

**NATIONAL EXTERNAL QUALITY  
ASSESSMENT SCHEME  
IN  
CLINICAL CYTOGENETICS**

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**ANNUAL REPORT**

**2009**

**UK NEQAS for Clinical Cytogenetics**

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## Personnel

**Scheme Organiser (S.O):**  
**Deputy Scheme Organiser:**  
**Quality Manager**

Dr Ros Hastings (Oxford, JR)  
Mr Eddy Maher (Edinburgh)  
Mrs Bettina Quellhorst-Pawley (Oxford, JR)

## Assessors

### Constitutional Scheme

Dr Heleen Schuring (Utrecht, Netherlands)  
Dr Ron Hochstenbach (Utrecht, Netherlands)  
Mrs Kath Smith (Sheffield)  
Dr Lorraine Gaunt (Manchester)  
Mrs Sian Morgan (Cardiff)

Dr Carol English (Newcastle)  
Mr Eddy Maher (Edinburgh)  
Mrs Carolyn Campbell (Oxford, Churchill)  
Mr Graham Fewes (Birmingham)

### Haemato-Oncology Scheme

Mrs Helen Dickinson (Leeds)  
Mrs Sarah Ryley (KGC, Harrow)  
Mr David Betts, (Dublin, Ireland)  
Mr Paul Roberts (Leeds)  
Dr Fiona Ross (Salisbury)  
Mrs Sandra Birdsall (Cardiff)

Mrs Amy Logan (Belfast)  
Mrs Polly Talley (Sheffield)  
Mr Nick Bown (Newcastle)  
Dr Manual Teixeira (Oporto, Portugal)  
Dr Sheila O'Connor (HMDS, Leeds)  
Dr Markella Mikkelsen (Manchester)

### Molecular Rapid Aneuploidy (MRA) Joint EQA with Molecular Genetics (MG)

Dr Eric Sistermans (Amsterdam, Netherlands)  
Dr Ros Hastings (S.O, Oxford, JR)

Mrs Cathy McConnell (Glasgow)  
Dr Sandi Deans (MG S.O, Newcastle)

### Microarray Pilot EQA

Mrs Nicole de Leeuw (Nijmegen, The Netherlands)  
Mr Dom McMullan (Birmingham)

Mr Eddy Maher (Edinburgh)  
Mr Björn Menten (Ghent, Belgium)

## Steering Committee

Dr Tony Parkin\* (Chair, Nottingham)  
Mr Eddy Maher (Deputy S.O, Edinburgh)  
Mrs Sandra Birdsall (Cardiff.)  
Mrs Carolyn Campbell (Oxford)  
Dr Sheila O'Connor (Leeds)  
Prof Andrew Green (Dublin)  
Mr Roger Mountford (NQAAP, Liverpool)

Dr Ros Hastings (S.O, Oxford, JR)  
Mr Paul Roberts (Secretary, Leeds)  
Mrs Helen Dickinson (Leeds)  
Mrs Sarah Ryley (London)  
Dr Lorraine Gaunt\* (Chair, Manchester)  
Dr Sandi Deans (MG S.O, Newcastle)

\* Dr Tony Parkin stepped down as chair in December 2009. The new chair is Dr Lorraine Gaunt

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## 1. Introduction to the Scheme

The National External Quality Assessment Scheme (NEQAS) for Clinical Cytogenetics has been a member of the UK NEQAS Consortium since 1983. The Scheme is accredited to the new CPA guidelines (ILAC 43). The Scheme has been accredited with CPA (UK) Ltd since July 2007. The next full accreditation inspection is due in November 2010.

The annual management review for the 2009 EQA seasons was completed in January 2010 and sent to the CPA office. The annual management review was reviewed by the Steering Committee in February. Quality objectives for 2010 have been set and are available on request.

For further information about the Clinical Cytogenetics Scheme please contact the Scheme Organiser ([ros.hastings@orh.nhs.uk](mailto:ros.hastings@orh.nhs.uk)) or visit the Scheme web site at [www.cneqas.org.uk](http://www.cneqas.org.uk) or via the UK NEQAS web site, [www.ukneqas.org.uk](http://www.ukneqas.org.uk)

## 2. External Quality Assessment (EQA) distributions in 2009

The EQA assessments consider **technical**, **analytical** and **interpretive performance**. All EQAs offered in 2009 were fully interpretative EQAs

- Technical proficiency tested via submitted slides, DNA samples and cell suspensions;
- Analytical proficiency tested via validated cell suspensions, DNA and online EQA;
- Interpretive proficiency tested via case scenarios and retrospective external audit of reports on work undertaken in diagnostic laboratories, specifically looking at interpretation.

### 2.1 Constitutional Scheme

In 2009 there was a single distribution for each of the following EQAs -

- Amniotic fluid (retrospective reports)
- CVS (slide distribution)
- Blood (online)
- Solid Tissue (case scenario)
- Molecular Rapid Aneuploidy (MRA) (DNA distribution)

### 2.2 Haematological Scheme

In 2009 there was a single distribution for each of the following EQAs -

- CML (retrospective reports)
- MDS (slide distribution)
- ALL (case scenario)
- Tumour (online/image distribution)
- LPD (online/cell suspensions)

### 2.3 Pilot EQA Schemes

- Microarray/Array CGH (DNA distribution)

The online Microarray pilot involved the analysis of a single DNA sample (one case). 34 laboratories registered for the pilot and 32 participated.

## 3. Scheme participation

In 2009, 116 laboratories participated in the scheme; 40 UK cytogenetic laboratories, and 76 non-UK cytogenetic laboratories. The haematology and histopathology laboratories participate in either the LPD EQA or the Tumour EQA. A total of 456 EQA distributions were sent out by the Scheme Office and more than 1100 cases were assessed. UK cytogenetic laboratories generally participate in more EQAs than non-UK laboratories (ratio approx 2:1).

## 4. Scheme submissions

- 27 laboratories failed to remove their laboratory identification on the reports or referral cards this year. This is more than in previous years and was not limited to new participants.
- For non-UK labs:- Interpretation of a cytogenetic result is an essential part of the diagnostic report. In this EQA scheme, laboratories must submit an interpretation with the report. If the interpretation is routinely done by a clinician or Clinical Geneticist in your department, please (a) involve them when completing the case online and (b) submit a copy of the clinician's or Clinical Geneticist's letter with the retrospective reports.
- UK NEQAS for Clinical Cytogenetics does not determine the Professional Guidelines. The ACC Professional Standards Committee (UK), CPA UK Ltd and other European or International bodies (e.g. ECA, ISO standards, ISCN, leukaemia trial studies) produce the guidelines and standards. UK NEQAS for Clinical Cytogenetics has referred issues arising out of the EQA rounds to the ACC Professional Standards Committee and the ISCN Committee in the past and will continue to approach the professional organisations if additional guidance/clarification is required
- UK NEQAS marks the laboratory submissions against its interpretation of these guidelines/standards. If you have issues in the way the guidelines/standards have been interpreted by UK NEQAS please submit them to the Scheme Office through the appeals process.

### 4.1 ISCN 2009

- Laboratories will be expected to use ISCN 2009 in all their reports from April 2010. For the 2009 EQAs laboratories were marked against ISCN 2005 but only against ISCN 2009 if this nomenclature was submitted by the laboratory.

### 4.2 Interpretation and reporting

For the written report the interpretation is marked. The reporting format and style are not marked but can be commented upon. The full score for interpretation and reporting is 2 marks

## 5. EQA structure and format

- Details of all EQAs are available online (download document under diary).
- All EQAs involve submission of documentation or analysis online. In addition, the slide distribution EQAs will require laboratories to submit slides via the post; MRA and Micorarray/Array CGH EQAs will involve analysis of DNA samples; the LPD EQA will involve an online case plus FISH analysis of a cell suspension sample.
- All EQA summary letters include the range of actual scores, so laboratories can see how their performance compares with other laboratories. The standard that should be obtained is 'satisfactory'.
- UK laboratories receiving additional EQA rounds following a poor performance will be charged an additional fee of £100 to cover the increased administration costs. Non-UK laboratories will be notified by letter of any poor performance.
- Laboratories have 15 working days to appeal against any penalties/comments in their individual laboratory reports.

## 6. Performance scoring

In accordance with the performance criteria, the standard for all laboratories to reach is "satisfactory" (CPA (EQA) Standards E5 and F5). The laboratories' performance scores (after completion of the appeals process) for the 2009 constitutional and haemato-oncology EQA schemes are given in Appendix A.

## 6.1 Consistency across the Scheme

The Scheme tries to be consistent between EQA schemes and across both constitutional and haemato-oncology areas but inconsistencies sometimes occur (see slight differences in the marking in the constitutional and haemato-oncology cytogenetics performance criteria). There are several ideas being discussed at the moment to achieve more consistency which the Scheme will develop and hopefully be able to introduce during 2010.

In addition, joint EQAs may sometimes identify inconsistencies in reporting, for example Molecular Rapid Aneuploidy results between Cytogenetic departments and Molecular Genetic departments.

## 6.2 Appeals

The performance criteria (v3.3) were used to assess all the EQA rounds and pilots this year. There were 58 appeals to the Scheme, of which 16 were fully upheld (had the appealed penalties rescinded), 16 were partially upheld (had some but not all the appealed penalties rescinded) and 21 appeals were not upheld. The remaining five appeals were due to clerical errors that were rectified. See Appendix B for details.

## 6.3 Poor performance

A zero mark in the analytical or interpretative score will automatically result in poor performance (see Performance Criteria). Poor performance may also occur if the laboratory accumulates four or more penalty points. Since Autumn 2007, non-UK laboratories with a poor performance are requested to review their reporting policy and no obligatory additional EQA rounds are sent.

A total of 45 different laboratories received a poor performance in the 2009 EQAs. In addition, Three non-UK laboratories failed to participate in the EQAs for which they had registered for and were therefore automatically given a poor performance (see Appendix A and Performance Criteria).

## 6.4 Persistent poor performance

Two non-UK labs received a persistent poor performance categorisation (three poor performances within a rolling three year period) for the first time in 2009; in addition three non-UK laboratories continued to receive persistent poor performance.

## 7. Scheme personnel

- **Scheme Organiser:** Dr Ros Hastings was appointed in June 2003.
- **Deputy Scheme Organiser:** Mr Eddy Maher was appointed in November 2003.
- **Quality Manager:** Bettina Quellhorst-Pawley was appointed in October 2005. Bettina is also the CEQA (European Cytogenetics EQA) QM/administrator.
- **Steering Committee:** Dr Tony Parkin stepped down as chair of the Steering Committee and was replaced by Dr Lorraine Gaunt in December 2009
- **Steering Committee Executive:** Consists of the Chair, Scheme Organiser, Deputy Scheme Organiser, Secretary and a senior cytogeneticist specialising in haemato-oncology (Helen Dickinson) from the Steering Committee.

### 7.1 Assessors –

The Scheme is keen to recruit new assessors for 2011, as some assessors are completing their term of office. UK assessors will normally have part 1 of the FRCPath and will be regularly involved in reporting. Non-UK assessors are normally recognised experts with a minimum of 10 years experience in their specialist area. Potential assessors need to send a brief curriculum vitae to the Scheme Office ([ros.hastings@orh.nhs.uk](mailto:ros.hastings@orh.nhs.uk)) in the first instance. All assessor appointments will be ratified by the Steering Committee.

There were 7 non-UK and 21 UK assessors (including the MRA assessors but excluding the Scheme Organiser).

In 2010 the following new assessors will join the Scheme

- Mrs Marianne Grantham
- Mr Richard Hall
- Dr Kathy Mann
- Mrs Kate Martin
- Dr Ingrid Simonic
- Mrs Heather Ward
- Mr Jerome Evans
- Mr David Delmege

## **8. Changes to the Scheme for 2010**

### **8.1 Constitutional Scheme –**

- Urgent Blood will replace the Solid Tissues EQA.
- The Micorarray/Array CGH pilot will involve one DNA sample to analyse and report.
- Molecular Rapid Aneuploidy (MRA) will run in the Autumn EQA season in collaboration with UK NEQAS for Molecular Genetics. There will be a single distribution of 3 cases.
- Fanconi Anaemia, an online Pilot EQA will be offered in the Spring EQA season.

### **8.3 Haemato-Oncology Scheme –**

- AML will replace the MDS EQA.

### **8.4 Laboratory codes**

Please use your unique laboratory code in all communications with the Scheme (including emails).

### **8.5 Future Developments to Management System (QA Manager)**

The static website has been updated with the 2010 timetable and Participants' Manual for 2010.

## **9. Scheme finances**

The Scheme finances are healthy and financial returns are submitted annually to UK NEQAS Central Office in Sheffield. Laboratories who provide assessors for the 2009 Scheme will receive a credit of £100 per assessor on their invoice for 2010.

## **10. CPD recognition for activities within the Scheme**

Scheme-based activities performed by the Assessors are accredited by the Royal College of Pathologists for CPD (6 CPD credits).

## **11. Scheme presentations**

The Scheme Organiser or Quality Manager for UK NEQAS for Clinical Cytogenetics have given presentations on quality issues at the following meetings:-

- ACC Spring Meeting (including the Participants' Meeting), Edinburgh, April 2009 (RJH)
- ESHG Conference, Vienna, May 2009 (RJH)
- Italian Cytogenetic Laboratories Meeting, Florence, September 2009 (RJH)

➤ ECA Conference, Stockholm, July 2009 (RJH, BQP)

The participants' meeting expenses were met from UK NEQAS income. Conference fees and travel expenses for the Italian meeting, and the ESHG and ECA conferences were met from other income sources.

## **12. Annual Participants' Meeting**

A full day Participants' Meeting will be held on Monday, 12<sup>th</sup> July 2010 in London. This meeting is open to all staff.

The 2011 Participants meeting will be held during the ACC Spring Conference.

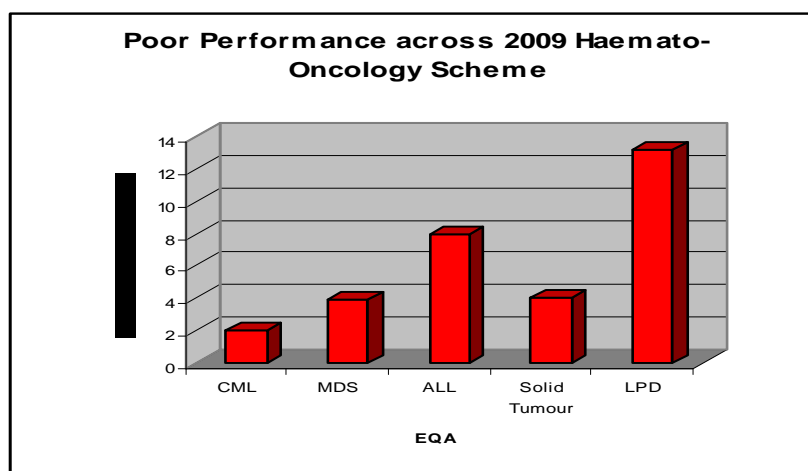
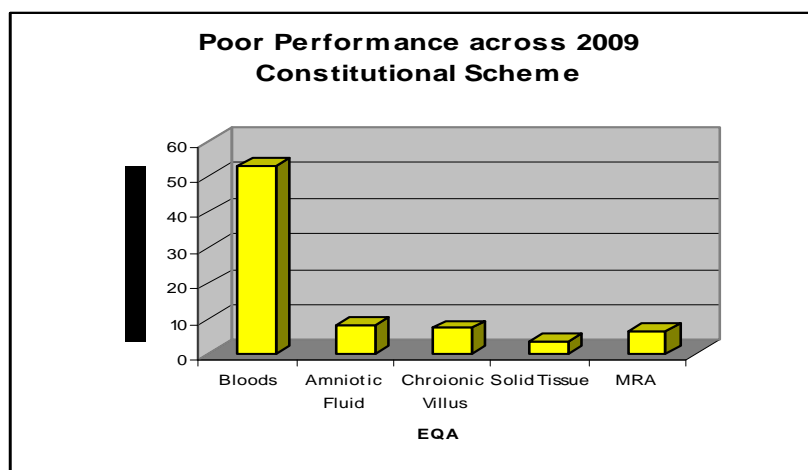
## Appendix A

### Final summary reports scores

Constitutional Scheme	Registered	Non Subm.	Satisfactory	Poor	Disqualified	% PP*
Bloods	64	2	30	32	0	53
Amniotic Fluid	49	0	43	4	2	8
Chroionic Villus	41	1	38	2	0	7
Solid Tissue	27	0	26	1	0	4
MRA	31	0	27	2	1	6
Micorarray	34	2				6
<b>Total Constitutional</b>	<b>246</b>	<b>5</b>	<b>164</b>	<b>41</b>	<b>3</b>	<b>19</b>

Haemato-Oncology Scheme	Registered	Non subm.	Satisfactory	Poor	Disqualified	% PP*
CML	51	1	50	0	0	2
MDS	51	1	47	1	2	4
ALL	50	0	46	4	0	8
Solid Tumour	25	0	24	1	0	4
LPD	38	0	33	5	0	13
<b>Total Haemato-Oncology</b>	<b>215</b>	<b>2</b>	<b>200</b>	<b>11</b>	<b>2</b>	<b>6</b>

\* %PP of total labs registered, includes PP due to Non Submission



## Appendix B

### Appeals Summary 2009

	Clerical	Fully upheld	Partially upheld	Not upheld	TOTAL
<b>ALL</b>				3	3
<b>BLOOD</b>	3	4	6	15	28
<b>CML</b>	0	2	4	0	6
<b>CVS</b>	2	1	1	2	6
<b>LPD</b>	0	0	3	1	4
<b>TISSUE</b>	0	9	2	0	11
<b>TOTAL</b>	<b>5</b>	<b>16</b>	<b>16</b>	<b>21</b>	<b>58</b>

