</td>
<td>72</td>
</tr>
<tr>
<td>2012</td>
<td>105</td>
<td>26</td>
<td>70</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**

**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**

<table>
<thead>
<tr>
<th>Scheme</th>
<th>Number of labs</th>
<th>% of labs reported all genotypes correctly</th>
<th>Average genotype score</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>61</td>
<td>69</td>
<td>9.8</td>
</tr>
<tr>
<td>2010</td>
<td>76</td>
<td>67</td>
<td>9.1</td>
</tr>
<tr>
<td>2011</td>
<td>124</td>
<td>72</td>
<td>9.9</td>
</tr>
<tr>
<td>2012</td>
<td>105</td>
<td>75</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

**Conclusion**

- The ESP KRAQ 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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