UK NEQAS
Reproductive Science

Andrology & Embryology
External Quality Assessment (EQA) Schemes

ANNUAL REPORT
2017-2018

UK NEQAS
Reproductive Science

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 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 cingulate,* 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 logo.

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UK NEQAS
Reproductive Science

Reproductive Science Schemes - Organiser's Report 2017/18

UK NEQAS Reproductive Science (RS) currently operates two schemes: Andrology and Embryology. The Andrology External Quality Assessment (EQA) scheme celebrated twenty four years of operation at the Annual Participants' Meeting in March 2018. The Embryology Scheme launched in 2009 has been operating for nine years.

Achievement of accreditation by UKAS in 2018 to IEC/ISO 17043:2010 standards means we can demonstrate our competence with a set of internationally-recognised requirements for the planning and implementation of proficiency testing programmes.
We already have 296 participants in 26 countries worldwide and hope that the hard work by the UK NEQAS team to ensure our compliance with ISO 17043:2010 standards will lead to even more laboratories selecting us as their EQA provider.

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 (UK only).

The RS Schemes were represented at the ESHRE Fertility 2017 Conference, Geneva, and at the Association of Clinical Embryologists Conference, January 2018, Liverpool. We will also attend the ESHRE Fertility 2018 Conference in Barcelona.

The total number of units in the combined Schemes stands at 296, 281 in Andrology and 100 in Embryology (approx. 34% of participants are from abroad - Argentina, Austria, Belgium, Bulgaria, Canada, Czech Republic, France, Germany, Greece, Hong-Kong, Iran, Israel, Italy, Kenya, Luxembourg, Malta, Nigeria, Portugal, Republic of Ireland, Romania, Russia, Serbia, South Africa, Spain, Switzerland, Thailand and United Arab Emirates).

At present we use distributors in Israel, Italy, Switzerland, Portugal and South Africa.

Where there are problems, scheme staff are available to offer support and advice and generally this is well received by participants. In cases of persistent unsatisfactory performance a referral to the NQAAP is made (UK labs).

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 improve the schemes.

With best wishes

Diane Critchlow

Scheme Organiser

UK NEQAS
Reproductive Science

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. Since 2013 we have used the 'ABC' scoring system to the Andrology scheme and over the past few years we have had some good feedback from Participants. The focus of performance is on a rolling 12 month period rather than targeting labs that have 'one off' unsatisfactory results. The reports have a summary page which will tell you at a glance how you are doing.

In the Embryology scheme we are 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 for Reproductive Science.

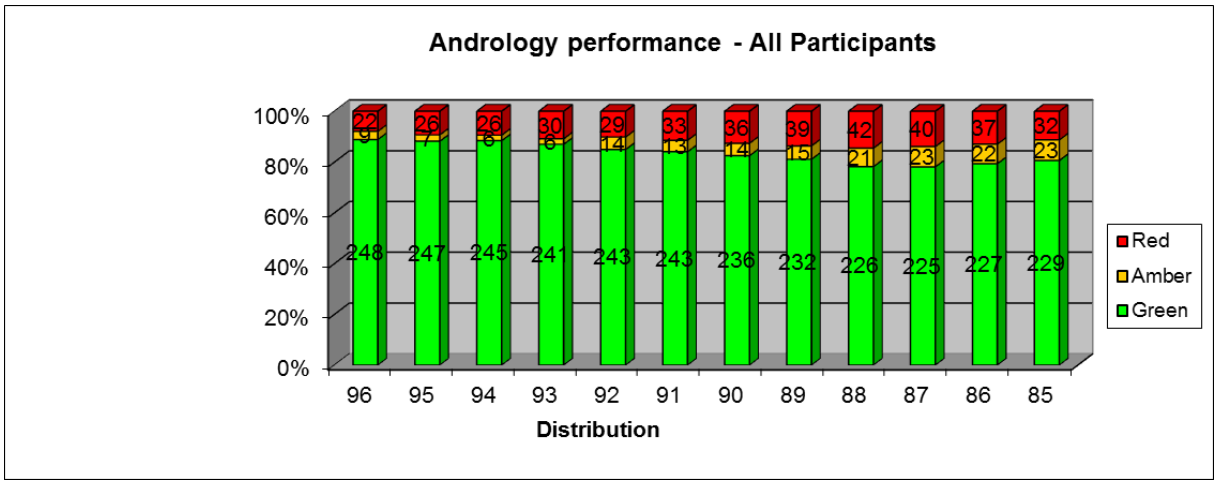
* Non return of results is due to be separated out from unsatisfactory performance from April 2018.

(This traffic light system should not be confused with the traffic lights in the ABC scoring system).

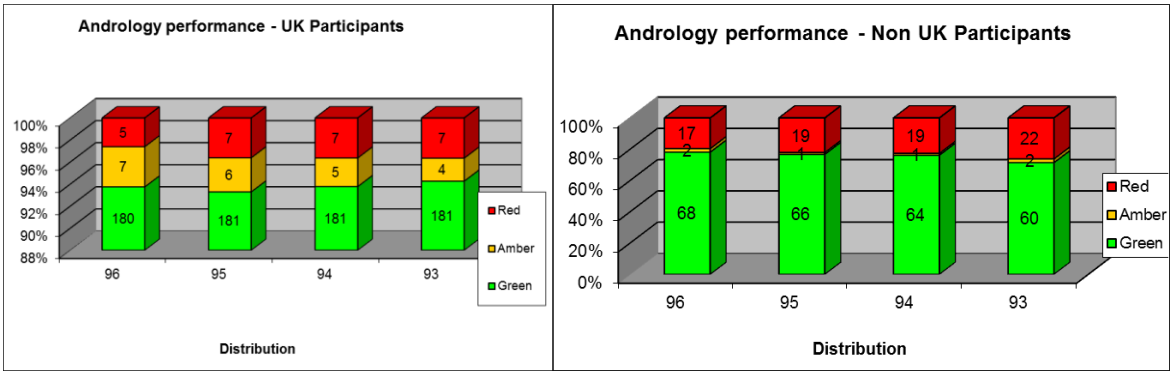
Andrology scheme

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).



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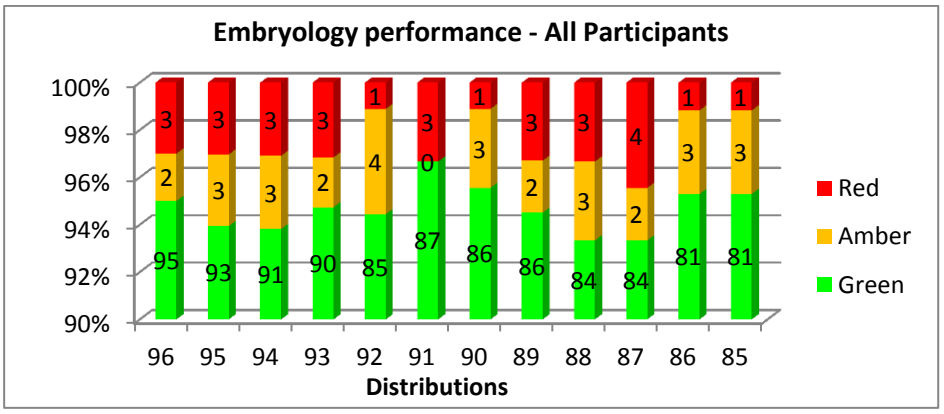
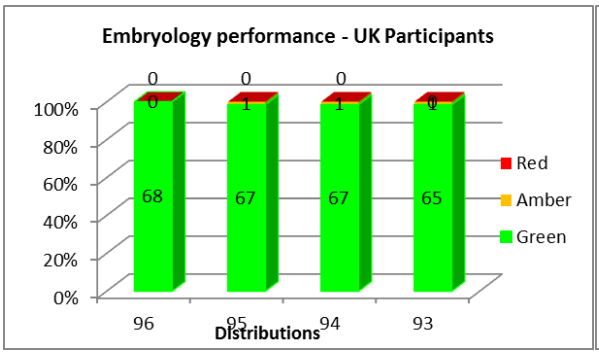
Embryology scheme

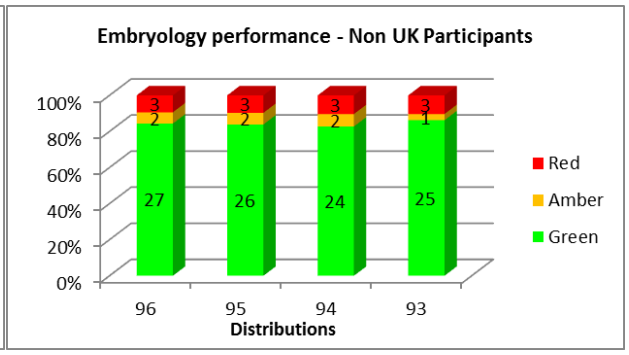
A penalty point system is used to determine performance in the Embryology scheme. However, the biggest cause of persistent unsatisfactory performance is due to non-return of results.

The chart below shows performance in the Embryology 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).





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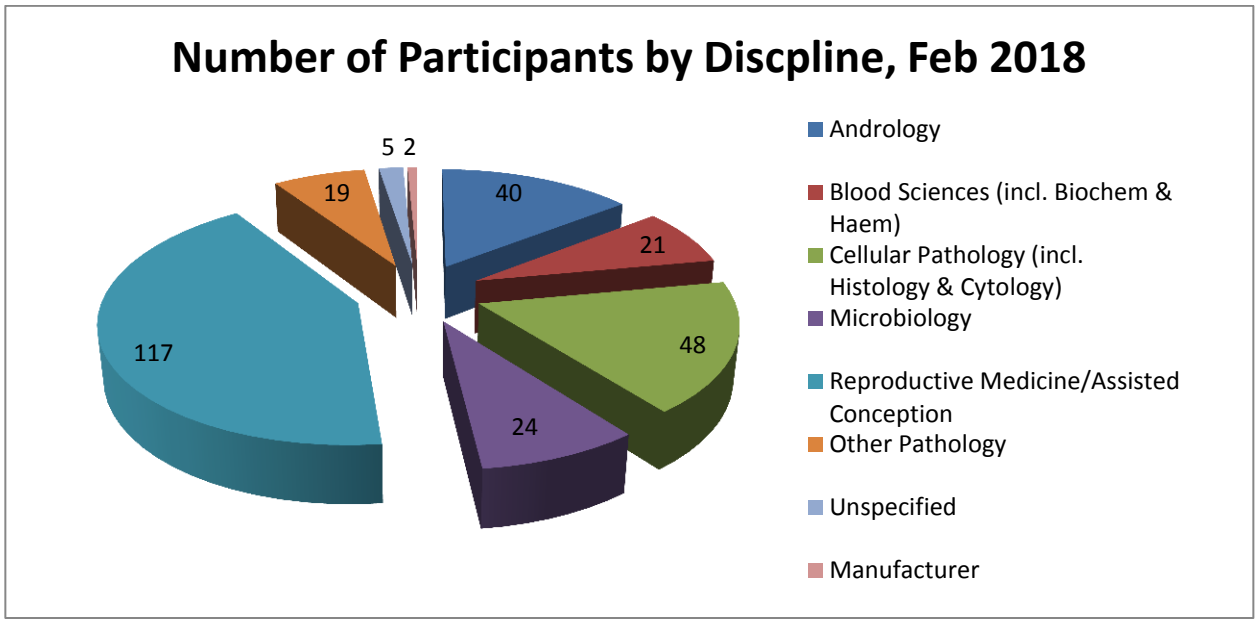
Scheme Participation

Andrology Scheme

As of February 2018 there were a total of 281 participants (195 from the UK & 86 Non-UK) (February 2017: 287 participants (199 from the UK & 88 Non-UK)).

UK NEQAS services were originally designed for UK NHS or Private Clinical Laboratories. It is suitable for 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.



Distributions

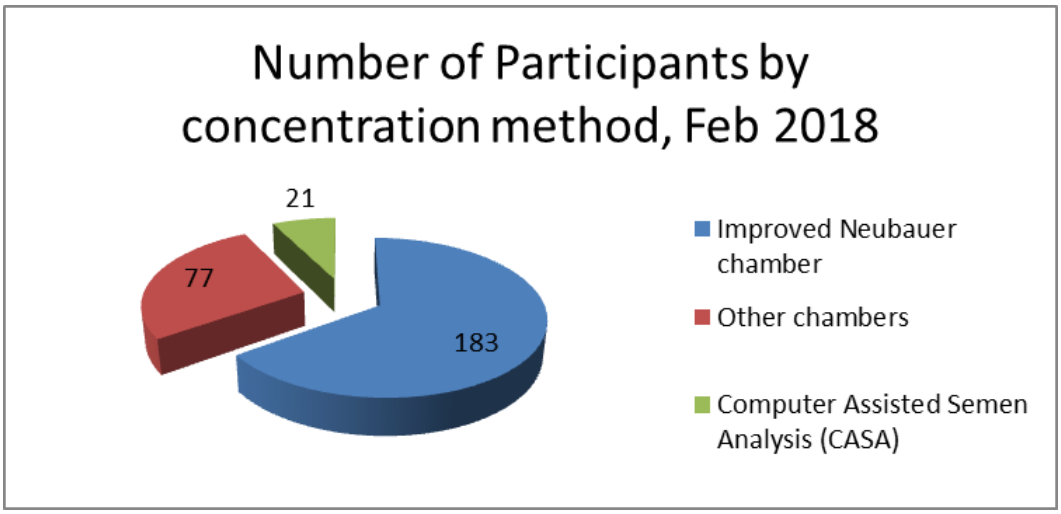
The Andrology Scheme distributes samples and images four times per year. The dates for all distributions are set each year in advance and if samples are not received by the due date, the responsibility lies with each participant to let us know.

Distribution Dates for 2017/18

- 8 May 2017, 7 Aug 2017, 6 Nov 2017 and 5 Feb 2018

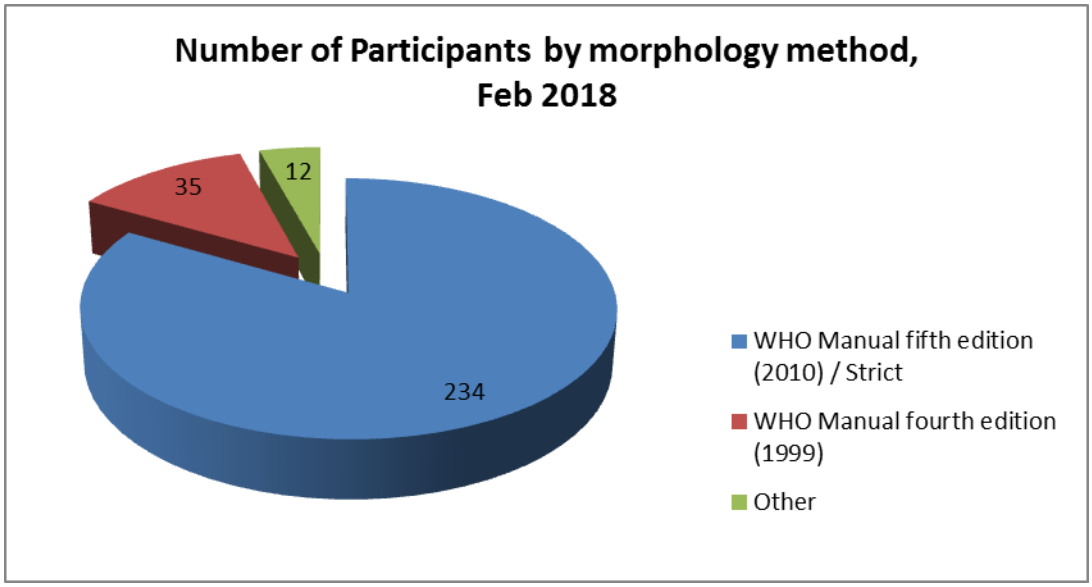
Closing dates for each distribution are usually four weeks after the Distribution date.

Sperm Concentration Assessment



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 (practical) Assessment



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 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. A penalty point system keeps track of how Participants are performing.

Starting in 2017/18 this scheme is now scored for performance. See Appendix 2 for the Performance Criteria for this period.

Embryo Morphology Scheme

As of February 2018 there were a total of 100 participants (68 from the UK & 32 Non-UK) (February 2017: 90 participants (63 from the UK & 27 Non-UK)).

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 is by email from Gamete Expert. If participants are unable to access/login to the Gamete Expert website to complete the assessments, the responsibility lies 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 2017/18

- 8 May 2017, 7 Aug 2017, 6 Nov 2017 and 5 Feb 2018

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 the 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). The National Grading Scheme has been under review by an ACE working group during 2016. Amendments are to be implemented from April 2017.

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.uknegas.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. The Gamete Expert reports are completely independent of UK NEQAS without scientific input from our steering committees. The reports are for individual information only i.e. they are not used by UK NEQAS to monitor your performance. A new 'archive gallery' is now available from Gamete Expert for both

online Andrology and Embryology, enabling access to video clips and results of 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.

Pilot scheme for time-lapse annotation

A pilot scheme for EQA of time-lapse annotation using EmbryoScope® has been introduced from Distribution 90 (September 2016). The timings of nine embryo development stages are annotated. The pilot scheme replaced the interpretive questions. Again, results are for 'information only' and are not used to monitor laboratory performance. This part of the scheme is not included in the accreditation process for ISO/IEC 17043:2010.

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 8th March 2018

The Annual Participants' meeting was held at Manchester Conference Centre. The meeting was well attended and a full analysis of the feedback sheets will be described in the Annual Quality Report (available via the website). The meeting was in the usual format of formal lectures and participant short talks. The programme was as follows:

23rd ANNUAL PARTICIPANTS' MEETING
Thursday 8th March 2018

Manchester Conference Centre
Sackville Street, Manchester, M1 3BB
Web: www.pendulumhotel.co.uk

PROGRAMME

09.00	**Registration and Coffee**
09.30	Introduction - Overview and Progress Report of Scheme **Dr Diane Critchlow**
09.45	'The end user – a clinician's perspective on laboratory reports' **Dr Muhammad Akhtar**
10.30	Sperm cryopreservation in wildlife conservation- from wombat to elephant **Imke Lüders**
11.15	Tea/Coffee
11.45	Hyaluronic acid binding sperm selection for ICSI (HABSelect): Study outcomes and conclusions **Dr David Miller**
12.30	Lunch
13. 30	Pinheads - causes and reasons not to ignore them **Sue Kenworthy**
14.00	Sperm telomeres and lifestyle factors **Dr Stephane Berneau**
14.15	'To Err is Human' - Why mistakes happen and what can be done to mitigate the risks of error in an IVF clinic or donor bank. **Matt Pettit**
15.00	The NHS Scientist Training Programme (STP) for Embryology and Andrology **Dr Michael Carroll**
15.30	Open Forum – **Chair: Dr Rachel Gregoire & Trudy Johnson**
16.00	**Close**

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Workshops

Three semen analysis workshops were held between April 2017 and March 2018. All workshops were fully booked. There were 40 attendees overall and 38 completed the questionnaires. As in previous years, feedback was very positive.

Practical sessions covered sperm concentration, motility and morphology. Course manuals were supplied and staff were available to answer questions throughout the day. The workshops were accredited for CPD by IBMS as a professional activity.

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.

More information can be gained from repscience@uknegas.org.uk and in the quality report available on the website.

Quality Report Summary for UK NEQAS Reproductive Science

Justine Hartley
Quality Manager

The UK NEQAS Reproductive Science Service has received largely positive feedback again this year in all aspects of the Scheme.

A common request from participants responding to the annual questionnaires is for more detailed information on interpreting results. We are still intending to produce quick guide booklets for both Andrology and Embryology in the future.

Two samples within D95 were affected by a yeast contaminant. Investigations occurred and corrective action has been introduced to prevent recurrence. The decision was taken not to score performance on the samples affected or to include them in overall performance scores.

UK NEQAS RS has been investigating methods to provide a cryptozoospermia scheme following the results of the survey last year, however it is taking longer than anticipated.

The Scheme underwent its first surveillance visit for ISO 17043:2010 in January 2018 and maintenance of accreditation was confirmed in April.

Further information on quality aspects of the schemes, and results of all questionnaires are available on the website.

UK NEQAS
Reproductive Science

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 2017/2018

- **Chair: Professor Allan Pacey MBE**
  Professor of Andrology, University of Sheffield.
- **Deputy Chair: Trudy Johnson**
  Departmental Manager, Queen Elizabeth Hospital, Gateshead.
- **Stephanie Brooks**
  Senior Biomedical Andrologist, The Hewitt Centre, Liverpool Women's NHS Foundation Trust
- **Sue Kenworthy**
  Biomedical Andrologist, Portsmouth Hospitals NHS Trust
- **Janine Smith**
  Advanced Biomedical Scientist, Andrology Unit, Seacroft Hospital
- **Denise Riddell**
  Fertility Manager, Hampshire Hospitals NHS Foundation Trust.
- **Kathryn Howarth**
  Senior Biomedical Scientist, Airedale Hospital NHS FT.
- **Dr Raj Mathur**
  Clinical Lead, Reproductive Medicine, Manchester University NHS FT

Membership of the Embryology Steering Committee 2017/2018

- **Chair: Dr Rachel Gregoire**
  Scientific Director, The Hewitt Centre, Liverpool Women's NHS Foundation Trust
- **Ella Mair**
  Senior Embryologist, Newcastle Fertility Centre at Life
- **Dr Helen Clarke**
  Senior Clinical Embryologist, Assisted Conception Unit, Sheffield Teaching Hospital.
- **Su Barlow**
  Senior Embryologist, Midland Fertility Services.
- **Dr Bryan Woodward**
  Senior Embryologist, IVF Consultancy Services, Leicester
- **Amy Barrie**
  Clinical Embryologist, The Hewitt Centre, Liverpool Women's NHS Foundation Trust
- **Charlene Freeman**
  Embryologist, Leicester Fertility Centre.
- **Lucy Richardson**
  Senior Embryologist, Herts & Essex Fertility Centre.

UK NEQAS
Reproductive Science

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 initially granted for 3 years.

Membership of the NQAAP for Reproductive Science

- **Chair: Dr Bryan Woodward -** Royal College of Pathologists
- **Chair Elect:** Vacant
- **Dr Paul Bishop -** Royal College of Pathologists
- **Dr Jackson Kirkman-Brown MBE -**British Andrology Society
- **Joanne Adams -** Association of Biomedical Andrologists
- **Dr Rachel Gregoire -** Association of Clinical Embryologists
- **Kathryn Howarth -** Institute of Biomedical Sciences
- **Kevin McEleny** – British Fertility Society

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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.

Joint Working Group for Quality Assurance in Pathology, August 2010.

UK NEQAS
Reproductive Science

Appendix 2 Performance criteria - limits of acceptable performance in UK NEQAS Reproductive Science 2017/18

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**

Below are the performance limits for each scheme in the four distribution time-window. Participants whose scores go above these limits may be contacted about their performance. If a participant does not return results they will also be contacted and it may affect their performance status.

Andrology (Semen Analysis) Scheme

The 'ABC of EQA'	A score limit	B score limit (+/-)	C score limit
Semen concentration	200	20	25
Sperm morphology	200	75	75
Sperm motility – progressive	200	20	40
Sperm motility – non-progressive	200	75	140
Sperm motility – Immotile	200	20	50

	Penalty limit
Interpretive morphology	30

Embryology scheme	Penalty limit*
Embryo grading	15

*N.B. only national grading scheme parameters (i.e. cell number, even-ness, fragmentation, blastocyst expansion, inner cell mass and trophectoderm) 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 unsatisfactory score does not constitute "unsatisfactory performance", and while repeated transgressions will trigger internal scrutiny by the Scheme Organiser this does not automatically mean that the laboratory will be contacted