Andrology & Embryology
External Quality Assessment (EQA) Schemes

ANNUAL REPORT
2013-2014
The bee pictured on the cover was adopted by the UK NEQAS Reproductive Science scheme as its logo in March 2013. As part of harmonisation within UK NEQAS it was felt that different schemes should adopt a logo to assist participants in directing follow-up enquiries to the correct centre.

The bee has for centuries been a symbol of industry and is featured on the coat of arms of the city of Manchester, UK, where the scheme is based. It has also has its connections in reproduction in the old English language euphemism “The birds and the bees”.

The drawing features the Australian native Blue Banded Bee, *Amegilla cingulata* and was drawn by Ebony Bennett a Natural History Illustrator, Wildlife and Landscape artist from Newcastle, NSW, Australia. We would formally like to thank Ebony for her kind permission for us to use this image as our new logo.

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<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
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<tbody>
<tr>
<td>Scheme Organiser:</td>
<td>Mr. Gregory Horne</td>
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<tr>
<td>Deputy Scheme Organiser:</td>
<td>Dr. Diane Critchlow</td>
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<tr>
<td>Scheme Manager:</td>
<td>Mr. Peter Goddard</td>
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<tr>
<td>Scheme Administrator:</td>
<td>Mrs. Diane Shearden</td>
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<tr>
<td>Scheme Quality Manager:</td>
<td>Miss. Justine Hartley</td>
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<tr>
<td>Scheme Training Officer:</td>
<td>Mr. Mike Hooper</td>
</tr>
<tr>
<td>Scheme H&amp;S Adviser:</td>
<td>Mr. Peter Goddard</td>
</tr>
</tbody>
</table>

Email:  
repscience@ukneqas.org.uk  
gregory.horne@cmft.nhs.uk  
pete.goddard@cmft.nhs.uk
Dear Colleague

UK NEQAS Reproductive Science currently operates two schemes. The Andrology External Quality Assessment (EQA) scheme is now in their twenty first year of operation. The Scheme applied for CPA accreditation this year.

The Andrology Steering Committee (ASC) and Embryology Steering Committee (ESC) meet twice a year to discuss the operation of the schemes and advise the Scheme Organiser on future developments. The National Quality Assurance Advisory Panel for Reproductive Science (NQAAP) meets twice a year, actively working to promote quality in Andrology & Embryology both within the scheme and at a national level.

The scheme was represented at the ESHRE in July 2013 in London, at the Association of Clinical Embryologist meeting and British Fertility meeting, January 2014 in Sheffield. We are continuing to distribute the schemes beyond the UK and currently have laboratories participating in Ireland, France, Spain, Belgium, Portugal, Italy, Poland, Germany, Switzerland, Greece, Bulgaria, Serbia, South Africa, United Arab Emirates, Argentina, Nigeria, Malaysia, Hong Kong, Iran and Israel.

Participants of the scheme are welcome to make comments and suggestions at any time and, in fact, many people do contact us. Any feedback is always welcome and is reported to the ASC & ESC to help us to continually develop and, hopefully, improve the schemes. Following continued interest in the one-day practical workshops, we have again run several sessions. This year 7 workshops were offered with 99% uptake. Participants find these workshops very useful and we will be organising more of them in the next 12 months.

Appendix 1 of this report are the Conditions of Participation (COP). As a member of the Scheme it is assumed that you have read and accepted the COP in full.

I would like to remind participants that it is not within the NEQAS scheme remit to endorse or discredit any method used to perform sperm concentration, motility and morphology. It is the responsibility of the individual laboratory to validate any changes within their own methodology.

Kevin Lindsay and Debbie Falconer stepped down from the Andrology Steering committee this year. Stephen Harbottle and Emma Stephenson have stepped down from the Embryology Steering committee. I would like to thank them for all their hard work.

With best wishes,

Mr. Gregory Horne B.Sc., M.Sc.  F.R.C.Path
UK NEQAS Reproductive Science Scheme Organiser
Participant Performance

We continue to alert participants as soon as a distribution falls outside the accepted criteria or if they fail to return any results. Although it increases our workload most laboratory managers tell us it is helpful to be alerted to any problems at an early stage.

This year has been a busy one for the scheme. In April 2013 we introduced the ‘ABC’ scoring system to the Andrology scheme. The focus of performance is now more focused on a rolling 12 month period than targeting labs that have ‘one off’ unsatisfactory results. The reports also now have a summary page which will tell you at a glance how you are doing.

In the Embryology scheme we are now scoring for performance using a penalty point system. This takes into account the embryo grading factors (except the three quality analytes). Performance decline and improvement is monitored and addressed in the same way as the Andrology scheme (see Participants’ Handbook for further information).

Persistent Unsatisfactory Performance

**Criteria of Performance:** Laboratory performance is assessed over a running analytical window of 4 Distributions (12 months) for both Andrology and Embryology schemes. See appendix 2 for current performance criteria details.

**Persistent Unsatisfactory Performance:** Defined as being in the Unsatisfactory Performance category for three or more successive Distributions.

For UK participants this is followed up in accordance with the Conditions of Participation (Appendix 1). Non UK participants are contacted by email each time they show unsatisfactory performance.

There are three performance status categories:

- **Green:** Overall satisfactory performance.
- **Amber:** Lab has had unsatisfactory rolling scores for 3 distributions (or 2 non return of results) without signs of improvement
- **Red:** Lab has had unsatisfactory rolling scores for 4 distributions (or 3 non return of results). In the UK these labs are referred to the RCPath National Quality Assurance Advisory Panel.

(This traffic light system should not be confused with the traffic lights in the ABC scoring system).
Embryology scheme
Currently (as of Distribution 80) there are no Persistent Unsatisfactory Performers in the Embryology scheme.

Andrology scheme
For performance, the Andrology scheme is taken as a whole. Therefore, Persistent Unsatisfactory Performance in any one aspect of the scheme classifies Participants as unsatisfactory in the scheme.

The chart below shows performance in the Andrology scheme over the past three years. The Distribution axis runs right to left.

The below charts separate out performance of UK labs from non UK laboratories (for the past 12 months).
Andrology Scheme

UK NEQAS services are designed principally for UK NHS or Private Clinical Laboratories. Participation is however open to Research, Industrial and non-UK Laboratories. Enrolment can take place at any time. Current charges are available on request.

Reports are presented as histograms and each unit’s result is shown as a figure and also indicated by an arrow on the graph. Different methodologies are listed and the shaded area on the graph indicates all the units using the same as the one to whom the report relates. There are a number of statistical values quoted on reports. These relate to individual specimen reports. There are also graphs that relate to performance over 4 distributions. Explanations for the derivation of values and examples of format are available in the Participants’ Handbook.

February 2014 Membership by Discipline:

As of February 2014 there were a total of 299 participants.

Distributions

The Andrology Scheme distributes samples and images four times per year. The dates for all distributions are set each year in advance and if samples are not received by the due date, the responsibility lies with each participant to let us know.

Distribution Dates for 2013/14

- 13\textsuperscript{th} May 2013
- 12\textsuperscript{th} August 2013
- 11\textsuperscript{th} November 2013
- 10\textsuperscript{th} February 2014
Closing dates for each distribution are usually four weeks after the Distribution date.

**Sperm Concentration Assessment**

Number of Participants by concentration method, February 2014:

For the semen concentration the Method Related Trimmed Mean (MRTM) is taken from participants using Improved Neubauer chambers. This is the recommended method according to the World Health Organisation laboratory manual for the examination of human semen (2010) Fifth Edition.

**Morphology Assessment**

Number of Participants by Morphology criteria, February 2014:

The MRTM taken from results of laboratories reporting the use of WHO (2010)/strict criteria is used for morphology.
Sperm Motility Assessment

Each motility distribution consists of four samples with several clips of sperm for each sample.

External quality assessment of this important aspect of semen analysis is challenging to organise. Live gametes are likely to deteriorate during distribution of samples. Also, CASA machines generally can only assess videos filmed on the specific make of analyser.

This is why we use online examination of filmed samples.

WHO derived assessment methods for motility are necessary in order to make analysis and presentation of the results possible. This is not always ideal, since EQA should reflect the routine methods used in a participating laboratory. Nevertheless, one of the primary aims of the EQA scheme is to promote standardisation in laboratories by recommending use of methods proposed by the World Health Organisation laboratory manual for the examination of human semen (2010) Fifth Edition. The motile sperm are graded as progressive, non-progressive or immotile. Examples of the report format can be found in the Current Participants’ Handbook.

Designated values are calculated from the mean of each motility category, rather than results from reference laboratories, but, as with the other schemes, setting of designated values remains a permanent agenda item for the ASC. In the report format running graphs, the progressively motile sperm form one graph and the non-progressive and immotile form the other. Explanations for the derivation of values and examples of format are available in the Participants’ Handbook.

An All Laboratory Trimmed Mean (ALTM) is used for motility.

Interpretive Morphology Assessment

The Interpretive Morphology distributions consist of a series of images containing 24 sperm for assessment.

Consensus values of 60% agreement are used in interpretive morphology.

During 2013/14 this scheme was not scored for performance.
Embryo Morphology Scheme

January 2014 Membership

Reproductive Medicine/Assisted Conception  56 UK participants
                                               21 overseas participants

Distributions

The Embryology Scheme distributes images four times per year. The dates for all
distributions are set each year in advance. All assessments are made on line via the Gamete
Expert website. Notification for each distribution will be by email from Gamete Expert. If
participants are unable to access/login to the Gamete Expert website to complete the
assessments, the responsibility has to lie with each participant to let us know. Each
distribution consists of four ‘virtual’ patients, each with 2-4 embryos for assessment. Embryos
stages for assessment range from early cleavage stage (day 2, day 3 of culture post egg
collection), to blastocyst stage (day 5, day 6 of culture post egg collection).

Distribution Dates for 2013/14

- 13<sup>th</sup> May 2013
- 12<sup>th</sup> August 2013
- 11<sup>th</sup> November 2013
- 10<sup>th</sup> February 2014

Closing dates for each distribution are usually four weeks after the Distribution date.

Embryo morphology parameter assessment

Cell number, cell size/evenness and degree of cell fragmentation of early cleavage embryos
are assessed separately for each embryo using the National Grading Scheme recommended
by ACE and BFS (Cutting et al, 2008) Blastocyst stage embryos are also assessed using the
National Grading Scheme. The grading schemes have been endorsed by NICE and are
included in their current guidelines for Fertility (February 2013).

Reports are presented as histograms and each unit’s result is shown as a figure and also
indicated by an arrow on the graph. Only one set of results from each participating laboratory
are used for External Quality Assessment. Reports can be viewed at
https://results.ukneqas.org.uk using your UK NEQAS laboratory number and password.

Participants may also purchase individual licences. The results are presented on line via the
Gamete Expert website after each distribution has closed. Results are calculated from all
individuals participating in the scheme, and will therefore be different to the results from UK
NEQAS, where only one result per laboratory is used. A new ‘archive gallery’ is now available
from Gamete Expert for both online Andrology and Embryology, enabling access to video
clips and results previous distributions.
There are currently no ‘gold standard’ methods to determine ‘correct’ or target values for embryo morphology assessment. It was decided in April 2011 that target values for embryo cell number, cell size/evenness and percentage cell fragmentation would be derived from all laboratory results to give a ‘consensus’ result. A consensus result is given if more than 50% of laboratories agree. If fewer than 50% agree, then there is no target value given. Performance criteria have not been used for the first full year of the scheme. From April 2013, laboratories have been monitored for performance.

**Embryo quality assessment**

These parameters are not currently used to monitor performance, but help participating laboratories compare how they assess embryo ‘quality’ to other laboratories. E.g. choice of best embryo (probably indicating the choice of embryo for transfer in a clinical setting) and comparison of how laboratories grade embryos considered to be ‘top quality’, good, poor quality etc. Embryo quality will continue to be used as an ‘interpretive scheme’ only from April 2013, and the quality parameters will be used for educational/information purposes only and not used to monitor laboratory performance. However, the reports provided will still show match with consensus etc. as detailed above for embryo grading parameters

Each ‘whole’ embryo is assessed for the following:

Quality ranking: embryos for each patient are assessed and ranked ‘best’ to ‘worst’ quality

Suitability for cryostorage: this will depend on each individual participant policy for cryostorage, but is useful for comparison with other laboratories and also for internal quality control purposes (where individual licences are used)

Interpretive questions: Time-lapse imaging from the EmbryoScope™ is used post fertilisation to blastocyst stage. Participants are asked to note any abnormalities in embryo development at certain time points. This is intended to be used as an educational tool rather than to monitor laboratory performance.

Cutting et al, Elective Single Embryo Transfer: Guidelines for Practice British Fertility Society and Association of Clinical Embryologists Human Fertility, September 2008; 11(3): 131–146
Meetings and workshops:

**Annual Participants’ Meeting 6th March 2014**

The Annual Participants’ meeting was held at the Portland Thistle Hotel, Manchester. The meeting was well attended and a full analysis of the feedback sheets will be described in next year’s Annual Quality Report (available via the website). The meeting was in the usual format of formal lectures in the morning followed by seminar type discussion groups in the afternoon. The programme was as follows:

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>09.00</td>
<td>Registration and Coffee in Lakeland Bar &amp; Foyer</td>
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<tr>
<td>09.30</td>
<td>Introduction - Overview and Progress Report of Scheme</td>
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<tr>
<td></td>
<td><strong>Greg Horne</strong></td>
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<tr>
<td>09.45</td>
<td>HIV and Fertility</td>
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<tr>
<td></td>
<td><strong>Dr Chitra Babu</strong></td>
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<tr>
<td>10.30</td>
<td>Evolution of the Penis</td>
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<tr>
<td></td>
<td><strong>Dr Michael Carroll</strong></td>
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<tr>
<td>11.15</td>
<td>Tea / Coffee in Lakeland Bar &amp; Foyer</td>
</tr>
<tr>
<td>11.45</td>
<td>Evolution of the Sperm</td>
</tr>
<tr>
<td></td>
<td><strong>Dr John Fitzpatrick</strong></td>
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<tr>
<td>12.30</td>
<td>Lunch in Portland Restaurant</td>
</tr>
<tr>
<td>13.30</td>
<td>Sperm Morphology: Is Everyone Too Strict For The Naughty Step???</td>
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<tr>
<td></td>
<td><strong>Diana Jackson</strong></td>
</tr>
<tr>
<td>13.45</td>
<td>Host-Pathogen Interaction and Female-Male Fertility Interface</td>
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<tr>
<td></td>
<td><strong>Nadja Rodrigues de Melo</strong></td>
</tr>
<tr>
<td>14.00</td>
<td>ISO 15189 Preparation</td>
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<tr>
<td></td>
<td><strong>Sharon Fensome-Rimmer</strong></td>
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<tr>
<td>14.30</td>
<td>ISO 15189 – An Inspector’s View</td>
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<td></td>
<td><strong>Stephen Harbottle</strong></td>
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<tr>
<td>15.00</td>
<td>Open Forum – Chair: Dr Rachel Gregoire (ESC)</td>
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<tr>
<td>16.00</td>
<td>Close</td>
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</tbody>
</table>

**Semen Analysis – One Day Workshops.**

Seven semen analysis training days were held between April 2013 and March 2014. A total of 99 people attended and the feedback from those participating was positive.

Practical sessions covered sperm concentration, motility and morphology. Course manuals were supplied and staff were on hand to answer questions throughout the day. The training days were eligible for IBMS CPD points.

Requirements for delegates wishing to attend future courses are that they are:

1. Able to operate a microscope
2. Able to perform dilutions using automatic pipette.
3. Able to use a counting chamber.
The UK NEQAS Reproductive Science Service has received largely positive feedback again this year in all aspects of the Scheme.

As a result of participant comments received, there have been some improvements to the scheme this year. These include improved recording and response to participant comments received during distributions. In the semen analysis scheme this has resulted in new methods for sample preparation to reduce aggregation of sperm and improve homogeneity. The motility improvements include an upgrade of the online server for increased capacity, addressing accessibility issues during peak times. Other improvements include easier enrolment through the NEQAS Birmingham Quality site.

UK NEQAS Reproductive Science underwent a CPA inspection in March 2014. The feedback from the inspectors was largely positive and a final decision is due in July.

The Annual Quality report in full is available online at http://www.cmft.nhs.uk/saint-marys/our-services/ukneqasrepsci.aspx
Andrology & Embryology Steering Committees (ASC)/(ESC)

Function
All established UK NEQAS Schemes are supported by advice from an appropriate UK NEQAS Steering Committee, accountable to the UK NEQAS Board. The Chairman is normally independent of UK NEQAS operational interests, and membership will include appropriate experts, participants and advisors. Members and the Chair are appointed by the UK NEQAS Board, on the advice of appropriate professionals, and sit in their own right and normally not as representatives of any professional or other group (though some may fulfil an invaluable liaison function with such groups). Steering Committees do not consider the performance of individual participating laboratories, except in advising on performance criteria or where this may indicate a failure in the operation of the Scheme (and even in such cases the laboratories will not be identifiable).

Remit
1. To advise the Scheme Organiser(s) on the overall design and operation of the Scheme(s), including aspects such as:
   - appropriateness of the investigations surveyed;
   - nature of the specimens distributed;
   - number and frequency of specimen distribution;
   - source of target values;
   - data analysis and performance assessment;
   - data presentation;
   - communication with participants, including meetings, newsletters, educational activities;
   - communication with the diagnostics industry;
   - research and development for the Scheme(s);

2. In consultation with the Scheme Organiser, to liaise with the relevant National Quality Assurance Advisory Panel in setting performance criteria.
3. To promote harmonisation, in scheme design and practice, with other UK NEQAS schemes as appropriate.
4. To consider, and advise the Scheme Organiser(s) on, the need for initiation or termination of EQA services for investigations in the area covered.
5. To review Schemes' annual reports.
6. To receive any representations, to Chairman, members or Organiser, from participants concerning the Schemes.
7. To advise the UK NEQAS Board, and where appropriate other relevant organisations (e.g. Department of Health, Joint Working Group on Quality Assurance, CPA (UK) Ltd, Medical Devices Agency, Royal College of Pathologists), on any aspect of EQA or quality assurance in the area covered.

The Organiser ensures that notes and reports from the ASC are reported directly to the UK NEQAS office. The ASC meets formally at least twice a year and the Scheme Organiser and Manager keep in touch with members when the occasion demands this, particularly the Chair.
Membership of the Andrology Steering Committee 2013/2014

- **Chair**: Dr. Allan Pacey  
  Senior Lecturer in Andrology, University of Sheffield.

- **Deputy Chair**: Trudy Johnson  
  Departmental Manager, Queen Elizabeth Hospital, Gateshead.

- **Beverley Duffy**  
  Senior Biomedical Scientist, Whiston Hospital, Merseyside.

- **Dr. D. Iwan Lewis-Jones**  
  Senior Lecturer and Consultant Clinical Andrologist, Reproductive Medicine Unit, Liverpool Women’s Hospital.

- **Paul Hancock**  
  Representative of the Association of Biomedical Andrologists

- **Sue Kenworthy**  
  Biomedical Andrologist, Portsmouth Hospitals NHS Trust

- **Janine Smith**  
  Advanced Biomedical Scientist, Andrology Unit, Seacroft Hospital

Membership of the Embryology Steering Committee 2013/2014

- **Chair**: Dr Rachel Gregoire  
  Senior Clinical Embryologist, The Hewitt Centre for Reproductive Medicine, Liverpool Women’s Hospital

- **Ella Mair**  
  Senior Embryologist, Newcastle Fertility Centre at Life

- **Dr Emma Stephenson**  
  Senior Embryologist, Assisted Conception Unit, Guy’s and St Thomas’ NHS Foundation Trust

- **Dr Helen Clarke**  
  Senior Clinical Embryologist, Assisted Conception Unit, Sheffield Teaching Hospital.

- **Su Barlow**  
  Senior Embryologist, Midland Fertility Services.

- **Bryan Woodward**  
  Senior Embryologist, IVF Consultancy Services, Leicester
National Quality Assurance Advisory Panel (NQAAP) for Reproductive Science

Function
The NQAAP Panels are professional groups which have executive responsibility for maintaining satisfactory standards of analytical and interpretative work in laboratories in the UK, whether in the private or in the public sector, in which investigations are performed for the detection, diagnosis or management of disease in humans. The Royal College of Pathologists, the Institute of Biomedical Science and two or three other appropriate professional bodies each nominate one member, who normally serve for four years. The Chairperson of each of the Panels reports to the Joint Working Group on Quality Assurance.

The Panels work closely with the Organisers of the relevant UK NEQAS and other approved EQA schemes, who bring to their attention laboratories whose performance and/or frequency of returns are judged unsatisfactory by criteria agreed by the Panels with the appropriate Steering Committee. At this stage the Panels identify the laboratory only by code. A Panel reviews information provided by the Organiser and if it decides to intervene in the case of a particular laboratory, the Chairman writes a 'Dear Colleague' letter, which is forwarded to the laboratory by the Organiser. This asks about problems which have been identified and remedial action taken and offers to provide help and advice. Recipients are assured of the professional relationship which exists between the Panel and participants and are invited to disclose their identity when they reply. If a participant remains anonymous, choosing not to disclose their identity to the Panel Chairman, and the poor performance continues, the Panel Chairman will then ask the Organiser for the address of the laboratory. The Panel Chairman will then communicate directly with the Head of Department.

Terms of reference and membership
1. NQAAP are responsible to the pathology professions and the Health Departments for monitoring the maintenance of satisfactory standards of laboratory performance in the United Kingdom, whether in the private or public sector.
2. Their members are nominated by the Royal College of Pathologists, the Association of Clinical Pathologists and the Institute of Biomedical Science, as well as by specialist professional bodies, with the approval of the Joint Working Group. Members may be co-opted subject to approval by the Joint Working Group.
3. Panel Members’ relationship with scheme participants is professional, and information obtained regarding performance in EQA schemes is strictly confidential within the JWG/Panel/Scheme Organiser’s network.
4. Panel Members are accountable to the professions through the Joint Working Group.

Remit
1. To be responsible for monitoring the maintenance of satisfactory standards of laboratory performance in the United Kingdom, whether in the private or public sector.
2. For Histopathology, Cytopathology, Cytogenetics, and Molecular Genetics, to consider appropriate EQA Schemes for approval for the time being, until alternative arrangements acceptable to the professions and DH have been agreed.
3. To relate to approved EQA Schemes. This will involve appointing a designated Panel member to act as a 'link person' on the Steering Committee of the Scheme or group of
Schemes. Scheme Organisers must report to the Panel on performance matters and may be invited to attend when appropriate.

4. To approve the criteria for satisfactory and unsatisfactory performance in relevant EQA Schemes and to review these criteria from time to time, to ensure that the Schemes achieve their aims and reflect good laboratory practice.

5. Where regional schemes exist, to promote co-ordination among such schemes.

6. To inform participating laboratories when their performance persistently falls below that considered to be acceptable and to offer advice, appropriate assistance and support. The Panel's relationship with the participants in a Scheme is strictly professional and is governed by the guidelines drawn up by the Joint Working Group.

7. To ensure that, where there is clear evidence of a problem with a 'product' in general use (kit, instrument, reagent etc), the Medical Devices Agency of the department of health is informed in the first instance by the Scheme Organiser.

8. To report annually (or more often if necessary) to the professions directly and to the Joint Working Group on Quality Assurance, on the effectiveness of the advisory machinery and on problems arising out of the operation of EQA Schemes.

The Joint Working Group (JWG) on EQA set up a NQAAP for Andrology (now Reproductive Science) in 2003. The panel meets every 6 months. Membership is usually granted for 3 years.

<table>
<thead>
<tr>
<th>Membership of the NQAAP for Reproductive Science</th>
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<tr>
<td>• Chair: Dr Paul Bishop - Royal College of Pathologists</td>
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<td>• Chair Elect: Dr Bryan Woodward - Royal College of Pathologists</td>
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<tr>
<td>• Dr Jackson Kirkman-Brown MBE - British Andrology Society</td>
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<td>• Karla Biddick - Association of Biomedical Andrologists</td>
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<td>• Dr Rachel Gregoire - Association of Clinical Embryologists</td>
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<td>• Beverley Duffy - Institute of Biomedical Sciences</td>
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<td>• Kevin McEleny – British Fertility Society</td>
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Appendix 1:

**Joint Working Group for Quality Assurance: Conditions of EQA Scheme Participation**

The Joint Working Group for Quality Assurance (JWG) is a multidisciplinary group accountable to the Royal College of Pathologists for the oversight of performance in external quality assurance schemes (EQA) in the UK. Membership consists of the Chairmen of the National Quality Assurance Advisory Panels (NQAAPs), and representatives from the Institute of Biomedical Sciences, the Independent Healthcare Sector, the Department of Health and CPA (UK) Ltd.

1. The Head of a laboratory is responsible for registering the laboratory with an appropriate accredited EQA scheme.

2. The laboratory should be registered with available EQA schemes to cover all the tests that the laboratory performs as a clinical service.

3. EQA samples must be treated in exactly the same way as clinical samples. If this is not possible because of the use of non-routine material for the EQA (such as photographs) they should still be given as near to routine treatment as possible.

4. Changes in the test methodology of the laboratory should be notified in writing to the appropriate scheme organiser and should be reflected in the EQA schemes with which the laboratory is registered.

5. Samples, reports and routine correspondence may be addressed to a named deputy, but correspondence from Organisers and NQAAPs concerning persistent poor performance (red – see below) will be sent directly to the Head of the laboratory or, in the case of the independent healthcare sector, the Hospital Executive Director.

6. The EQA code number and name of the laboratory and the assessment of individual laboratory performance are confidential to the participant and will not be released by Scheme Organisers without the written permission of the Head of the laboratory to any third party other than the Chairman and members of the appropriate NQAAP and the Chairman and members of the JWG. The identity of a participant (name of laboratory and Head of Department) and the tests and EQA schemes for which that laboratory is registered (but not details of performance) may also be released by the Scheme Organiser on request to the Health Authority, Hospital Trust/Private Company in which the laboratory is situated after a written request has been received.

7. A NQAAP may, with the written permission of the Head of a laboratory, correspond with the Authority responsible for the laboratory, about deficiencies in staff or equipment which, in the opinion of the NQAAP members, prevent the laboratory from maintaining a satisfactory standard.

8. Laboratories’ EQA performance will be graded using a traffic light system; green will indicate no concerns, amber poor performance, red persistent poor performance, with black being reserved for the tiny number of cases that cannot be managed by the Organiser or NQAAP and that have to be referred to the JWG. The criteria for poor performance (amber) and persistent poor performance (red) are proposed by the EQA scheme Steering Committee in consultation with the EQA Provider/Scheme Organiser and approved by the relevant NQAAP.

9. When a laboratory shows poor (amber) performance the Organiser will generally make contact with the participant in accordance with the Scheme Standard Operating Procedure for poor performance. Within 2 weeks of a laboratory being identified as a persistent poor performer (red), the Organiser will notify the Chairman of the appropriate NQAAP together with a resume of remedial action taken or proposed. The identity of a persistently poor performing laboratory (red) will be made available to members of the NQAAP and JWG. The NQAAP Chairman should agree in writing any remedial action to be taken and the timescale and responsibility for carrying this out; if appropriate, this letter will be copied to accreditation/regulatory bodies such as CPA (UK) Ltd, UKAS and HFEA who may arrange an urgent visit to the laboratory. Advice is offered to the Head of the Laboratory in writing or, if appropriate, a visit to the Laboratory from a NQAAP member or appropriate agreed expert may be arranged.

10. If persistent poor performance remains unresolved (black), the NQAAP Chairman will submit a report to the Chairman of the JWG giving details of the problem, its causes and the reasons for failure to achieve improvement. The Chairman of the JWG will consider the report and, if appropriate, seek specialist advice from a panel of experts from the appropriate professional bodies to advise him/her on this matter. The Chairman of the JWG will be empowered to arrange a site meeting of this panel of experts with the Head of the Department concerned. If such supportive action fails to resolve the problems and, with the agreement of the panel of experts, the Chairman of the JWG will inform the Chief Executive Officer, or nearest equivalent within the organisation of the Trust or Institution, of the problem, the steps which have been taken to rectify it and, if it has been identified, the cause of the problem. The Chairman of the JWG also has direct access and responsibility to the Professional Standards Unit of the Royal College of Pathologists. Should these measures fail to resolve the issues, the laboratory will be referred to the Care Quality Commission for further action.

11. Problems relating to EQA Schemes, including complaints from participating laboratories, which cannot be resolved by the appropriate Organiser, Steering Committee or NQAAP, will be referred to the Chairman of the JWG.

For all UK NEQAS Reproductive Science schemes the current rolling ‘time-window’ period of assessment is 4 distributions.

Analytes, for which performance criteria have been agreed by the National Quality Assurance Advisory Panel (NQAAP) for Reproductive Science, on recommendation from the relevant UK NEQAS Steering Committee, are shown in green

Analytes (which are not yet scored for performance and) for which performance limits are provided for participants’ guidance are shown in blue

Andrology (Semen Analysis) Scheme

<table>
<thead>
<tr>
<th>Analytes</th>
<th>A score</th>
<th>B score</th>
<th>C score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Semen concentration</td>
<td>200</td>
<td>20</td>
<td>25</td>
</tr>
<tr>
<td>Sperm morphology</td>
<td>200</td>
<td>50</td>
<td>75</td>
</tr>
<tr>
<td>Sperm motility – progressive</td>
<td>200</td>
<td>30</td>
<td>40</td>
</tr>
<tr>
<td>Sperm motility – non-progressive</td>
<td>200</td>
<td>100</td>
<td>140</td>
</tr>
<tr>
<td>Sperm motility – Immotile</td>
<td>200</td>
<td>40</td>
<td>50</td>
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<tr>
<th>Sensitivity/Specificity/Accuracy</th>
<th>Sensitivity %</th>
<th>Specificity %</th>
<th>Accuracy %</th>
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<tr>
<td>Interpretive morphology</td>
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<td>70</td>
<td>60</td>
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Embryology scheme  

<table>
<thead>
<tr>
<th>Analytes</th>
<th>Penalty limit*</th>
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</thead>
<tbody>
<tr>
<td>Embryo grading</td>
<td>20</td>
</tr>
</tbody>
</table>

*N.B. only national grading scheme parameters (i.e. cell number, even-ness, fragmentation, blastocyst expansion, inner cell mass and trophoderm) are used to monitor satisfactory performance. Embryo suitability for freezing and quality ranking are not, as clinics may have different policies/criteria for this. Therefore, this part of the scheme is for interpretive/educational purposes only.

*It must be emphasised that a single poor score does not constitute “poor performance”, and while repeated transgressions will trigger internal scrutiny by the Scheme Organiser this does not automatically mean that the laboratory will be contacted.*