

# Participants' Handbook Reproductive Science Schemes



#### Changes for version 18.0

- Standardisation of the name of the ARCS Embryo Morphology Grading System.
- Change of Target Value definition for 'practical' Morphology from Distribution 121 (May 2024).
- Deputy Scheme Organiser updated to Dr Anna Burdina.
- Statement on ISO/IEC 17043:2023 standards. Page 17.

#### Changes for version 17.1

- Scheme Organiser changed to Annette Lloyd
- Scheme Quality Manager changed to Tamanda Timvere-Hartley



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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 enquires 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 connections to 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 logo.

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# **Contacting the Scheme:**

Email: repscience@ukneqas.org.uk

Web: https://mft.nhs.uk/saint-marys/services/gynaecology/reproductive-medicine/uknegasreproductive-science/

Tel No: +44 (0) 161 276 6437/6456

Participants are requested to give their Laboratory Code Number when contacting the Centre. Email to <a href="mailto:repscience@ukneqas.org.uk">repscience@ukneqas.org.uk</a> is the preferred method of contact. The office is staffed between the hours of 08:30 and 16:00 Monday to Friday.

Callers will be asked the nature of their request or enquiry and transferred to the appropriate member of staff. All calls and the actions taken are logged.

**UK NEQAS Reproductive Science** 

Manchester University NHS

Foundation Trust

Department of Reproductive

Medicine

Old Saint Mary's Hospital

Oxford Road

Manchester. M13 9WL

United Kingdom

Scheme Organiser:

Deputy Scheme Organiser:

Scheme Manager: Scheme Administrator Scheme Administrator

Scheme Quality Manager
Deputy Scheme Quality Manager

Scheme Training Officer

Scheme H&S Adviser

Annette Lloyd

Dr Anna Burdina Peter Goddard

Lauren Leech Diane Shearden

Tamanda Timvere-Hartley
Delimar Recio Toro

Vacant

Peter Goddard

# How to join the Scheme:

Please contact repscience@ukneqas.org.uk for enrolment information.

# **Additional equipment:**

As well as the equipment you are using for routine patient work you may need to acquire the following equipment for participation in our UK NEQAS schemes:

#### Andrology:

Vortex mixer

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- Computer with Internet connection is required. Tablets and smartphones are not recommended.
  - Screen recommendation: ≥ 1200 pixels width, ≥ 600 pixels height, ≥ 15inch (381mm) diagonal.

#### **Embryology:**

- Computer with Internet connection is required. Tablets and smartphones are not recommended.
  - Screen recommendation: ≥ 1200 pixels width, ≥ 600 pixels height, ≥ 15inch (381mm) diagonal.



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# **Getting Started – Semen Concentration & Morphology**

**Receipt:** Sample packs are sent out on the opening day of the distribution by either post or courier (according to the participants' requirements).



Upon receipt, note the date of receipt (you will need to enter this date with your results).

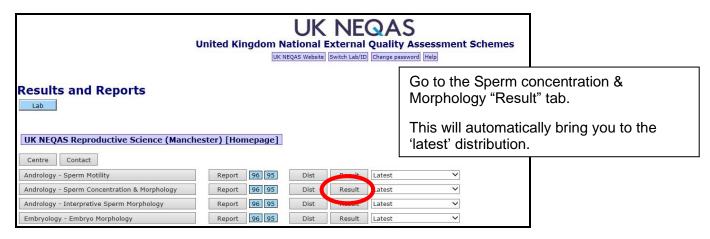
Store between 2-8°C when not in use.

Check samples on receipt to be sure that the correct samples are in the pack and there is no damage to the ampoules. Contact <a href="mailto:repscience@ukneqas.org.uk">repscience@ukneqas.org.uk</a> immediately if replacement samples are required. Scan QR code on packaging to view Distribution letter (also emailed to participants.

**Processing:** Samples should be processed as soon as possible after receipt using the same methods used for your patient samples (where possible). Methods used should be referenced to current recognised guidelines (for example the WHO laboratory manual for the examination and processing of human semen 6<sup>th</sup> edition (2021)).

Samples can settle out during transit so it is important that they are mixed using a vortex mixer for up to a minute each before processing (do not over-mix). If for any reason the samples are damaged or unsuitable for processing, please contact us at <a href="mailto:repscience@ukneqas.org.uk">repscience@ukneqas.org.uk</a> and request a repeat set.

**Results:** Log on to the UK NEQAS results and reports service <a href="https://results.ukneqas.org.uk/scripts/scheme-select.pl">https://results.ukneqas.org.uk/scripts/scheme-select.pl</a> (using your lab ID number and password).







Select methods, enter results, and state date of receipt in the boxes provided.

Comments about the distribution can be added in the comments box at the bottom of the page. Click "Submit" (results will not be saved unless you do this)

This takes you to a new page which has a summary of the results and the comment "Results submitted" you may wish to print this page out for your records.

If extended morphology assessment is not used clinically at your workplace, you are welcome to use it for training and information purposes.

**Reports:** Once the distribution has closed you will receive an email telling you that reports are now available.

Log on to the UK NEQAS results and reports service

https://results.ukneqas.org.uk/scripts/scheme-select.pl (using lab ID number and password).



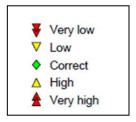
For the latest distribution results click on the 'Report' tab for Semen Analysis. This will display a 'PDF' copy of the report.

For older reports amend the distribution number in the 'drop down' box.

Page 1 of the report is a summary of the results. For individual specimen results 'traffic light' icons are used to aid interpretation. Results with red icons should be reviewed. Green and yellow are satisfactory.

Running A, B & C scores analyse results over several distributions. Red scores should be investigated. Green and yellow scores are satisfactory. Trend arrows indicate whether results are improving or declining.

|   | Specimen                         | Result                       | Target                           | Specimen<br>%bias  | A score | B score | C score | A   | В   | С   |
|---|----------------------------------|------------------------------|----------------------------------|--|---------|---------|---------|-----|-----|-----|
| Sperm concentration<br>(millions/mL)          | \$473<br>\$474<br>\$475<br>\$476 | 31.5<br>52.6<br>47.1<br>81.9 | 32.24<br>42.38<br>41.72<br>78.83 | -2.3 ♦<br>+24.1 <b>±</b><br>+12.9 △<br>+3.9 ♦                    | 79      | +17.1   | 24.2    | • / | 0.7 | 0 / |
| Sperm morphology<br>(% normal)                | \$473<br>\$474<br>\$475<br>\$476 | 4<br>3<br>4<br>2             | 3.34<br>2.80<br>2.90<br>3.26     | +19.6 ◆<br>+7.2 ◆<br>+37.9 ◆<br>-38.6 ◆                          | 46      | +12.4   | 26.5    | • 2 | • > | 0 7 |
| Abnormal heads<br>(%)                         | \$473<br>\$474<br>\$475<br>\$476 | 86<br>89<br>88<br>91         | 89.35<br>90.93<br>90.40<br>90.45 | -3.7 <b>•</b><br>-2.1 <b>•</b><br>-2.7 <b>•</b><br>+0.6 <b>•</b> | 23      | -0.7    | 3.2     | • ↔ | • ↔ | • ↔ |
| Abnormal midpieces<br>(%)                     | \$473<br>\$474<br>\$475<br>\$476 | 25<br>27<br>29<br>30         | 27.97<br>28.03<br>29.15<br>26.77 | -10.6 <b>•</b> -3.7 <b>•</b> -0.5 <b>•</b> +12.1 <b>•</b>        | 129     | -11.8   | 17.1    | 0 7 | • ↔ | • ↔ |
| Abnormal tails<br>(%)                         | \$473<br>\$474<br>\$475<br>\$476 | 9<br>8<br>9<br>8             | 7.75<br>8.16<br>8.05<br>7.72     | +16.1 •<br>-2.0 •<br>+11.8 •<br>+3.6 •                           | 168     | -4.1    | 22.2    | 07  | • ↔ | • 2 |
| Excess residual cytoplasm<br>(%)              | \$473<br>\$474<br>\$475<br>\$476 | 4<br>2.5<br>3<br>2           | 3.16<br>3.32<br>3.21<br>3.16     | +26.6 ♦<br>-24.7 ♦<br>-6.5 ♦<br>-36.6 ♦                          | 322     | +21.0   | 83.5    | • 2 | • 2 | • 2 |
| Teratozoospermia index<br>(TZI (1.00 - 4.00)) | \$473<br>\$474<br>\$475<br>\$476 | 1.4<br>1.3<br>1.4<br>1.3     | 1.37<br>1.38<br>1.39<br>1.37     | +2.0 <b>♦</b> -5.8 <b>♦</b> +0.7 <b>♦</b> -5.1 <b>♦</b>          | 47      | -4.3    | 4.4     | • ↔ | • ↔ | • ↔ |



Further information about performance criteria and interpretation of results can be found in this handbook.



# **Getting Started – Sperm motility.**

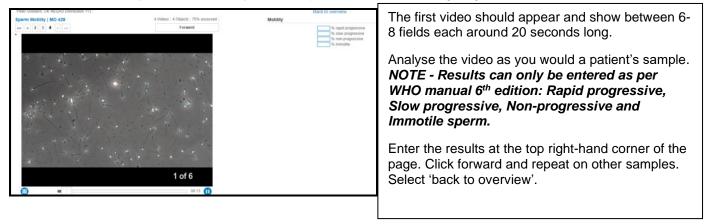
**Notification:** Participants should receive an email shortly after the distribution opens from UK NEQAS and the host website (gamete-expert.com). Log onto <a href="http://gamete-expert.com">http://gamete-expert.com</a> using your username and password.



In the 'Sperm Motility' box select 'Assessment'.

#### **Processing:**

You will be asked if your lab routinely uses 4 speed classes before going to the videos.



To enlarge video screen press Ctrl and rotate the scroll wheel of your mouse anticlockwise. To reset, press Ctrl 0.

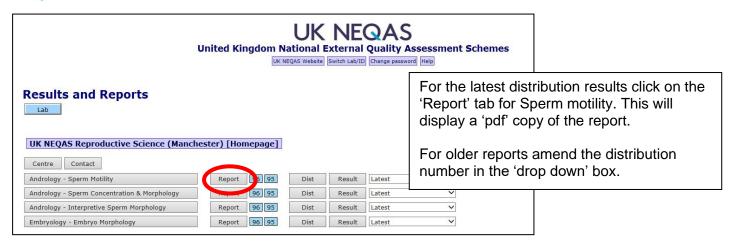
Once all videos have been assessed, please check that your 'Sperm Motility' box now states: 'Status: 100% assessed'. Results can be amended up until the deadline for the distribution.

**Reports:** Once the distribution has closed you will receive an email telling you that reports are now available (usually within five working days of the close of distribution).

Log on to the UK NEQAS results and reports service <a href="https://results.ukneqas.org.uk/scripts/scheme-select.pl">https://results.ukneqas.org.uk/scripts/scheme-select.pl</a> (using lab ID number and password).

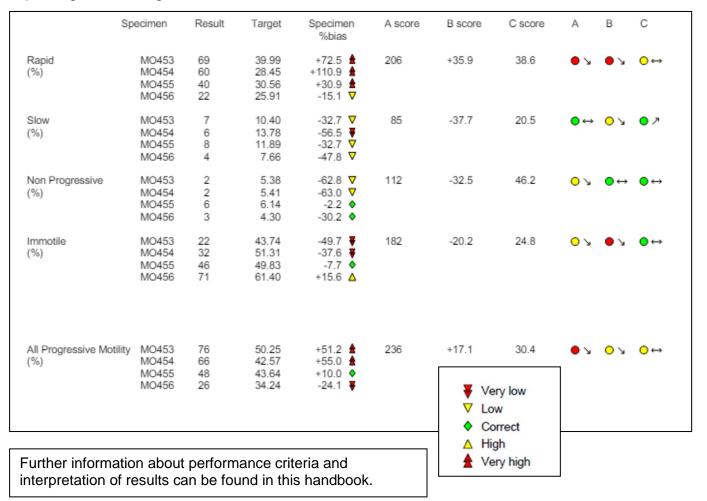


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Page 1 of the report is a summary of the results. For individual specimen results 'traffic light' icons are used to aid interpretation. Results with red icons should be reviewed. Green and yellow are satisfactory.

Running A, B & C scores analyse results over four distributions. Red scores should be investigated, green and yellow scores are satisfactory. Trend arrows indicate whether results are improving or declining.





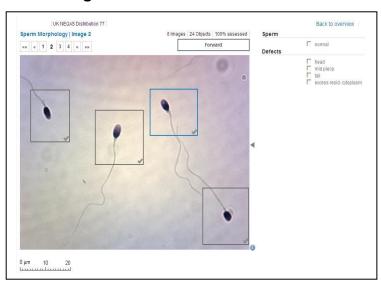
# **Getting Started – Interpretive morphology.**

**Notification:** Participants should receive an email shortly after the distribution opens from UK NEQAS and the host website (gamete-expert.com). Log onto <a href="http://gamete-expert.com">http://gamete-expert.com</a> using your username and password



In the 'Sperm Morphology' box select 'Assessment'.

#### **Processing:**



The first image should appear and show 'boxed' sperm for assessment.

Click within the box of the sperm you wish to assess. Analyse as you would a patient's sample. If the sperm is normal check the 'normal' box (top right). If 'abnormal' list the defects. If entire sperm cannot be viewed, assess on what is displayed.

Once the sperm has been assessed a tick will appear within its 'box'

Click forward and repeat on other images. Select 'back to overview'.

**Microscope function:** The triangle on the right image side shows the focus position. When on the top, the sperm head is in focus. In the bottom position the tail is focused. The focus position is altered using the mouse wheel.

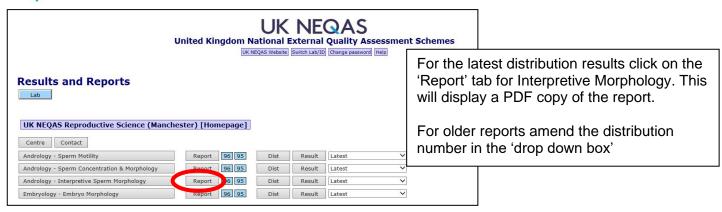
Once all sperm have been assessed, please check that your 'Sperm Morphology' box now states: 'Status: 100% assessed'. Results can be amended up until the deadline for the distribution.

**Reports:** Once the distribution has closed you will receive an email telling you that reports are now available.

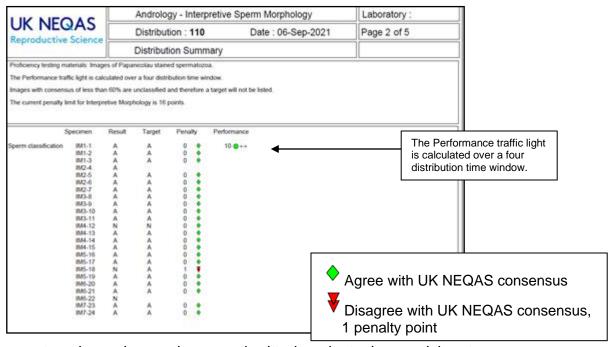
Log on to the UK NEQAS results and reports service <a href="https://results.ukneqas.org.uk/scripts/scheme-select.pl">https://results.ukneqas.org.uk/scripts/scheme-select.pl</a> (using lab ID number and password).



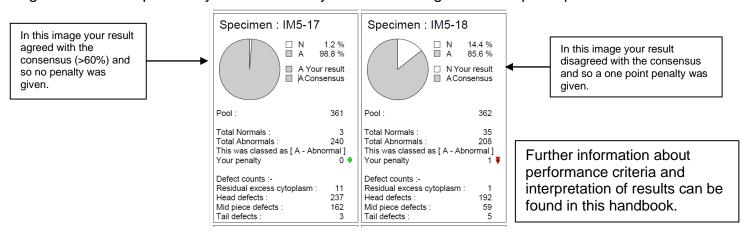
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Page 1 of the report summarises the results and any penalty points gained:



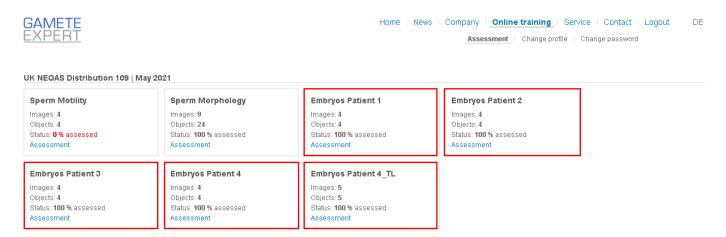
Page 2&3 of the report analyses the results you submitted against other participants:





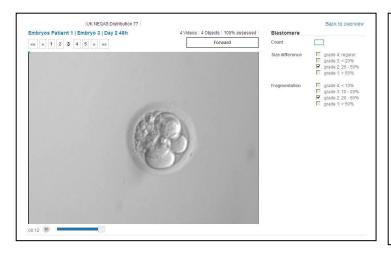
# **Getting Started – Embryo morphology**

**Notification:** Participants should receive an email shortly after the distribution opens from UK NEQAS and the host website (gamete-expert.com). Log onto http://gamete-expert.com using your username and password.



Select 'Assessment' in the 'Embryo Patient' box that needs assessing.

#### **Processing:**



The first video should appear and show a 'rolling' embryo lasting around 40-50 seconds.

Analyse the video as you would a patient's sample.

NOTE - Results can only be entered using the ARCS Embryo Grading System – click on the 'i' for information or see Appendix 3.

Enter the results at the top right-hand corner of the page. Click forward and repeat on other samples.

Select 'back to overview' and repeat on another 'Embryo Patient'.

To enlarge video screen press 'Ctrl' and rotate the scroll wheel of your mouse anticlockwise. To reset, press Ctrl 0.

To use the slider backwards and forwards: Please start the video. Go on the slider (while running video). Click left mouse button and keep it down (do not click back). The video stops. Move the slider with the down clicked mouse button. After release of the left mouse button the video starts again.

For the time-lapse annotation analyte with Patient 4 – please see appendix 7 for instructions.

# UK NEQAS Reproductive Science

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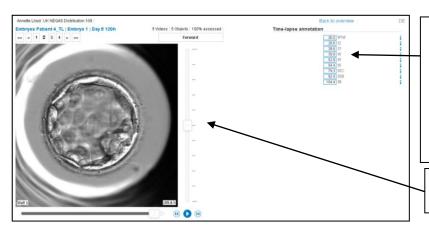


Patient 4 Time-lapse:

Please mark box to state whether you routinely use or don't use Time-lapse annotations in your clinical setting.

Embryo should be annotated as you would in a clinical setting. If portion of embryo cannot be viewed, assess on what is displayed.

If not used clinically you are welcome to use it for training and information purposes.



Enter Time-lapse annotations time point to 1 decimal place for each of the time points listed from tPNf to tB.

Use the blue information button for further information.

Complete for all 4 videos

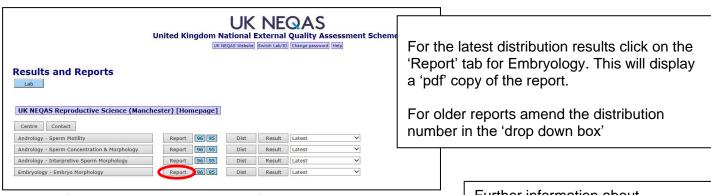
Ability to move up and down through the planes throughout the video.

Please check that each of your 'Embryo Patient' boxes now state: 'Status: 100% assessed'. Results can be amended up until the deadline for the distribution.

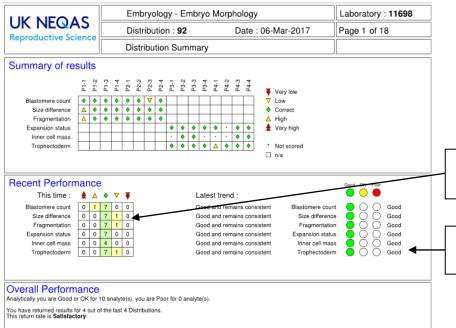
**Reports:** Once the distribution has closed you will receive an email telling you that reports are now available.

Log on to the UK NEQAS results and reports service <a href="https://results.ukneqas.org.uk/scripts/scheme-select.pl">https://results.ukneqas.org.uk/scripts/scheme-select.pl</a> (using lab ID number and password).





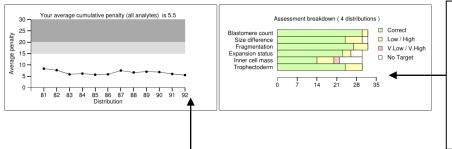
Page 1 of the report is a summary of the results



Further information about performance criteria and interpretation of results can be found in this handbook. Quality parameters are excluded from this summary as they are not used to assess performance, but are used for the 'hub and spoke' reports (to compare inter-laboratory variation)

Count of each type of symbol for the current distribution (not the penalties)

Rolling pen.



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**Green** = no penalties (or match with target value).

**Amber** = one penalty/one step away from target value.

**Red** = 2 penalties for 2 or more steps away from the target value.

**White** = results with no consensus (not scored).

Only embryo grading parameters are used to assess satisfactory performance (quality parameters are **excluded** from this graph). A rolling average of penalties (over 4 distributions) is used.



# Getting Started – Embryo morphology Hub and Spoke reports

You can also see all the individual login returns made by your staff on one report. This should assist with your Internal Quality Control (IQC).

Go to <a href="https://results.uknegas.org.uk">https://results.uknegas.org.uk</a>.

Enter Hub Number (HB###) as username and password. (*Please note HB#### where '#' is a single digit.*) If you do not have these details, contact <a href="mailto:repscience@ukneqas.org.uk">repscience@ukneqas.org.uk</a>.

# Results and Reports

| UK NEQAS Manchester [Homepage]  |        |      |         |        |  |
|---------------------------------|--------|------|---------|--------|--|
| Centre Contact                  |        |      |         |        |  |
| LIK NEOAS for Embryology (Hubs) | Report | Dist | Network | Latest |  |

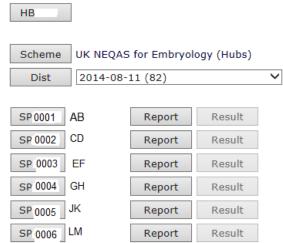
Click on the "Report" button to view the Hub report for the selected distribution (default latest).

Click on the Network button to access Spoke information (see below).

Each spoke will be listed with its SPnnnnnn number and any mnemonic (for example users' initials)

The Hub coordinator can view the reports for individual spokes.

# **Results and Reports**

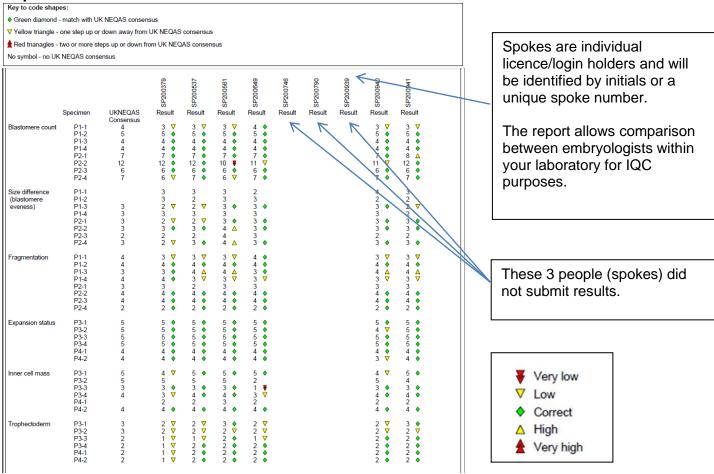


Where applicable, spoke results can be viewed/edited, otherwise this option is greyed out.

Access to spoke reports by individuals is available on request from <a href="repscience@ukneqas.org.uk">repscience@ukneqas.org.uk</a>.



#### **Reports:**

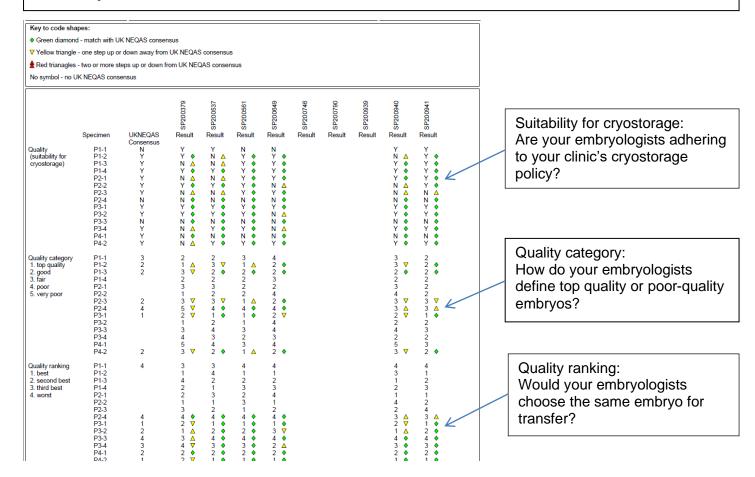


Continued on next page.

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The quality categories below are very useful for comparisons between the embryologists in your laboratory.





# Schemes provided

SCHEMES: Andrology (Semen Analysis) Embryology

Sperm Concentration (practical) Embryo Morphology (online)
Sperm Morphology (practical) Time lapse annotation (online)

ANALYTES: Sperm Motility (online)

Interpretive Sperm Morphology (online)

### **Aims**

The UK NEQAS Reproductive Science Scheme aims to:

- Provide professionally led and scientifically based schemes with a primarily educational objective.
- · Provide regular distributions of appropriate specimens.
- Provide rapid feedback of performance, with reports that are comprehensive and readily understood.
- Provide data on method performance.

# **Organisation**

UK NEQAS Reproductive Science is part of Manchester University NHS Foundation Trust. It is administered as a self-financing unit within the St Mary's Managed Clinical Service division of the Trust.

UK NEQAS Reproductive Science is a member of the UK NEQAS consortium.

Some aspects of our services may be subcontracted; where this occurs, competent subcontractors are used, and UK NEQAS Reproductive Science remains responsible for their activities. Scheme design, performance evaluation and report authorisation are never subcontracted.

# Changes to the scheme

Changes to Scheme Design or function would be announced in advance at the Participants' Meeting (if possible), emailed to current participants and then implemented for the new scheme year (April) into the Participants' Handbook and summarised in the 'changes for this version' box on page 1 of this document. If the change needed to occur during a scheme year (April – March) the same process will occur but without announcement at the Participants' Meeting.

# **Deviations from Contract**

The scheme will inform participants (generally by email), subcontractors and suppliers of any deviation in their contract with UK NEQAS Reproductive Science. This would include any error or Non-Conformance that would affect the participants. This may be raised both internally and, because of, subcontractor work.



# **External Oversight of our EQA Services**

#### Accreditation to ISO/IEC 17043:2010

UK NEQAS Reproductive Science is accredited by UKAS against the requirements of ISO/IEC 17043:2010 – Conformity Assessment – General requirements for proficiency testing. The scope of accreditation can be viewed on the UKAS website: <a href="Scope of Accreditation">Scope of Accreditation</a>. UKAS number for UK NEQAS Reproductive Science is 8228.

The ISO/IEC 17043 standards were updated in 2023 and UK NEQAS Reproductive Science is currently working towards implementing the revised standards.

#### **UK NEQAS Consortium**

We have close ties with other UK NEQAS operations through the UK NEQAS Consortium. All UK NEQAS-designated services comply fully with the UK NEQAS Code of Practice (available from UK NEQAS).

#### **Steering Committees**

All EQA providers are required to seek advice from and report to Steering Committees and/or Specialist Advisory Groups. The Reproductive Science scheme of UK NEQAS is presently served by a Reproductive Science Steering Committee (RSSC) with representatives from both the field of Andrology and Embryology that advises on overall policy matters and provides external scientific advice.

#### **RCPath National Quality Assurance Advisory Panel**

UK NEQAS Reproductive Science reports to the Royal College of Pathologists' National Quality Assurance Advisory Panel (NQAAP) for Reproductive Science.

The names of RSSC and Panel members are available via the website <a href="https://mft.nhs.uk/saint-marys/services/gynaecology/reproductive-medicine/ukneqasreproductive-science/">https://mft.nhs.uk/saint-marys/services/gynaecology/reproductive-medicine/ukneqasreproductive-science/</a> for any participants who wish to express comments or concerns about our schemes and their operation.

#### **Ethics**

Manchester University NHS Foundation Trust has an active Clinical Ethics Committee who can advise the scheme on ethical issues that may be encountered during the running of the scheme.

#### **Other Links**

We have close links (formal & informal) with UK professional groups and EQA providers in other sectors.



# **Terms and Conditions of Participation**

**Eligibility** - Our services are designed principally for UK public and private sector clinical laboratories serving clinicians and patients. Non-UK clinical laboratories, those with purely research or industrial roles, manufacturers of diagnostic instruments and reagents and other laboratories are also welcome to participate. Manufacturers may do so on an 'information only' basis (without receiving samples and returning results).

Participation of non-UK laboratories in the Andrology scheme may be subject to the availability of a suitable specimen postal transport system.

Andrology scheme – The latest recommended World Health Organisation (WHO) guidelines for processing semen. WHO laboratory manual for the examination and processing of human semen (6th edition), can be found here: https://www.who.int/publications/i/item/9789240030787

Embryology scheme – This scheme uses a standardised grading system developed by the Association of Clinical Embryologists (ACE) in association with UK NEQAS Reproductive Science. This grading system has been endorsed in the UK by the National Institute for Health and Care Excellence (NICE) and ratified by the Association of Clinical Reproductive Scientists (ARCS) in 2020 (see Appendix 3).

All UK clinical service laboratories must agree to current **Quality Assurance Pathology Committee** (previously known as Joint Working Group (JWG)) **conditions of participation** (click <a href="https://www.rcpath.org/profession/committees/jwgga.html">https://www.rcpath.org/profession/committees/jwgga.html</a> to view terms and conditions).

**Period** - Participation in all UK NEQAS Reproductive Science Schemes is deemed to be continuous with automatic annual renewal and invoicing for subscription fees for each NHS financial year (1st April to 31st March), unless we are advised to the contrary in writing in advance of annual renewal. Participation may begin at any time during the year; part-year charges are higher than *pro rata*.

**Enrolment procedure -** Participation begins at the first distribution following receipt of fully completed enrolment questionnaires sent in response to a formal request to participate. As indicated above, enrolment may take place at any time.

The following enrolment documents can be downloaded at the scheme website: <a href="https://mft.nhs.uk/saint-marys/services/gynaecology/reproductive-medicine/uknegasreproductive-science/">https://mft.nhs.uk/saint-marys/services/gynaecology/reproductive-medicine/uknegasreproductive-science/</a>:-

- Participants' handbook
- · Distribution schedules and price list
- 'New lab' Enrolment form

**Annual re-registration** – Re-registration notification is sent out to participants early in each new calendar year. This should be done on the <a href="https://results.ukneqas.org.uk">https://results.ukneqas.org.uk</a> website.

**UK NEQAS laboratory identifier code** - On enrolment, each participant is given a unique laboratory code (now shared across all UK NEQAS centres), which remains associated with that participant indefinitely. Reattribution of codes and data can be accomplished where laboratories close, merge or de-merge. Participant codes must not be disclosed to third parties.

Please quote your laboratory code number in all communications.

**Charges** - Annual subscription charges are based on the full actual costs of providing EQA services according to the not-for-profit terms of the UK NEQAS Code of Practice. As such they are subject to continuous review and may be reduced as participation increases or if surpluses are generated.



Equally they may be increased if costs rise or if participation decreases, though any such increase must be justified to the UK NEQAS Executive Committee before they can be implemented. Current charges are available in the Andrology & Embryology Scheme leaflets at the scheme website <a href="https://mft.nhs.uk/saint-marys/services/gynaecology/reproductive-medicine/ukneqasreproductive-science/">https://mft.nhs.uk/saint-marys/services/gynaecology/reproductive-medicine/ukneqasreproductive-science/</a>

**Refunds** - Refunds of subscription charges are only payable under exceptional circumstances.

**Confidentiality** - The fact of participation, raw data and performance scores are currently confidential between the individual laboratory and Reproductive Science scheme, unless the participant waives confidentiality. For online aspects of the schemes, the fact of participation, raw data and performance scores are currently confidential between the individual laboratory, UK NEQAS Reproductive Science scheme and Gamete-Expert (as a subcontractor of the scheme). Input of results via the Gamete-Expert.com website presumes understanding of this by the participants.

All information provided by a participant to UK NEQAS Reproductive Science shall be treated as confidential.

When an interested party requires the proficiency testing results to be directly provided by UK NEQAS Reproductive Science, the participants shall be made aware of the arrangement in advance of participation.

In exceptional circumstances, when a regulatory authority requires UK NEQAS Reproductive Science results to be directly provided by UK NEQAS Reproductive Science, the affected participants shall be notified of this action in writing.

Performance scores (and some raw data) may be shared with the relevant NQAAP under defined circumstances as part of the routine reporting of persistent unsatisfactory performance. This data may be shared with local management, regional QA officers, accrediting bodies and suppliers of equipment and reagents where appropriate and necessary, but the participant shall be informed. UK NEQAS Reproductive science reports are copyright and may not be copied, distributed, published, or used for publicity and promotion in any form without the written consent of the relevant scheme Organiser on each and every occasion, though performance data may be shared with individual clients (for example GPs, clinicians, pharmaceutical companies) without consultation.

**Use of residual material -** The materials distributed are provided as specimens for the sole purpose of enabling external quality assessment at the recipient's laboratory during the current distribution. They do not constitute In Vitro medical diagnostic Devices (IVDs) and EQA specimens are explicitly excluded from the scope of the IVD Directive. No claim is made that they may be suitable for any other purpose or at any other point in time. Resale or distribution to third parties is strictly prohibited. It is accepted, however, that residual material may be retained by the participant and used for method evaluation, although it is recommended that fresh samples are obtained from us (see below) for this purpose. If materials are to be used in research which is expected to be published or, if participation forms part of contractual agreements with third parties, written consent must be obtained from the Scheme Organiser on each, and every occasion.

Samples are obtained under RCPath guidelines (page 13) from semen analysis patients and QA donors. Additional consent is gained from patients/donors in the form of a signed consent slip.

**Repeat samples** - Single samples or sets from a particular distribution are usually freely available at no charge to full participants who may wish to check aberrant results or evaluate new methods. We reserve the right to ask why repeat samples are needed and limit their supply if this would compromise the service to other participants.

For the online portions of the schemes a library of the images and videos analysed by participants is available (this function is unavailable during an open distribution).



**Reporting of results** - All full participants are expected to return results promptly within the specified reporting period. Those under the remit of the NQAAP are expected to return 100% of results within the relevant cumulative performance scoring period. Where a laboratory is unable to return a set of results, an explanation should be provided.

**Subcontractors** – The scheme makes use of subcontractors for various aspects of running the scheme (e.g. sample procurement, website hosting). As far as is practicable we ensure that these providers adhere to the same standards as ourselves. If participants encounter any issues regarding a subcontractor, please email <a href="mailto:repscience@ukneqas.org.uk">repscience@ukneqas.org.uk</a>.

Terms & Conditions – A full list of our terms and conditions can be found in appendix 5 of this document.

# Participant objectives

The purpose of the Reproductive Science Schemes is to test a participant's ability to analyse a sample. The following objectives should be followed:

- EQA samples should (where possible) be treated in an identical manner to a laboratory's routine clinical samples.
- Participants must inform the Centre of any problems with their testing facilities.
- Participants must inform the Centre of any method changes.
- · Participants should use recognised methods and guidelines for processing samples.
- Participants should process the UK NEQAS samples in a timely manner and submit results before the deadline.
- Failure to pay subscription fees on presentation of an invoice will result in discontinuation of participation and automatic referral to the NQAAP (or equivalent overseas body where appropriate).
- All reports and the data they contain are copyright and may not be published in any form without the permission of the Scheme Organiser.
- Collusion between laboratories prohibited. If a laboratory was suspected of collusion, the Centre would review its participation in its schemes.

Participation in the scheme does not of itself validate that a laboratory is correctly performing semen analysis or embryo morphology. A laboratory can repeatedly fail to meet requisite criteria in the scheme but continue to participate as the scheme is designed to encourage them to meet accepted standards. When assessing a laboratory any interested party should ask to be provided the EQA results of that laboratory. The scheme cannot provide those results directly.

# Scheme Design

All UK NEQAS Reproductive Science schemes are designed to mimic diagnostic and interpretive procedures in participant laboratories. The schemes have been formulated with participants and experts in the reproductive sciences. Our steering committee also contain experts (who have relative technical expertise in the reproductive sciences) and participants in the schemes.

UK NEQAS Reproductive Science is solely responsible for the planning and design of the schemes. This aspect is never subcontracted.

All samples, images and videos are obtained with written consent and according to appropriate regulatory and ethical requirements.

Further information on the proficiency testing material and the number and frequency of samples we send out in our distributions can be found in our 'Schedule of Analytes' section.



# **Schedule of Analytes**

**Andrology scheme** 

| / ((larolog)                                | Sperm Concentration   | Sperm Morphology<br>(practical)   | Sperm Motility   | Interpretive Sperm<br>Morphology   |  |  |  |
|---|---|---|--|--|--|--|--|
| Accreditation                               | Accredited by UKAS against the requirements of ISO/IEC 17043:2010   |   |  |  |  |  |  |
| Date started                                | 1994  | 1994  | 1995 2011  |  |  |  |  |
| Units of Reporting                          | x10 <sup>6</sup> /ml  | Percentage (%) for Normal forms, abnormal heads, abnormal midpieces, abnormal tails, excess residual cytoplasm and TZI for Teratozoospermia Index | Percentage (%) for<br>Rapid Progressive (A),<br>Slow progressive (B),<br>Non-Progressive (C)<br>and Immotile (D) sperm.  | Normal/Abnormal  |  |  |  |
| Proficiency testing materials               | Human semen containing<br>preservative (10% neutral<br>buffered formalin)   | Human semen containing<br>preservative (10% neutral<br>buffered formalin)   | Video clips of fresh<br>semen  | Images of Papanicolau stained spermatozoa  |  |  |  |
| Distributions per year                      |   | 4   |  |  |  |  |  |
| Samples per<br>Distribution                 | 4   | 4   | 4  | 24   |  |  |  |
| Frequency of<br>Distributions               | Every three months as<br>outlined in the Scheme<br>Leaflet  | Every three months as<br>outlined in the Scheme<br>Leaflet  | Every three months as outlined in the Scheme Leaflet   | Every three months as<br>outlined in the Scheme<br>Leaflet   |  |  |  |
| Examination                                 | Assessment of sperm concentration using Participants' own procedure (where practicable).  | Assessment of sperm morphology using Participants' own procedure (where practicable).   | Assessment of sperm motility using Participants' own procedure (where practicable).  | Assessment of sperm morphology using Participants' own procedure (where practicable). If entire sperm cannot be viewed, assess on what is displayed. |  |  |  |
| Schedule of<br>Analysis                     | Data entry is via the UK NE<br>service for the submission<br>commenced 28 days after sa<br>are not a  | of results. Data analysis is ample dispatch. Late returns ccepted.  | Data entry is via the Gamete-Expert.com website for the submission of results. Data analysis is commenced 28 days after sample dispatch. Late returns are not accepted |  |  |  |  |
| Data Analysis                               | of the WHO laboratory manual for the examination and processing of human semen (6th edition)  recommended methor the WHO laborator manual for the examination and processing of human semen (6th edition) |   | All Laboratory Trimmed<br>Mean (ALTM).   | Consensus. All participants' results are compiled and must reach 60% consensus to be classified.   |  |  |  |
| Performance<br>Scoring                      | ABC system  |   |  | Penalty points system  |  |  |  |
| Criteria of<br>Performance                  | Laboratory performance  | is assessed over a running an<br>appendix 2 fo  |  | itions (12 months) See   |  |  |  |
| Persistent<br>Unsatisfactory<br>Performance | Defined as being in the Unsatisfactory Performance category for three or more successive Distributions without improvement.   |   |  |  |  |  |  |



# **Embryology scheme**

|  | Embryo Morphology  | Embryo Time Lapse Annotation  |  |  |  |
|--|--|---|--|--|--|
| Accreditation  | Accredited by UKAS against th  | e requirements of ISO/IEC 17043:2010  |  |  |  |
| Date Started   | 2011   | 2016  |  |  |  |
| Units of   | ARCS Embryo Gradi  | ing System (see Appendix 3)   |  |  |  |
| Reporting  | ,  | , , , ,   |  |  |  |
| Proficiency testing materials  | Video c  | lips of embryos   |  |  |  |
| Distributions  |  | 4   |  |  |  |
| Samples per<br>Distribution  |  |   |  |  |  |
| Frequency of Distributions   | •  | Every three months as outlined in the Scheme Leaflet  |  |  |  |
| Examination  | Assessment of embryo morphology using<br>Participants' own procedure (where<br>practicable) in conjunction with the ARCS<br>Embryo Grading System (see Appendix 3) | Assessment of time-lapse annotations in conjunction with the Ciray et al (2014) Embryo annotation timing System. If entire embryo cannot be viewed, assess on what is displayed.  |  |  |  |
| Schedule of<br>Analysis  |  | ebsite for the submission of results. Data analysis is e dispatch. Late returns are not accepted.   |  |  |  |
| Data Analysis  | Consensus. All participants' results are compiled and must reach 50% consensus to be classified  | All Laboratory Trimmed Mean (ALTM)  |  |  |  |
| Performance<br>Scoring   | Penalty points system for embryo morphology Rolling B score (ABC system)   |   |  |  |  |
| Criteria of Performance  Laboratory performance is assessed over a running analytical window of 4 Distributions (12 months) See appendix 2 for details |  | Laboratory performance is assessed over a running analytical window of 4 Distributions (12 months). Formal monitoring for assessment purposes from May 2021. For full details of the time-lapse annotation analyte please see Appendix 7. |  |  |  |
| Persistent Unsatisfactory Performance  | Defined as being in the Unsatisfactory Performance category for three or more successive  Distributions without improvement  |   |  |  |  |



### **Materials**

#### Sources of semen & embryos

All samples, images and videos are obtained with written consent and according to appropriate regulatory and ethical requirements.

Semen used by the Scheme is pooled from residual semen obtained from volunteers or from patients (by permission) or from participant laboratories. Semen specimens for concentration and morphology assessment are pooled specimens.

All specimens, images and video clips are human in origin.

The sperm motility component consists of video clips and is viewed online.

The Interpretive Morphology scheme consists of images of stained sperm and is viewed online.

The Embryology scheme consists of video clips of embryos and embryo development and is viewed online.

#### **IMPORTANT SAFETY NOTICE**

Semen specimens are preserved with 10% neutral buffered formalin. Please handle EQA semen specimens with the same precautions as are normally adopted in the handling of patient specimens in accordance with your departmental safety arrangements. Appropriate procedures should be used to minimise contact with samples and for their disposal. A Material Safety Data Sheet is available on request.

**Initial analysis & storage** – Semen samples are stored between 2-8°C after analysis. After a week the samples are viewed to eliminate contamination and then pooled.

**Pool processing** - The principal features of routine pool processing are available on request, but the emphasis is placed on minimum number of donations per pool and minimal disturbance to the matrix. From time to time, special pools are prepared to address specific problems or scientific/clinical issues.

**Participant handling and storage** - EQA samples should **always** be handled, stored, and analysed by participant laboratories as closely as possible to the way they handle, store, and analyse patients' samples. This means that results submitted should be an individuals from within the laboratory, **NOT** an average of several individuals results.



# **Online services**

UK NEQAS Reproductive Science recognises the importance of the internet for communication with and provision of services to participants, as well as interaction with oversight committees, professional bodies and the diagnostic industry.

We are committed to the development of unified, easy to use web interfaces which enhance the utility of existing services to participants and enable new services to be developed. Wherever possible, this will be done in collaboration with other UK NEQAS centres and schemes, to maintain a pan-UK NEQAS unified approach. Reporting of results for the semen concentration and 'practical' morphology analytes is done using the UK NEQAS Results and Reports service which is used by many other UK NEQAS schemes. Reports for all Andrology and Embryology analytes can be also downloaded from this site.

Gamete-Expert.com – We use the gamete-expert.com website to host videos for the sperm motility analyte, images for the Interpretive Morphology analyte and videos for the Embryology scheme. Results inputted onto gamete-expert are automatically transferred to the UK NEQAS results and reports service for processing and reporting at the close of the distribution.

### **Individual logins**

Individual logins can also be purchased for online analytes to assist in the development of Internal Quality Control (IQC). These are generated by Gamete-Expert and are based on a ranking system of results from all the logins in the schemes.

Further information can be obtained from Gamete-Expert.com.

These reports do not represent a proficiency testing report from UK NEQAS Reproductive Science and they are not accredited to ISO 17043:2010 or ISO 17043:2023.

### **Hub and Spoke Reports**

In the Embryology scheme you can also see all the individual login returns made by your staff on one report. This should assist with your Internal Quality Control. See 'Getting Started' section for details.

#### Transfer of Data

As explained above, UK NEQAS Reproductive Science schemes utilises two data collection points. One is the UK NEQAS results and reports service and the other is Gamete-Expert.com.

**UK NEQAS results and reports service** - The layout and validation of the online data entry web forms replicates that of the Birmingham Quality (Wolfson) EQA software.

This is achieved by means of a 'distribution export file' which creates a copy of all the relevant scheme setups. This file, which includes participation, result validation, method options and any other relevant scheme design and setup information, is subsequently imported into the web service database for each distribution.

The web service does not permit the user to independently add or modify the validation or associated setups. This ensures it fully replicates the manual data entry options and result validation as defined in the Wolfson software. The participants are responsible for accurately entering their results.

Results entered online are thus pre-validated and can be imported directly into the Wolfson EQA software (again by file transfer).

Gamete-Expert – Following submission of results by the Participant to Gamete-Expert the results are then transferred as raw data to Birmingham Quality. Checks are then made that there aren't multiple identities for the UK NEQAS lab numbers and that every lab has a UK NEQAS lab number. Where there are two identities



for a UK NEQAS lab, these are cross checked with the Gamete-Expert "EQA assignments" spread sheet to confirm that these match the two separate identity numbers allocated for Andrology and Embryology.

Due to individual IQC logins there could be many identities for a UK NEQAS lab number. The "EQA assignments" spread sheet provides the list of usable ID / Lab numbers.

If any ID fails to find a UK NEQAS lab number, or the EQA assignments don't cross-check with the IDs then Gamete-Expert would be contacted.

Provided this step has a satisfactory outcome, the data associated with each Gamete-Expert ID will automatically be associated with the correct UK NEQAS lab number.

There is a final check after the data has been imported.

Random checks are made from each scheme and the data from both the Gamete-Expert data file and the EQA database are extracted and compared.

# **Operations**

**Distribution cycle** - All schemes operate according to a regular cycle of activity, based on 4 distributions per year. A distribution has a unique identifier (numeric) with fixed sample dispatch and results return dates.

**Pool distribution policy** - It is intended that within any given performance assessment period a number of different materials/images will be distributed that assess the range of analyte concentrations agreed by our expert groups and advisors to be clinically important. How successfully this policy is delivered in practice also depends on scheme size and analytes, and whether materials are multi- or single analyte.

**Distribution dates** – Once distributions go live, they usually remain open for four calendar weeks for all schemes (this can be extended in certain circumstances). The schedule for the current calendar year (and the following year when finalised) is available at <a href="https://mft.nhs.uk/saint-marys/services/gynaecology/reproductive-medicine/ukneqasreproductive-science/">https://mft.nhs.uk/saint-marys/services/gynaecology/reproductive-medicine/ukneqasreproductive-science/</a>, dates are subject to minor changes dependent upon operational circumstances.

**Method classification** - A crucial element of participation for the concentration and 'practical' morphology analytes is the correct assignment of method codes, since performance scoring may be method based.

Considerable effort is expended by our staff to ensure the accuracy of method coding and updating records when this changes. Participants are required to co-operate with this process by informing us when their methods change and for errors, omissions, or changes at the earliest opportunity.

If semen specimens and email notification of the online schemes do not arrive on time or are incorrect it is essential that participants inform <a href="mailto:repscience@ukneqas.org.uk">repscience@ukneqas.org.uk</a> as soon as possible. Replacement samples will be sent.

**Packaging & Mailing (Andrology scheme)** - Participation fees include basic postal rates. Samples of semen for each distribution are mailed to the registered scheme contact as appropriate. Semen specimens are distributed quarterly by first class post within the UK. "International Tracked and Signed" postal services are used for overseas participants at an additional cost. Alternatively, non-UK participants may want to arrange an international courier at their expense.

Packaging complies with current UK legislation for the mailing of 'Human Exempt Specimens'. All tubes are labelled with the scheme name and sample number. The naming convention for the latter is a sequential numeric sample identifier plus a letter where there are multiple specimens in a distribution (for example S401, S402, S403, S404).



**Receipt of samples:** Check samples on receipt to be sure that the correct samples are in the pack and there is no damage to the ampoules. Contact <a href="mailto:repscience@ukneqas.org.uk">repscience@ukneqas.org.uk</a> immediately if replacement samples are required.

If your samples do not arrive within an appropriate time frame (5 working days for most participants, may take longer for overseas post) please contact <a href="mailto:repscience@ukneqas.org.uk">repscience@ukneqas.org.uk</a>.

**Sample handling** - The general rule is that participants should treat EQA samples identically to those from patients. However, this will not apply exactly for the online parts of the schemes. In principle, however, accession numbering and assay should be the same as for patients. In order that there should be uniformity of handling amongst participants, it is recommended that if an assay is not to be performed on the day of receipt, EQA semen samples should be stored at 2-8°C and with thorough mixing using a vortex mixer just prior to analysis. Unless instructed otherwise, participants should ensure that ALL samples in a given distribution are analysed on the same day to ensure that unknown additional variability is not introduced.

#### Semen specimens

The semen analysis specimens (four per distribution) are used to estimate both sperm concentration and 'practical' sperm morphology.

#### Sperm Motility and Interpretive Morphology (online)

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

The Interpretive Morphology distributions consist of a series of images containing 24 sperm for assessment. If entire sperm cannot be viewed, assess on what is displayed.

#### Embryo Morphology

The Embryo Morphology distributions contain videos of embryos (rolling and 'time-lapse') from patients for assessment.

Please note - videos used for assessment purpose may be longer than the time taken to grade embryos in a clinical setting, to allow participants to have sufficient time to assess.

#### **Processing UK NEQAS samples in your laboratory**

#### Receipt and analysis

UK NEQAS distributions are intended to monitor your performance on routine patient specimens. Please process them through your normal reception, analytical and reporting procedure.

#### Result reporting procedure

**Results should be entered in the units shown** onto the correct results document (or online service form), taking care to match sample numbers and avoid transcription or transposition errors. In the numerical analytes, concentration results should be reported to 2 significant figures, motility and 'practical' morphology results should be reported to the nearest whole number (as stated in WHO manual 2021).

**Users may enter/update/amend their results** for online service enabled schemes at any time while the distribution is open. Late results are not accepted.

#### Semen concentration & morphology

Results must be returned by the distribution closing date (usually 4 weeks after distribution open), if they are to be included in the report. Results are reported online at <a href="https://results.ukneqas.org.uk/scripts/scheme-select.pl">https://results.ukneqas.org.uk/scripts/scheme-select.pl</a>. All labs will have been allocated a username and password. Reports will be available from this site once the distribution has been closed and processed.



#### Motility & Interpretive Morphology

Results must be entered while viewing the images/videos online at <a href="http://gamete-expert.com/">http://gamete-expert.com/</a>. Participants are allocated a username (usually an email address) and a password. This will not be the same username as for sperm concentration & motility. Reports will be available shortly after processing from <a href="https://mft.nhs.uk/saint-marys/services/gynaecology/reproductive-medicine/ukneqasreproductive-science/">https://mft.nhs.uk/saint-marys/services/gynaecology/reproductive-medicine/ukneqasreproductive-science/</a>.

#### Embryo Morphology including time-lapse annotation

Results must be entered while viewing the images/videos online at <a href="http://gamete-expert.com/">http://gamete-expert.com/</a>. Participants are allocated a username (usually an email address) and a password. This will not be the same username as for sperm concentration & motility. Reports will be available shortly after processing from <a href="https://mft.nhs.uk/saint-marys/services/gynaecology/reproductive-medicine/ukneqasreproductive-science/">https://mft.nhs.uk/saint-marys/services/gynaecology/reproductive-medicine/ukneqasreproductive-science/</a>

#### Failure to return results.

If your laboratory makes no response to a distribution by the due date (non-return) your report will have a blank space for your results, and you will receive an email from the scheme informing you of a non-return. Regular participation is important if adequate data is to be obtained to establish satisfactory performance.

Failure to return results for 3 distributions within the last 4 distributions will mean there is insufficient data to establish satisfactory performance. The Scheme Organiser has the option to contact the RCPath's National Quality Assurance Advisory Panel (NQAAP) for advice if a UK lab persistently fails to return results.

#### Late returns.

Designated values are derived from a consensus of received results; therefore, late returns can only be accepted in exceptional circumstances.

#### Input errors.

Care must be taken when entering results that the intended answer is inputted. **Input errors cannot be** amended after the distribution is closed unless the participant has evidence that the correct results were recorded before the deadline.

#### Amendments to results prior to reporting deadline.

Amendments to results can only be made prior to the closing date. Although results cannot be amended in the computer system after the reporting deadline an explanation will be kept in your file, and this will be taken into account when assessing unsatisfactory performance.

#### **UK NEQAS errors.**

If you suspect that we have made an error, please let us know immediately. We audit all such errors, and it is important that we know about them so that we can improve our service.

# **Data processing**

#### Data handling.

All Scheme data are held on secure network servers which are backed up daily. Data processing is performed using special EQA software modules which have been developed in association with Birmingham Quality. These allow all schemes to be optimally configured according to Birmingham Quality house style.

#### Calculation of target values.

Target values are crucial to scheme design and usefulness and are the basis for accurate performance scores. In all cases, a robust estimator of the central tendency of the data set and its dispersion are calculated. Target values are derived from a consensus of participants' results which is a recognised statistical technique. Consensus limits are reviewed regularly along with other performance criteria (see appendix 2).

Clearly the larger the number of data points the better the estimate, which becomes important when methodrelated target values are employed rather than those from all laboratories or groups of methods. To eliminate the distorting effect of grossly atypical results, outliers are trimmed from both tails of the ranked data set, with a



corrected estimate of dispersion (SD or CV) usually by the method of Healy (1979)<sup>1</sup> to allow for the removal of extreme values which are not 'true' outliers. The data processing for individual schemes is conducted using individually configured modules within the computer system.

#### Validity of target values

UK NEQAS attaches great importance to validation of Target Values (TV). Target values should be accurate and stable, but this is difficult to achieve where reference methods are unavailable.

For the semen concentration the Method Related Trimmed Mean (MRTM) is taken from participants using Improved Neubauer chambers (See section 'Example Reports' - Fig 1).

The MRTM taken from results of laboratories reporting the use of WHO (2021)/strict criteria is used for morphology (Fig 2). This changed from Distibution 121 when uptake of WHO 2021 overtook WHO 2010.

An All Laboratory Trimmed Mean (ALTM) is used for motility (Fig 3).

Consensus values of 60% agreement are used in interpretive morphology (Fig 4).

For the embryo morphology grading scheme, a consensus is used to derive target values. More than 50% consensus for each result from participating laboratories is required to set a target value. This may mean a consensus may not be reached for all embryos assessed. Results without consensus are not included in performance monitoring within that distribution. **A consensus result is not a 'correct' or 'gold standard' result,** and only reflects how a majority (>50%) of participating laboratories are interpreting the ARCS Embryo Grading System (Figure 6). The 'correct answer' displayed on the Gamete Expert website is a consensus result for all participating laboratories (UK NEQAS target value) or for all participating individuals with personal logins (Gamete Expert target value). The Time-lapse annotation scheme uses an All Laboratory Trimmed Mean (ALTM). The ARCS embryo grading system is available in the Participants' Handbook via the website https://mft.nhs.uk/saint-marys/services/gynaecology/reproductive-medicine/uknegasreproductive-science/

#### **Calculation of performance scores**

As well as providing data on closeness to the target value in a given distribution, schemes employ scoring systems which yield a performance score averaged over a number of distributions and individual samples within a rolling time window to give a robust estimate of overall bias and its variability. The scoring method used for all numeric Reproductive Science analytes is the ABC of EQA system (concentration, motility and morphology).

Acceptable performance criteria - Schemes are required to provide information on persistent unsatisfactory performers to the RCPath's National Quality Assurance Advisory Panel (NQAAP) for Reproductive Science. Limits for acceptable performance scores are agreed by the NQAAP after due deliberation and consultation with Organiser and Steering committee, to reflect the state of the art of analysis and encourage improvement. Special procedures are used to identify those laboratories which have breached these limits on a set number of occasions within the cumulative reporting period. Current limits for our schemes are outlined in Appendix 2.

# Reports and Report interpretation

**Target Turn-Around Times for Reporting** - All fully accredited UK NEQAS services have the following associated performance target:

"Reports are to be published to the web server before the next Distribution is open to UK participants."

For most Schemes, the time between distribution closure and publication of reports will be less than 5 working days. The exact time is recorded and is regularly audited.



The situation for Pilot schemes is inherently more variable owing to their fluid nature, but we always aim to have reports published and available before the next Distribution is dispatched. Once again, these dates are recorded.

#### Reports.

Schemes' reports are the main interface with participants, and a great deal of effort has gone into making these informative and easy to interpret. All scheme reports are generated as A4 format PDF files, which display the data in a number of discrete tabular and graphic formats shared across related schemes. Scheme reports have 'traffic light' colour coding; where symbols and their colour (green, yellow or red) indicate how close individual percentage biases are to the target value, and whether performance scores lie within or outside acceptable limits. Examples are available on request, but all reports share most of the following features:

- Distribution summary (tabular)
- Overall performance summary (graphical)
- Current performance scores and limits of acceptable performance
- Individual results obtained, target values, deviation from the target value (tabular)
- Histogram of all results (method group and individual results marked)
- Graphical indication of performance scores
- 'Snapshot page' (ABC of EQA analytes only) showing a selection of useful graphs
- Standard Uncertainty measurement (numerical schemes only)

#### Distribution of reports.

The default status for EQA report distribution is electronic. Participants may download their reports as electronic PDF files from the secure Results and Reports website.

For online analytes of the scheme, you will also receive a report from gamete-expert.com. This is a ranking comparison of all the individuals in the scheme rather than focusing on one set of results per participating laboratory. This is a good snapshot of results and is more relevant to Internal Quality Control than External Quality Assessment.

#### Interpretation of routine scheme reports & performance scores.

You will need your username and password to access this information on the Results and Reports page. These should be studied carefully, and our staff consulted if clarification is needed. All are under continuous review with the intention to extend harmonisation of both aspects of scheme design throughout our schemes and in collaboration with other UK NEQAS centres.

The principal components of report interpretation may be summarised as follows:

#### Result validation

It should not be possible for anyone to download the wrong PDF report from the website as each is specific for the laboratory identifier and password entered. However, participants viewing reports should **check that they have received the correct report for their laboratory**. Mistakes do occur though these are very rare. Telephone or email us immediately and give the code number of the report received and your own, then delete the incorrect report. A new one will be issued to both laboratories.

Secondly, the results for that distribution should be **checked to ensure that they are the ones returned by your laboratory**. Mistakes can occur though these are very rare.

Results for all analytes are inputted by the participants and we would only amend any transcription errors in exceptional circumstances.



Thirdly, it is crucially important that **participants' methods (and sub-methods, where appropriate) are accurately identified,** especially where performance is assessed against the method mean. Any apparent discrepancies should be reported immediately.

#### Current distribution.

Use the **distribution summary pages** to examine the deviation of your results from the designated target value and (if not the target) the mean (or median) of your method group for each analyte. If deviations are consistent with usual overall or method-related bias and cumulative scores remain stable and within acceptable limits, then it may not be necessary to examine analyte-specific pages in detail. If, however, there are unusual deviations for certain analytes, types of material or analyte concentration which appear not to be shared by other users of the method, then detailed examination of the problem area will be required. (If these are very large, then non-analytical errors should be suspected.) Where appropriate, use the 'traffic light' colour coding to identify aberrant results.

In examining **analyte-specific pages**, participants should relate their results to the overall and method-related distribution of results for each sample as indicated by the histogram and table of method means and CVs.

#### **Standard Uncertainty**

On the reports for numerical analytes (motility, concentration, and practical morphology) a value is given for 'Standard Uncertainty'. This is done using the following formula:

Standard Uncertainty = 1.25xSD

SQRT (NTRIM)

Where:

SD = Standard deviation

SQRT = Square root

NTRIM = Number of Participants remaining once outliers are trimmed.

Standard Uncertainty is included for UK NEQAS quality purposes and is expressed in the unit of the analyte (for example in millions/ml for concentration). Participants should focus on the ABC scores for their performance indicators.

#### **Rolling Time Window performance scores**

One of the main purposes of a performance score derived from a number of distributions and many samples is to 'smooth out' the natural variation in deviations from target values over a number of distributions, by trimming extreme values and deriving a robust estimate of the central tendency for overall bias together with an index of its consistency. Thus, when interpreting the performance score elements of reports, it is important to note that (a) a small number of atypical results is unlikely to affect overall scores, and (b) aberrant results which are numerous enough to affect performance scores will take some time to work their way out of the scoring 'window'.

The principal concern of EQA is the overall bias of participants' results and the consistency (variability) of this bias over time with different materials and different analyte concentrations. It is important to note that when the score that relates to 'consistency of the bias' ('C' score) is high, then the confidence which can be placed in the overall bias score (B score) is reduced (and vice versa). Also, the C score may relate to assay imprecision (and/or reproducibility), but only if there are insignificant pool- or analyte concentration-dependent variations in deviations from the target value or changes over time. Only internal quality control (IQC) can give a clear assessment of analytical imprecision.

When interpreting performance scores, participants should look first for atypical results in a single isolated distribution (as above) and relate these to IQC data on the day of analysis, and then for shifts or trends over a number of distributions which might indicate a method related problem. Note that the C score always increases



when the B score changes in either direction, so that this will occur when bias shifts and again if a correction is made. Only after a full period of stable performance (with or without a change in bias) will the C score decrease to low levels. The graphical elements of cumulative reports show this clearly in relation to acceptable limits of performance (not all schemes) and the overall behaviour of different method groups. Attempts should be made to correlate trends and/or shifts in bias with IQC data, which in turn should indicate whether changes in personnel, data reduction, procedures, calibration, or instruments are implicated.

#### Calculation of Analytical Performance Scores for Concentration, morphology & motility

Laboratory performance is reported as a cumulative mean running Score using the UK NEQAS ABC system. A brief overview of this system is outlined in appendix 2. Examples of the report format are shown below (Fig 2-4). Current performance limits are detailed in Appendix 2.

#### Calculation of Analytical Performance Scores for Interpretive Morphology Scheme

Laboratory Performance is scored for this scheme from April 2017. Current performance limits are detailed in Appendix 2. An example of the report format is shown below (Fig 5). The performance criteria are based on penalty points where Participants get 1 penalty point for disagreement with the consensus.

#### Calculation of Analytical Performance Scores for Embryology Scheme

Laboratory Performance is scored for this scheme (April 2013) and is based on 'matching' with the target values (TVs) and penalty point accumulation. No penalty points are accrued for a 'match' with the consensus target value (TV); one point is accrued for one step either way from the TV; a maximum of two penalty points are accrued for two or more steps either way from the TV. An example of the report format is shown below (Fig 6). Only ARCS Embryo Grading System parameters (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 or criteria for this. Therefore, this part of the scheme is for interpretive and educational purposes only and for use in the 'hub and spoke' reports for comparing inter-laboratory variation. Current performance limits are detailed in Appendix 2.

Time-lapse annotation analyte (introduced April 2016): 9 annotations for assessment: Laboratory performance is formally assessed (from May 2021) after a trial period following the pilot scheme and UKAS accreditation (gained in March 2019). Target values (TVs) for each of the 9 annotations are given and are derived by consensus (from April 2022). Rolling performance is reported on page 20 of the report. This part of the scheme gained UKAS accreditation (ISO17043:2010) in March 2019.

# **Coincidence Monitoring**

Since Distribution 105, UK NEQAS Reproductive Science has been routinely performing 'coincidence monitoring'. If two or more participants submit the same set of results, this will be notified to the participants as a 'coincidence'. If this occurs on multiple occasions, the participants will be notified and the RCPath's National Quality Assurance Advisory Panel (NQAAP) informed (or for overseas participants, their equivalent professional body). The NQAAP will investigate further to determine if collusion or falsification of results between laboratories has occurred.

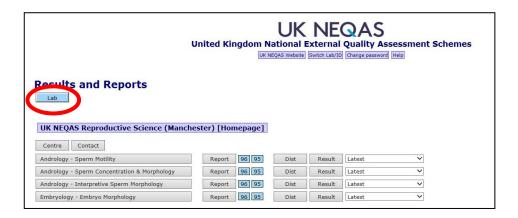
### **Enrolment Certificates**

A certificate of enrolment is available for each registered laboratory. To download an enrolment certificate, log on to the Results and Reports website <a href="https://results.ukneqas.org.uk/scripts/scheme-select.pl">https://results.ukneqas.org.uk/scripts/scheme-select.pl</a> using your laboratory ID number and password.

On the home page, next to your UK NEQAS ID number there is a button labelled 'Lab'. Click on this and you will see the certificates listed as 'MAN\_[UK NEQAS number]\_REGISTRATION\_YYYY.pdf'.

Participation certificates are not issued. Evidence of participation is displayed on your distribution report.





# **Performance Problems**

#### Non-analytical errors

These are defined as 'blunders' made by participants, which appear as anomalous results (which may or may not be classified as outliers), and may fall into the following categories:

- Assaying the wrong samples
- Assaying the right samples in the wrong order
- Incorrectly entering laboratory results.

These errors can also happen with patient samples so these will only be amended in exceptional circumstances.

#### Return rate.

According to NQAAP requirements for acceptable performance, participants are expected to return 100% of results within the relevant cumulative performance scoring period. Where a laboratory is unable to return a set of results, an explanation must be provided.

#### Performance surveillance and Advisory Panel liaison

Limits for acceptable performance are approved by the NQAAP for Reproductive Science in consultation with the RSSC where appropriate. The criteria include acceptable limits for BIAS and for return rate.

We are required to report to the NQAAP for Reproductive Science on laboratories whose performance scores move outside acceptable limits on a set number of occasions (see below) within the scoring time window, or who fail to return sufficient results. The computer system is used to generate a list of such laboratories for each scheme or analyte. The performance of each laboratory identified is then reviewed in association with any correspondence between Organiser and the participant, and a decision made on further action. This may be just to monitor, to stimulate dialogue between Organiser and participant and monitor improvement in performance, or to suggest that the Panel Chairman should make contact. Participants who cancel participation whilst under referral to NQAAP are highlighted to the Panel in case they are moving schemes to mask performance issues.

The latter course of action is relatively rarely undertaken and begins with a first Panel letter inviting the participant to make contact to discuss action to correct the unsatisfactory performance. If a satisfactory response is made and improvement in performance ensues, no further action is taken. If unsatisfactory performance persists or no response is made, then a second Panel letter (direct from Panel Chairman to Head of Department with lab code disclosed) is written requesting that decisive action is taken to re-establish satisfactory performance; this may include a site visit by Panel members. If this fails, the Quality Assurance Pathology Committee may take further action.



For concentration or 'practical' morphology, if the rolling A, B or C scores break the performance criteria limits (see Appendix 2) it will be noted as an unsatisfactory performance. If this happens on three distributions within the last 4 distributions (without improvement), the laboratory will be contacted as a persistent unsatisfactory performer.

For sperm motility if the rolling A, B or C scores break the performance criteria limits (see Appendix 2) for two of the three categories it will be noted as an unsatisfactory performance. If this happens on three distributions within the last 4 distributions (without improvement), the laboratory will be contacted as a persistent unsatisfactory performer.

For interpretive morphology, if the rolling penalty point total breaks the performance criteria limits (see Appendix 1) it will be noted as an unsatisfactory performance. If this happens on three distributions within the last 4 distributions (without improvement), the laboratory will be contacted as a persistent unsatisfactory performer.

For Embryology if the rolling penalty point total breaks the performance criteria limits (see Appendix 1) it will be noted as an unsatisfactory performance. If this happens on three distributions within the last 4 distributions (without improvement), the laboratory will be contacted as a persistent unsatisfactory performer.

# **Complaints & Appeals**

#### **Definition**

A complaint is any communication, written or verbal, from internal or external sources indicating deficiencies relating to the identity, quality, durability, reliability, safety, effectiveness or performance of the EQA service. Complaints and other communications which point out deficiencies, difficulties or problems (which we classify as errors) are recorded together with any response or action taken by us. These are audited by the Quality Manager.

#### Types of Complaint and How to make a Complaint.

Please study the sequence of actions indicated below and either write or email the appropriate individual. Emails of complaint to <a href="repscience@ukneqas.org.uk">repscience@ukneqas.org.uk</a> should contain the words 'complain' or 'complaint' in the subject line so these can be filtered to the complaint handling area. Most problems experienced by participants consist of minor misunderstandings or problems with specimens and reports, which can usually be resolved over the telephone by any member of staff. If difficulties persist, then participants with continued justified cause for complaint about any aspect of the service should communicate their concerns immediately to the relevant member of senior staff, preferably in writing (letter or email) though a preliminary telephone call may assist in clarifying the issue and establishing the requisite action. All 17043:2010 complaints shall be acknowledged within 5 working days of receipt. Wherever possible, a final response is given within 3 months of the acknowledgement.

- Where the complaint is about scheme logistics, then the Scheme Manager may be the most appropriate person to investigate via anonymised correspondence with the Administrators.
- Where the matter is related to performance assessment and scheme design, the Scheme
  Organiser or Scheme Manager may be the most appropriate person to assist if the participant
  waives their anonymity.
- If the complaint concerns the conduct of a member of UK NEQAS staff, or a satisfactory response
  has not been received from the individual first contacted, then the Scheme Organiser should be
  contacted.
- If matters remain unresolved, or the action taken by us is not satisfactory to the complainant, the next step is to refer the complaint to the Chairman of the **Steering Committee**.
- If the issue concerns performance assessment, the Chairman of the Advisory Panel may also be contacted.



- Where lack of compliance with ISO 17043 Standards is suspected by the complainant, then (in the first instance), contact the Quality Manager. If the complaint is not resolved to the satisfaction of the complainant, then the **Executive Chair of UKAS** may be contacted.
- Where the UK NEQAS Code of Practice itself is the issue of concern, the President of UK NEQAS may be appropriate.

In all cases, UK NEQAS Reproductive Science staff will provide the names and addresses of the appropriate individuals and can be contacted using the details on page 2 of this document.

#### Appeals Against the Evaluation of Your Performance and erroneous results.

If you wish to appeal against the evaluation of your performance, or if there are erroneous results, please contact UK NEQAS Reproductive Science using the details on page 2 of this document and putting appeal in the subject heading.

Your appeal will be handled according to our complaints procedure. If a lab submits an appeal more than twice within a two-year period, the RCPath's National Quality Assurance Advisory Panel for Reproductive Science shall be informed.

With regards to complaints against the evaluation of your performance, the Organiser's decision is final.

If a lab appeals more than twice on their results, the RCPath's National Quality Assurance Advisory Panel (NQAAP) for Reproductive Science shall be informed.



# **Feedback**

UK NEQAS Reproductive Science welcomes feedback from participants and potential customers. A user survey is circulated annually for each scheme and UK NEQAS Reproductive Science are active on Twitter (@UKNEQASReproSci).

### **Footnotes**

#### FEEDBACK ON THIS HANDBOOK

This handbook has been made as comprehensive as possible, but it is appreciated that revision may be required to reflect progress. Participants are invited to make comments and suggestions, not only on the handbook but any aspect of our schemes or procedures, so that amendments may be made for the next edition. Please email <a href="mailto:repscience@ukneqas.org.uk">repscience@ukneqas.org.uk</a> for your comments & suggestions, putting 'Participants' Handbook' in the subject line.

#### **ACKNOWLEDGEMENTS**

The careful work of all our staff, the support of colleagues at other UK NEQAS centres and advice from members of expert committees and professional bodies are gratefully acknowledged. UK NEQAS Reproductive Science are grateful for the work of the Manchester University Foundation Trust Andrology & Embryology laboratories, the Manchester University Foundation Trust's Finance Department, and our subcontractors. The continued loyalty of all participants, which has enabled the Schemes to develop and expand to meet the challenges of the proficiency testing environment, is also warmly acknowledged.

#### **FURTHER COPIES OF THIS HANDBOOK**

The current definitive version of the Participants Handbook may be downloaded (from <a href="https://mft.nhs.uk/saint-marys/services/gynaecology/reproductive-medicine/ukneqasreproductive-science/">https://mft.nhs.uk/saint-marys/services/gynaecology/reproductive-medicine/ukneqasreproductive-science/</a>) or printed by UK NEQAS Reproductive Science Scheme participants for their personal use.

#### REFERENCES

1. Healy MJR (1979) Outliers in clinical chemistry quality control schemes. Clin. Chem. 25: 675-679

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### **Example Reports**

Figure 1 - Address and Comments page

| LIK NEOAC                        | Andrology - Sperm Co | Laboratory :      |              |
|----------------------------------|----------------------|-------------------|--------------|
| UK NEQAS<br>Reproductive Science | Distribution : 118   | Date: 04-Sep-2023 | Page 1 of 11 |
|                                  | Address and Comment  | ts                |              |

Current contact person and address details we have for your laboratory. Pathology Laboratory Biochemistry Department Hospital Town County Postcode Current email address details on file for your laboratory. This Scheme is essentially web-based. We can alert you to information regarding the Scheme via email. The e-mail address (or addresses) we are currently using to contact your laboratory is shown below in red. If no e-mail address is deplayed or the information shown is incorrect, please email us with an appropriate contact e-mail address as soon as possible, using the word 'feedback' in the title line and stating your UK NEQAS lab number. Transit and analysis times (Sperm Concentration & Morphology only). Based on the date information you have provided, the transit time from specimen dispatch [] to receipt[] was day(s), and laboratorywas day(s). (Missing values indicate dates not provided. "0 days" represents same day receipt analysis). Any comments you made to us are shown below and have been acted upon where necessary Comments received from your laboratory and any response from UK NEQAS. Any specific comments applicable only to laboratory are shown below Any general comments applicable to all laboratories are shown below Please note that samples S470 and S472 are taken from the same sample pool (374) and therefore are the same sample General comments from UK NEQAS specific to this distribution. Authorisation signature, date and report type. UK NEQAS Internal QC: The homogeneity and stability assessment for this distribution was satisfactory.

For further details on the design, operation and statistical analysis of this scheme, please see the Participants' Handbook (a vailable to download from https://mit.nhs.uk/saint-marys/services/ukneqasreproductive-science/)

Final Report, authorised on Wednesday 6th September 2023 by Annette Lloyd. Scheme Organiser, UK NEQAS for Reproductive Science.



UK NEQAS Reproductive Science is a UKAS accredited proficiency testing provider No. 8228. Please see http://www.ukas.com for full details of the accreditation status of our services.



UK NEQAS Reproductive Science is proud to offer EQA services that adhere to the code of practice and have the badge of quality of UK NEQAS



QAS Reproductive Science is part of Manchester University Hospitats NHS Foundation Trust and provides NEQAS service from Andrology Laboratories, St Mary's Hospitat, Oxford Rd, Manchester. Mt3 SWL, UK.

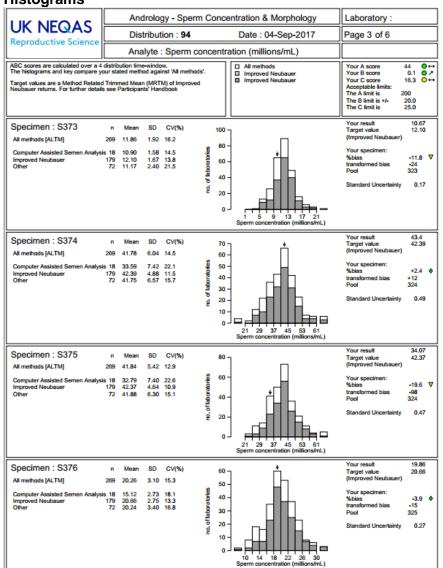
contact us errail repartence@ukneqss.org.uk or Tel +44 (0) 181 2 76 843? sees ratum results for Semen Concentration and Morphology via the Online Results and Reports Service. imple collection is partially subcontracted to other laboratories.

UK NEGAS Reproductive Science is a UKAS accredited proficiency testing provider, No. 8228. Published at 10:06 on Thursday 9 November 2023

## Reproductive Science

# **Example reports**

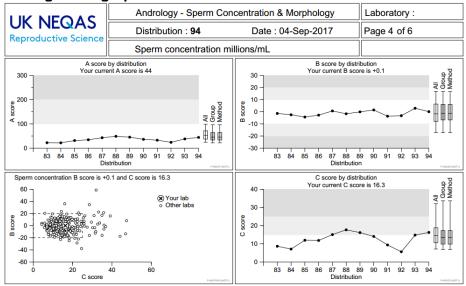
#### Figure 2 - Sperm concentration (millions/ml) **Histograms**



#### Summary

| oumma y  |                                  |                                 |                                  |  |           |            |         |            |             |            |
|--|----------------------------------|---------------------------------|----------------------------------|--|-----------|------------|---------|------------|-------------|------------|
| LIK NEC  |                                  | Androlog                        | gy - Sperm                       | Concentr                               | ation & N | /lorpholog | у       | La         | aboratory : |            |
| UK NEG<br>Reproductive   | Distribution : 94                |                                 |                                  | Date : 04-Sep-2017                     |           |            | Pa      | age 2 of 6 |             |            |
| Reproductive   | Science                          | Distribution Summary            |                                  |  |           |            |         |            |             |            |
| Proficiency testing materials: Human semen containing preservative (10% Neutral Buffered Formalin) Please note that samples S374 and S375 are taken from the same sample pool (324) and therefore are the same sample. |                                  |                                 |                                  |  |           |            |         |            |             |            |
| You have returned res<br>This return rate is <b>Sat</b><br>You have returned res<br>This return rate is <b>Sat</b>   | isfactory<br>sults for 4 out     |                                 |                                  |  |           |            |         |            |             |            |
| S  | pecimen                          | Result                          | Target                           | Specimen<br>%bias                      | A score   | B score    | C score | Α          | В           | С          |
| Sperm concentration (millions/mL)  | \$373<br>\$374<br>\$375<br>\$376 | 10.67<br>43.4<br>34.07<br>19.86 | 12.10<br>42.39<br>42.37<br>20.66 | -11.8 ▼<br>+2.4 ♦<br>-19.6 ▼<br>-3.9 ♦ | 44        | +0.1       | 16.3    | <b>○</b> ↔ | • >         | <b>○</b> ↔ |

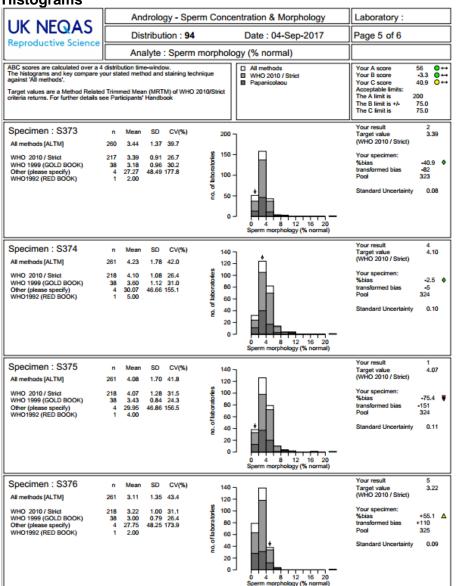
#### Rolling score graphs

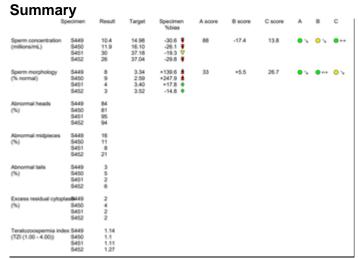


For current performance limits, see appendix 2.

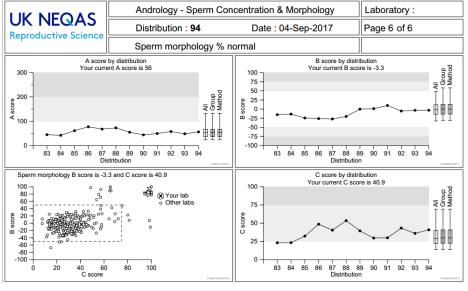
## Reproductive Science

# Figure 3 – Sperm Morphology (% normal) Histograms





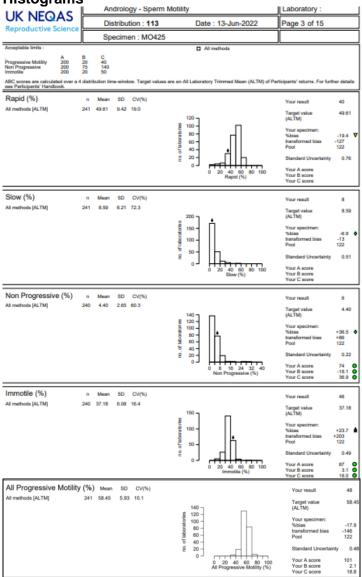
Rolling score graphs



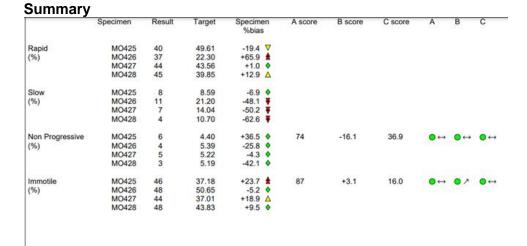
For current performance limits, see appendix 2.

## Reproductive Science

Figure 4 – Sperm Motility – update to follow Histograms



V18.0 23/05/2024

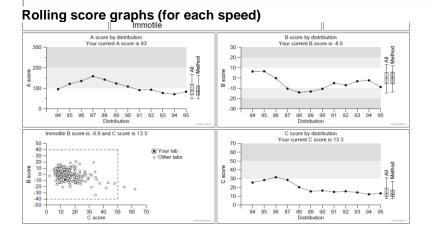


-17.9 V

+10.6 A

-11.8 V

+2.1



58.45

43.40

57.81

For current performance limits, see appendix 2.

All Progressive Motility

MO425

MO426

MO427

MO428

48 51

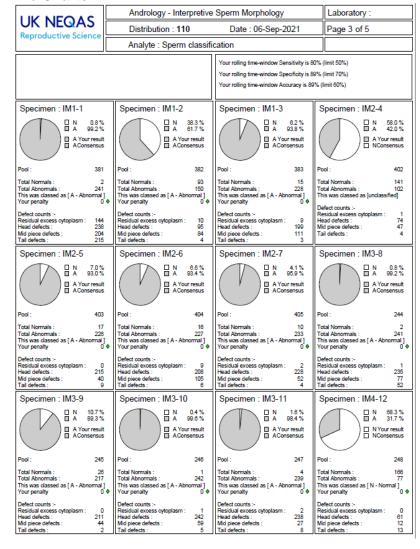
## Reproductive Science

# Figure 5 – Interpretive Morphology Report Summary

| LUZ NICO                                  | ) A C            |              | Androlo         | gy - Ir     | nterp       | oretive Sperm Morphology     | Laboratory : |
|---|------------------|--------------|-----------------|-------------|-------------|------------------------------|--------------|
| UK NEQAS  Reproductive Science            |                  |              | Distribu        | tion : '    | Page 2 of 5 |                              |              |
| Reproductive Science Distribution Summary |                  |              |                 |             |             |                              |              |
| Proficiency testing m                     | aterials: Ima    | ges of Papa  | nicolau stain   | ed sperm    | natoz       | oa.                          | ·            |
| The Performance train                     | ffic light is ca | lculated ove | er a four distr | ibution tir | me w        | ndow.                        |              |
| Images with consens                       | us of less th    | an 60% are   | unclassified    | and there   | efore       | a target will not be listed. |              |
| The current penalty li                    |                  |              |                 |             | 01010       | a target viii net be neteu.  |              |
| The current penalty ii                    | mit for interp   | retive Morp  | nology is 16    | points.     |             |                              |              |
|   |                  |              |                 |             |             |                              |              |
| 5   | Specimen         | Result       | Target          | Pena        | lty         | Performance                  |              |
| Sperm classification                      | IM1-1            | Α            | Α               | 0           | <b>•</b>    | 10 ● ↔                       |              |
|   | IM1-2            | Α            | Α               | 0           | •           |                              |              |
|   | IM1-3            | Α            | Α               | 0           | <b>•</b>    |                              |              |
|   | IM2-4            | Α            |                 |             |             |                              |              |
|   | IM2-5            | Α            | Α               | 0           | •           |                              |              |
|   | IM2-6            | Α            | Α               | 0           | •           |                              |              |
|   | IM2-7            | Α            | Α               | 0           | <b>•</b>    |                              |              |
|   | IM3-8            | Α            | Α               | 0           | •           |                              |              |
|   | IM3-9            | Α            | Α               | 0           | <b>•</b>    |                              |              |
|   | IM3-10           | Α            | Α               | 0           | •           |                              |              |
|   | IM3-11           | Α            | Α               | 0           | <b>•</b>    |                              |              |
|   | IM4-12           | N            | N               | 0           | •           |                              |              |
|   | IM4-13           | Α            | Α               | 0           | <b>•</b>    |                              |              |
|   | IM4-14           | Α            | Α               | 0           | •           |                              |              |
|   | IM4-15           | Α            | Α               | 0           | <b>•</b>    |                              |              |
|   | IM5-16           | Α            | Α               | 0           | <b>•</b>    |                              |              |
|   | IM5-17           | Α            | Α               | 0           | <b>•</b>    |                              |              |
|   | IM5-18           | N            | Α               | 1           | ₹           |                              |              |
|   | IM5-19           | Α            | Α               | 0           | <b>•</b>    |                              |              |
|   | IM6-20           | Α            | Α               | 0           | •           |                              |              |
|   | IM6-21           | Α            | Α               | 0           | <b>•</b>    |                              |              |
|   | IM6-22           | N            |                 |             |             |                              |              |
|   | IM7-23           | Α            | Α               | 0           | <b>•</b>    |                              |              |
|   | IM7-24           | Α            | Α               | 0           | <b>•</b>    |                              |              |

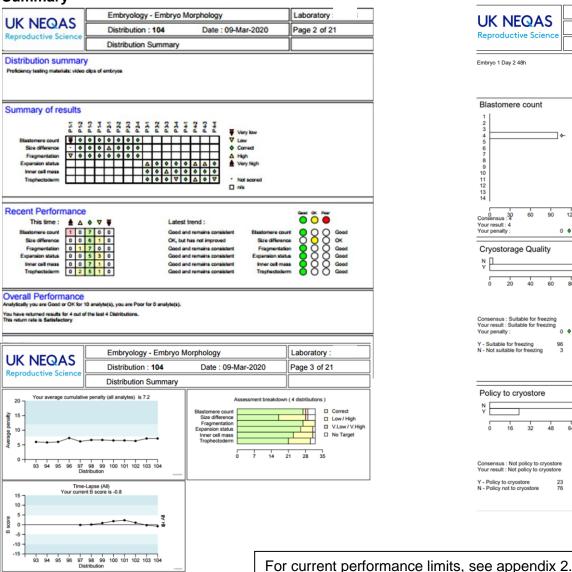
For current performance limits, see appendix 2.

#### **Pie Charts**



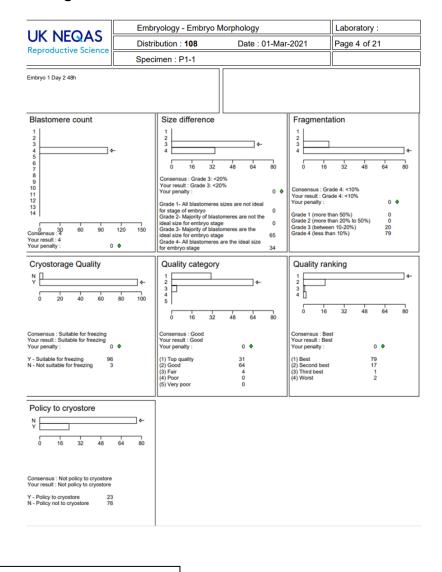
## Reproductive Science

# Figure 6 – Embryology Scheme Report (part 1) Summary



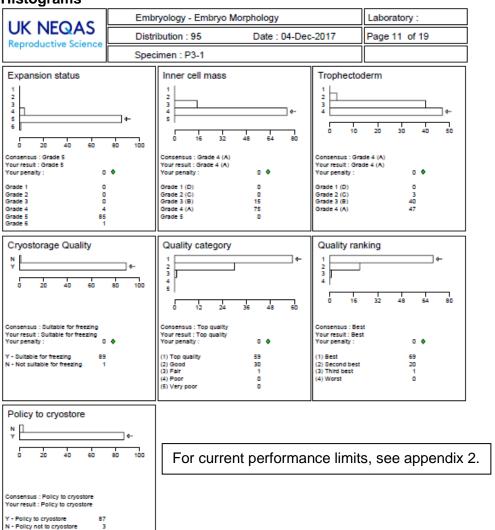
V18.0 23/05/2024

#### **Histograms**



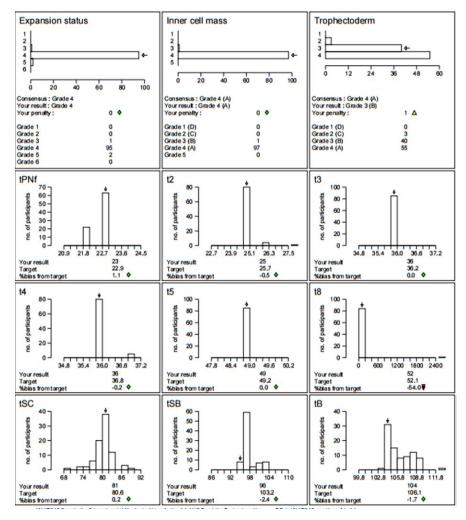
## Reproductive Science

#### Figure 6 – Embryology Scheme Report (part 2) **Histograms**



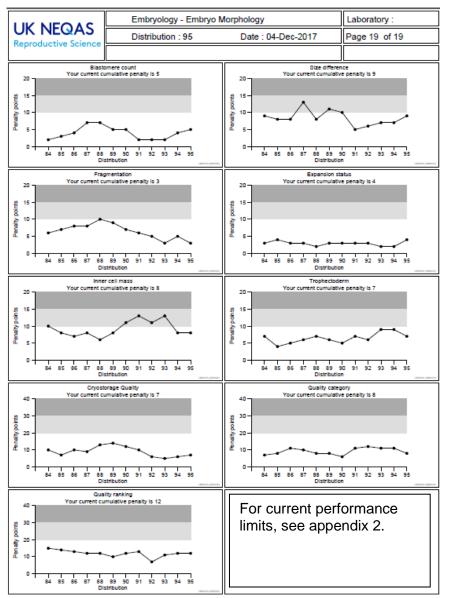
#### **Time Lapse Annotation Histograms**

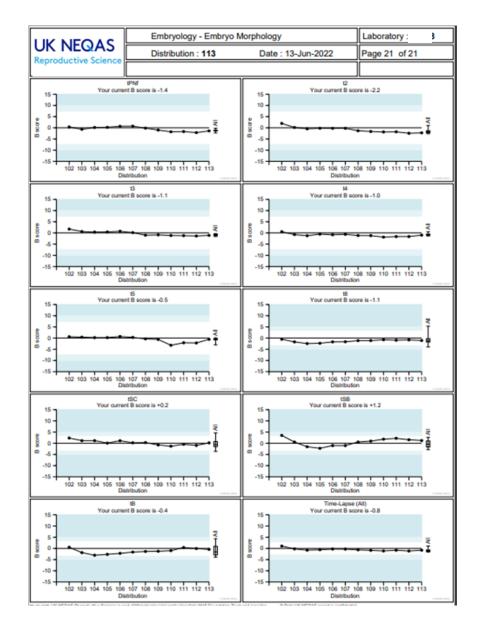
| LIKATEGAS                     | Embryology - Embryo | Morphology    | Laboratory : |
|-------------------------------|---------------------|---------------|--------------|
| UK NEQAS Reproductive Science | Distribution: 104   | Page 19 of 21 |              |
| Reproductive Science          | Specimen : P4-4     |               |              |



## Reproductive Science

Figure 6 - Embryology Scheme Report (part 3)







#### Appendix 1: The ABC Reporting system for motility, concentration & 'practical' morphology

In April 2013 the report format changed for the above analytes. The change harmonised the Andrology scheme into line with other UK NEQAS schemes which already use this system. Below is an explanation of the system:

The 'ABC of EQA' is an ISO 17043:2010 compliant framework which meets and surpasses the utility of existing systems. The main benefit for participant laboratories, EQA Organisers, Steering Committees, Specialist Advisory Groups and the RCPath's NQA Advisory Panels alike, is that it is a *single* system, which not only *works* across analytes, schemes, and disciplines, but can allow *meaningful comparisons* to be made between analytes, schemes and disciplines.

#### **Definitions**

There are three scores A, B and C

A is for Accuracy (total error)

B is for Bias

C is for Consistency of bias

These are conveniently referred to as the 'A score', 'B score' and 'C score', or simply A, B and C.

- Every laboratory will have an A, B and C score for each analyte they measure.
- All 3 scores should be used when assessing performance.
- The **B** and **C** scores (which have **not** been transformed) are best looked at together and provide analytical data on average bias and its consistency (pattern).
- The **A** score is weighted as part of a transformation process to take into account factors such as 'degree of difficulty' and normalised (median set at 100) to that attainable by the average laboratory at January 2000, to allow meaningful comparisons across analytes.
- The **A** score is primarily used as a quick 'comparator' or 'screening tool' for performance across all analytes. An **A** score of 100 is 'average', but this may of course be 'better' or 'worse' than what is required clinically, depending on the analyte.

#### A. B and C scores in detail

Each of the 3 scores is calculated over a **rolling time-window** and thus comprises data (results) from many specimens. At each distribution they are updated with fresh current data, while older data drops out of the 'time-window'.

For all UK NEQAS Birmingham Schemes, all scores are set so that a low score is 'good', a high score is 'bad'.

- The Accuracy A score tells you, on average, how good your overall performance is. This takes
  into account such factors as bias, consistency of bias, degree of difficulty etc. It has been
  transformed to ensure that A scores are broadly equivalent across analytes. For example, if
  you have an A score of 85 for TSH and you also have an A score of 85 for sodium, this would
  indicate that you are performing both, on average, equally well.
- The Bias **B score** tells you how far away from the 'target', on average, you are. It has **not** been transformed.
  - Therefore, a **B score** of 5% for TSH might be considered to be very acceptable, while a **B score** of 5% for sodium would suggest your assay is in urgent need of attention.
- The Consistency of bias **C score** tells you, on average, if you usually have the same bias pattern. It is also **not** transformed and can assist in answering the following questions. 'Do you have different bias depending on the concentration of analyte in the sample?' 'Does your bias vary depending on the specimen matrix?' 'Has your bias changed during the time window?' 'Are



you imprecise?' A high (poor) **C score** does not necessarily mean that you are imprecise, though if you are imprecise, it is impossible for you to have a very good (low) C score. *Poor consistency of bias is not the same as imprecision*.

#### A, B and C score calculation

The specimen-level % bias calculation (**specimen %bias**) is at the heart of all calculations:

If the target is 10 and you get a result of 11, then your bias is +10%; if the target is 10 and you get a result of 8, then your bias is -20%; if the target is 10 and you get a result of 10, then your bias is 0%, and so on.

We then calculate your **'B score'**, (i.e. your **average bias**), as the **trimmed mean** of all individual **'specimen %biases'** (including the sign) in the rolling time window.

The **'C score'** is simply the **standard deviation** (adjusted to take into account the degree of trimming) of the data which make up the B score.

The **A score** is an estimate of **accuracy [total error]** in UK NEQAS and is derived as follows:

- we take your Specimen % bias and transform it by a 'degree of difficulty' factor (see below) to get your Specimen transformed bias [this can be positive or negative]
- we then take the modulus of this Specimen transformed bias to give the Specimen Accuracy Index [as it is a modulus it has no sign]
- we calculate your 'A score' as the trimmed mean of all of your Specimen Accuracy Indices
  in the rolling time-window.

(Taken from "The 'ABC of EQA' harmonised scoring in UK NEQAS" (V6, January 2007))

## A, B, C system in relation to Reproductive Science schemes.

The individual sample results are compared to the Target Value to give each result a % Bias. The symbols for individual % biases (green diamond, yellow triangle and red double triangle) are for consistency based on the same levels as the rolling scores (below).

The time-window is set at 4 distributions (equivalent to 1 year). So the A, B & C scores are all based on data submitted in this time-window.

The reports also use a summary page to bring the report together in an easy to view format that includes the results, the rolling A, B & C scores, the colour icons and trend arrows.



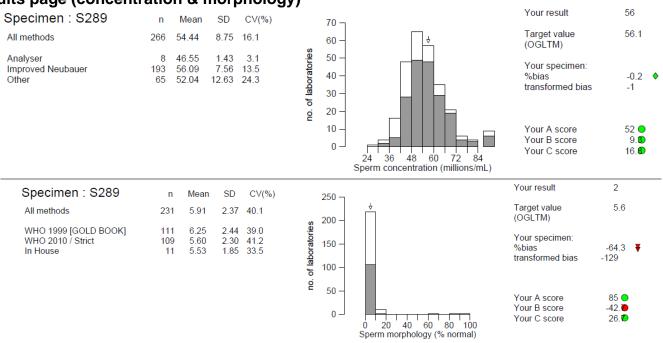
## Reproductive Science

### **Example reports:**

| Summary page (                    | concen                       | tration 8            | morpho                           | ology)                                  |         |         |         |                                       |                                       |  |
|-----------------------------------|------------------------------|----------------------|----------------------------------|---|---------|---------|---------|---------------------------------------|---------------------------------------|--|
|                                   | pecimen                      | Result               | Target                           | Specimen<br>%bias                       | A score | B score | C score | Α                                     | В                                     | С                                      |
| Sperm concentration (millions/mL) | S289<br>S290<br>S291<br>S292 | 56<br>72<br>52<br>16 | 56.09<br>59.79<br>40.77<br>14.35 | -0.2 ♦<br>+20.4 △<br>+27.5 △<br>+8.0 ♦  | 52      | +9.3    | 16.8    | $\color{red} \bullet \leftrightarrow$ | • >                                   | $\color{red}{\bullet} \leftrightarrow$ |
| Sperm morphology<br>(% normal)    | S289<br>S290<br>S291<br>S292 | 2<br>3<br>3<br>5     | 5.60<br>6.00<br>5.50<br>4.67     | -64.3 ▼<br>-50.0 ▼<br>-45.4 ▼<br>+7.1 ◆ | 85      | -42.7   | 26.7    | $\color{red} \bullet \leftrightarrow$ | $\color{red} \bullet \leftrightarrow$ | $\color{red}{\bullet} \leftrightarrow$ |

The 'trend' arrows help you to see if your results are improving, staying constant or getting worse.

### Results page (concentration & morphology)



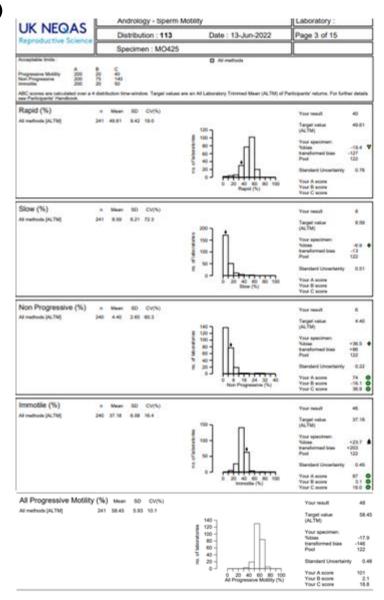
### Summary page (motility)

|                     | Specimen    | Result | Target | Specimen<br>%bias | A score | B score | C score | Α                          | В          | C                          |
|---------------------|-------------|--------|--------|-------------------|---------|---------|---------|----------------------------|------------|----------------------------|
| Rapid               | MO425       | 40     | 49.61  | -19.4 ▽           |         |         |         |                            |            |                            |
| (%)                 | MO426       | 37     | 22.30  | +65.9             |         |         |         |                            |            |                            |
| ( )                 | MO427       | 44     | 43.56  | +1.0 ♦            |         |         |         |                            |            |                            |
|                     | MO428       | 45     | 39.85  | +12.9 △           |         |         |         |                            |            |                            |
| Slow                | MO425       | 8      | 8.59   | -6.9 ♦            |         |         |         |                            |            |                            |
| (%)                 | MO426       | 11     | 21.20  | -48.1 ₹           |         |         |         |                            |            |                            |
|                     | MO427       | 7      | 14.04  | -50.2 ₹           |         |         |         |                            |            |                            |
|                     | MO428       | 4      | 10.70  | -62.6             |         |         |         |                            |            |                            |
| Non Progressive     | MO425       | 6      | 4.40   | +36.5 ♦           | 74      | -16.1   | 36.9    | $\bigcirc \leftrightarrow$ | <b>○</b> ↔ | <b>○</b> ↔                 |
| (%)                 | MO426       | 4      | 5.39   | -25.8 ♦           |         |         |         |                            |            |                            |
|                     | MO427       | 5      | 5.22   | <b>-4.3</b> ♦     |         |         |         |                            |            |                            |
|                     | MO428       | 3      | 5.19   | -42.1 <b>♦</b>    |         |         |         |                            |            |                            |
| Immotile            | MO425       | 46     | 37.18  | +23.7             | 87      | +3.1    | 16.0    | ○ ↔                        | 07         | $\bigcirc \leftrightarrow$ |
| (%)                 | MO426       | 48     | 50.65  | -5.2 ♦            |         |         |         |                            |            |                            |
|                     | MO427       | 44     | 37.01  | +18.9 △           |         |         |         |                            |            |                            |
|                     | MO428       | 48     | 43.83  | +9.5 ♦            |         |         |         |                            |            |                            |
|                     |             |        |        |                   |         |         |         |                            |            |                            |
| All Progressive Mot | ility MO425 | 48     | 58.45  | -17.9 ▼           | 101     | +2.1    | 18.8    | 0 ↔                        | 07         | <b>○</b> ↔                 |
| (%)                 | MO426       | 48     | 43.40  | +10.6 △           |         |         |         |                            |            |                            |
| Ø. 5.               | MO427       | 51     | 57.81  | -11.8 ▽           |         |         |         |                            |            |                            |
|                     | MO428       | 49     | 50.85  | -3.6 ♦            |         |         |         |                            |            |                            |

The 'trend' arrows help you to see if your results are improving, staying constant or getting worse.

## Reproductive Science

#### Results page (motility)



#### 'A' scores

The 'A' scores for samples is a 'transformed bias' (%bias x 100 / CCV). UK NEQAS normalise ABC data so that the median 'A' score at 1st January 2000 is 100 (setting the Chosen Co-efficient of Variation (CCV) to achieve this). More information on the current CCV values is available by contacting the scheme.

#### 'B' & 'C' scores

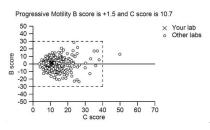
We have plotted the data and looked at the 5<sup>th</sup>/95<sup>th</sup> percentiles to determine suitable values for B & C. We have also introduced a colour system into the reports to make it easier to determine your performance.

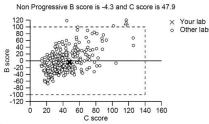
The allowance of % BIAS (B score) or (C score) is (where Green = satisfactory, Yellow = warning and Red = unsatisfactory):

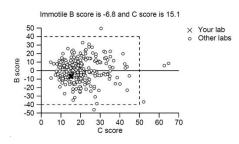
#### Motility

The below penalty box plots show the 95<sup>th</sup>/5<sup>th</sup> centiles used to determine the B & C score limits:

# Reproductive Science







#### B scores:

|                   | Green       | Yellow         | Red    |
|-------------------|-------------|----------------|--------|
| Rapid Progressive | 0 to +/- 10 | +/-10 to +/-20 | >+/-20 |
| Slow Progressive  | 0 to +/- 30 | +/-30 to +/-50 | >+/-50 |
| Non-Progressive:  | 0 to +/- 50 | +/-50 to +/-75 | >+/-75 |
| Immotile:         | 0 to +/- 10 | +/-10 to +/-20 | >+/-20 |
| All Progressive:  | 0 to +/- 10 | +/-10 to +/-20 | >+/-20 |

#### C scores:

|                   | Green    | Yellow     | Red  |
|-------------------|----------|------------|------|
| Rapid Progressive | 0 to 20  | 20 to 40   | >40  |
| Slow Progressive  | 0 to 70  | 70 to 100  | >100 |
| Non-Progressive:  | 0 to 100 | 100 to 140 | >140 |
| Immotile:         | 0 to 30  | 30 to 50   | >50  |
| All Progressive:  | 0 to 20  | 20 to 40   | >40  |

#### Concentration

B scores:

|               | Green      | Yellow          | Red    |
|---------------|------------|-----------------|--------|
| Concentration | 0 to +/-10 | +/-10 to +/- 20 | >+/-20 |

#### C scores:

|               | Green   | Yellow   | Red |
|---------------|---------|----------|-----|
| Concentration | 0 to 15 | 15 to 25 | >25 |



#### **Morphology (practical)**

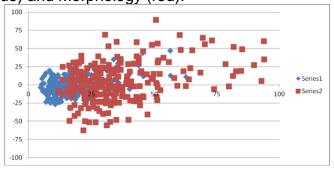
B scores:

|                              | Green      | Yellow          | Red    |
|------------------------------|------------|-----------------|--------|
| Morphology                   | 0 to +/-50 | +/-50 to +/- 75 | >+/-75 |
| Abnormal Heads               | 0 to +/-10 | +/-11 to +/- 20 | >+/-20 |
| Abnormal Midpiece            | 0 to +/-50 | +/-51 to +/- 75 | >+/-75 |
| Abnormal Tail                | 0 to +/-50 | +/-51 to +/- 75 | >+/-75 |
| Excess Residual Cytoplasm    | 0 to +/-50 | +/-51 to +/- 75 | >+/-75 |
| Teratozoospermia index (TZI) | 0 to +/-30 | +/-31 to +/- 50 | >+/-50 |

#### C scores:

|                              | Green   | Yellow   | Red |
|------------------------------|---------|----------|-----|
| Morphology                   | 0 to 25 | 25 to 75 | >75 |
| Abnormal Heads               | 0 to 10 | 11 to 20 | >20 |
| Abnormal Midpiece            | 0 to 50 | 51 to 75 | >75 |
| Abnormal Tail                | 0 to 50 | 51 to 75 | >75 |
| Excess Residual Cytoplasm    | 0 to 50 | 51 to 75 | >75 |
| Teratozoospermia index (TZI) | 0 to 30 | 31 to 50 | >50 |

The below penalty box plots show the 95<sup>th</sup>/5<sup>th</sup> centiles used to determine the B & C score limits: B vs.C for Concentration (blue) and Morphology (red).



#### Performance assessment

In essence, an A score of >200 (i.e. red) for two consecutive distributions would raise an unsatisfactory performance flag. However, if the median A score has improved with time (e.g. from Jan 1st 2000) because the "state of the art" of the scheme has improved, then few people will fail this criteria because A scores will generally be lower.

We therefore tend to use either a B score and/or C score failing (red) for 2 consecutive distributions.

We use 4 distributions (16 data points) for the rolling ABC time window. The format is designed so that the performance is determined automatically over a four-distribution period. 'RED' & 'AMBER' labs would then be contacted. (participants who have a red B and/or C score for >2 consecutive distributions). This would not include 'Non returns' which are addressed separately.



# Appendix 2: Performance criteria - limits of acceptable performance in UK NEQAS Reproductive Science

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 RCPath's National Quality Assurance Advisory Panel (NQAAP) for Reproductive Science, on recommendation from the 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.

#### **Andrology (Semen Analysis) Scheme**

#### The 'ABC of EQA'

|     |                                    | Consensus<br>limit | Penalty<br>limit  | B score<br>limit<br>( +/- ) | C score<br>limit |
|-----|------------------------------------|--------------------|-------------------|-----------------------------|------------------|
|     | Semen concentration                |                    |                   | 20                          | 25               |
|     | Sperm morphology                   |                    |                   | <b>75</b>                   | 75               |
|     | Abnormal Heads                     |                    |                   | 20                          | 20               |
|     | Abnormal Midpiece                  |                    |                   | 75                          | 75               |
|     | Abnormal Tails                     |                    |                   | 75                          | 75               |
|     | Excess Residual Cytoplasm          |                    |                   | 75                          | 75               |
|     | Teratozoospermia index (TZI)       |                    |                   | 50                          | 50               |
|     | Sperm motility – Rapid Progressive |                    |                   | 20                          | 40               |
|     | Sperm motility – Slow Progressive  |                    |                   | 50                          | 100              |
|     | Sperm motility – Non-Progressive   |                    |                   | <b>75</b>                   | 140              |
|     | Sperm motility – Immotile          |                    |                   | 20                          | 50               |
|     | Sperm motility – Progressive       |                    |                   | 20                          | 40               |
|     | Interpretive morphology            | 60%                | 16                |                             | .0               |
| Emb | oryology scheme                    | Consensus<br>limit | Penalty<br>limit* | B score<br>limit            |                  |

| Embryology scheme     | Consensus Penalty<br>limit limit* |    | B score<br>limit<br>(+/-) |
|-----------------------|-----------------------------------|----|---------------------------|
| Embryo grading        | 50%                               | 10 | ( /                       |
| Time-lapse annotation | 50%                               |    | 5                         |

\*N.B. only ARCS Embryo Grading System parameters (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.

| V18.0 23/05/2024 | Page 50 of 64   | PRH/DRM/NEQ/001          | Authorised by Peter Goddard |
|------------------|-----------------|--------------------------|-----------------------------|
|                  | Controlled Docu | ment (Photocopies are un | controlled)                 |



#### Appendix 3: ARCS Embryo Morphology Grading System (version 2, April 2017)

Grading system developed with the Association of Clinical Embryologists (ACE) and ratified by Association of Reproductive Clinical Scientists (ARCS) in 2020.

#### Cleavage stage embryo grading system

Assess blastomere number followed by grading of blastomere size and degree of fragmentation.

|        | First assess blastomere number   |               |
|--------|--|---------------|
|        |  | _             |
| Grades | Blastomere size  | Fragmentation |
| 4      | Same as ideal stage specific embryo*   | <10%          |
| 3      | Stage specific size for majority of blastomeres (i.e. slightly uneven sizes) | 10-20%        |
| 2      | Majority of blastomeres different sizes                                      | >20-50%       |
| 1      | Not stage specific   | >50%          |

<sup>\*</sup>Please see figure 1

#### Blastocyst stage embryo grading system

| Expansion Score | Expansion status   | ICM/ TE score* | Inner Cell Mass<br>(ICM)**  | Trophectoderm (TE)**                               |
|-----------------|--|----------------|---|--|
| 6               | Hatched blastocyst (the blastocyst has evacuated the ZP)                 |                |   |  |
| 5               | Hatching blastocyst (trophectoderm has started to herniate through ZP)   |                |   |  |
| 4               | Expanded (blastocoel volume larger than the embryo, with thinning of ZP) | А              | ICM prominent, easily seen, tightly adhered compacted cells                                 | Continuous layer of small identical cells          |
| 3               | Full blastocyst (blastocoel completely fills embryo)                     | В              | ICM less prominent<br>(cells appear<br>compacted and larger<br>in size, loosely<br>adhered) | Fewer cells with gaps, not continuous              |
| 2               | Blastocyst (blastocoel >50% volume of embryo)                            | С              | Very few cells visible (cells similar to TE)  | Fewer small cells with large cells, not continuous |
| 1               | Early blastocyst (blastocoel <50% volume of embryo)                      | D              | No visible cells or visible cells are degenerate or necrotic                                | Sparse cells,<br>large/flat/degenerate             |

<sup>\*</sup>A numerical score from 4 to 1 may be used for statistical purposes or where a 'cumulative' score is required e.g. where 4=A etc.

<sup>\*\*</sup> see Figure 2



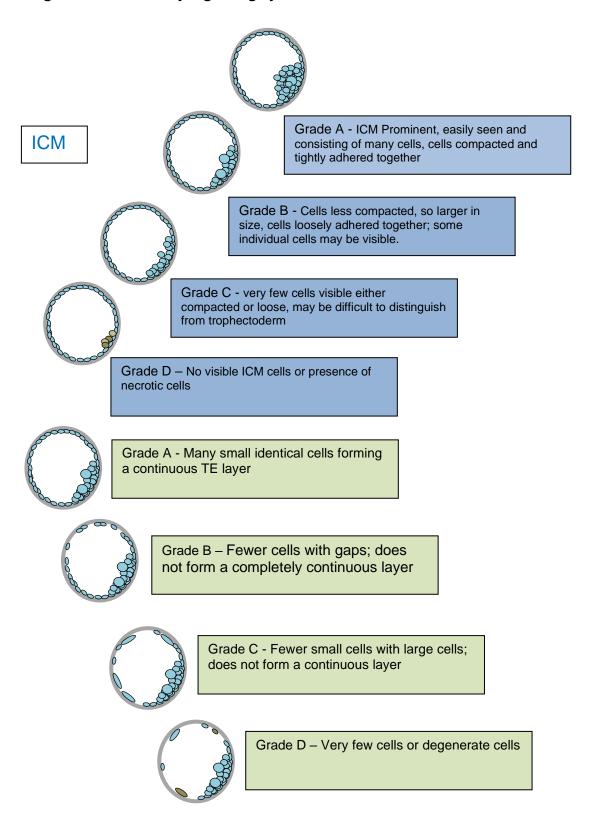
# Reproductive Science

Figure 1: The diagram below gives an illustration of the cell sizes in idealised embryos

| 1-cell |  |
|--------|--|
| 2-cell |  |
| 3-cell |  |
| 4-cell |  |
| 5-cell |  |
| 6-cell |  |
| 7-cell |  |
| 8-cell |  |

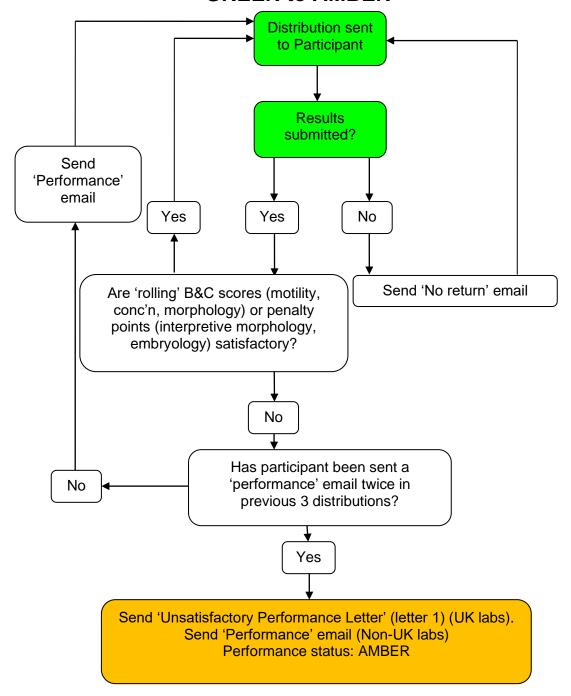


Figure 2: The blastocyst grading system is illustrated below



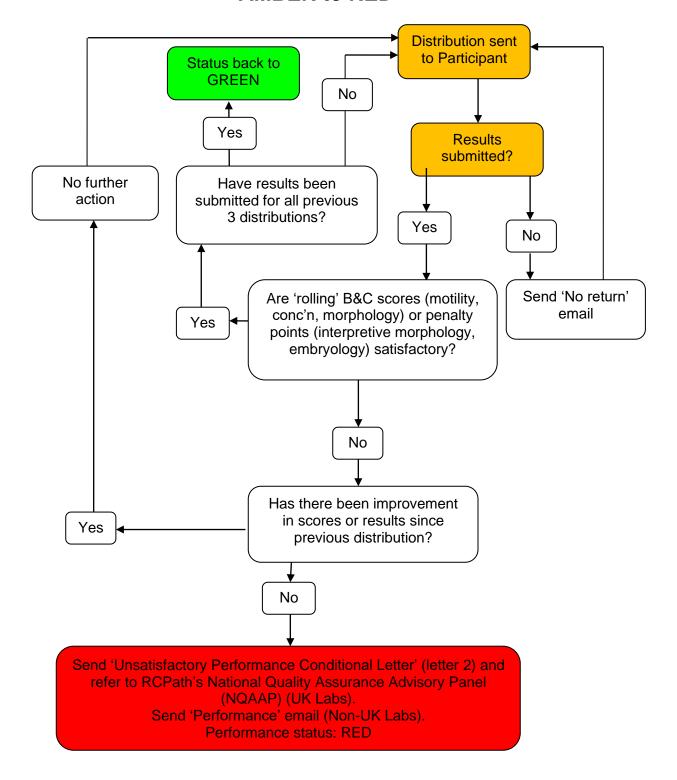


# Appendix 4: Performance in UK NEQAS Reproductive Science Schemes GREEN to AMBER



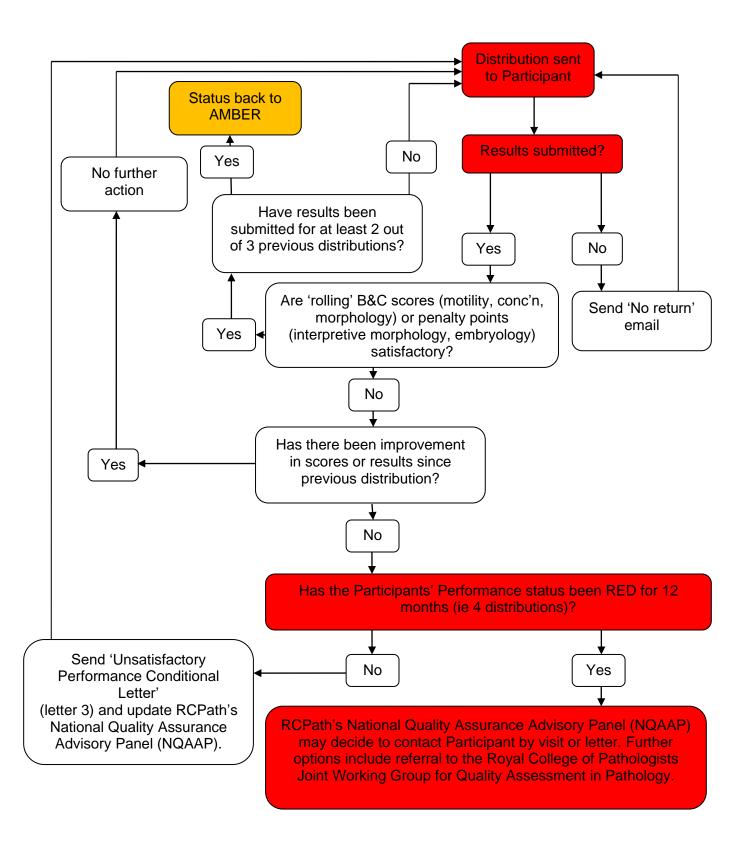


# Performance in UK NEQAS Reproductive Science Schemes AMBER to RED





# Performance in UK NEQAS Reproductive Science Schemes RED (UK Labs only)





## Reproductive Science

#### Appendix 5: UK NEQAS Reproductive Science terms and conditions of EQA participation.

V4.0 April 2023

- 1. The UK National External Quality Assessment Services for Reproductive Science (UK NEQAS RS), herein known as the Scheme, are hosted by Manchester University NHS Foundation Trust (MFT) who are the legal entity.
- 2. Samples distributed as part of the Scheme should be treated, handled, and disposed of as if they were clinical specimens. Participants must ensure that their laboratory facilities and expertise are adequate to ensure the safe handling of these specimens during their participation in the Scheme.
- 3. Membership of the Scheme starts on 1st April each year and continues until 31st March in the next year. If a participant joins part way through the annual period, a reduced fee may be payable reflecting the proportion of the annual service to be supplied for that part year. A participant may withdraw from the Scheme at any time, but no refund will be given of fees paid. UK NEQAS RS may amend the design of Schemes during the year and reserves the right to suspend services which are dependent on supply of clinical materials.
- 4. Each laboratory will be registered under a unique code number, which is common across UK NEQAS centres in the case of UK NEQAS services. The fact of participation, identifiable raw data and identifiable performance scores are confidential to the participant and will not be released by the Scheme Organiser to third parties other than under any agreed and defined mechanism for providing counselling to 'unsatisfactory performers. All participants offering a direct or indirect clinical service in the UK are subject to the Royal College of Pathologists Quality Assurance Pathology Committee (QAPC) conditions of EQA Scheme Participation. Participants are free to share information concerning their own individual participation or performance with individual clients without consultation (but not for advertising).
- 5. All reports, and the data they contain, issued by the Scheme are Copyright and may not be distributed, published, or used for promotion in any form without permission of the Scheme Organiser.
- 6. In the event of a participant failing to pay the membership fee by the due date the Scheme Organiser reserves the right to terminate, without notice, the membership of that participant without prejudice to any claim for payment for services already provided.
- 7. MFT and UK NEQAS RS shall not be liable in any circumstances for indirect or consequential loss howsoever caused, including, without limitation, loss of anticipated profits, goodwill, reputation, business receipts or contracts, or losses or expenses resulting from third party claims.
- 8. Participants in the Scheme have entire responsibility for all samples distributed to them under the Scheme and all activities carried out by them or any third party in relation to the samples from the time of their receipt.
- 9. 9 MFT and UK NEQAS RS warrant that all work carried out by it in relation to the Scheme will be carried out using all reasonable care and skill. All conditions, terms and warranties implied by common law, statute or otherwise are, to the extent permitted by law, hereby excluded.
- 10. The liability of MFT and UK NEQAS RS to the participant in any annual period resulting from or in connection with the provision of the Scheme by MFT and UK NEQAS RS to the participant shall under no circumstances exceed the amount of the annual fee paid by the participant in respect of that annual period.
- 11. Data provided to UK NEQAS RS by participants will be used solely for dealing with your UK NEQAS participation. UK NEQAS RS has a Privacy Policy which is available from our website. Your data will be stored in accordance with this policy.
- 12. Enrolment in the Scheme is not evidence that a laboratory is correctly performing reproductive science techniques to relevant recognised national or international standards (eg WHO, ISO, HFEA, ARCS)
- 13. Collusion between participants and falsification of results is not permitted.
- 14. Participants will be informed of changes to Scheme design or operation by email. This would also be reflected in the Participants' Handbook.
- 15. These conditions shall be governed by and construed in accordance with English law, and MFT and the participant submit to the exclusive jurisdiction of the English Courts.



#### Appendix 6: FREQUENTLY ASKED QUESTIONS (FAQ)

#### Q: How do I know when to expect the survey material?

A: You should have received a scheme leaflet that contains a schedule at registration or re-registration. A schedule can also be found on the website: <a href="https://mft.nhs.uk/saint-marys/services/gynaecology/reproductive-medicine/ukneqasreproductive-science/">https://mft.nhs.uk/saint-marys/services/gynaecology/reproductive-medicine/ukneqasreproductive-science/</a>

#### Q: What do I do if my specimens don't arrive when expected?

A: If they haven't arrived within 5 working days (UK Labs) after the published distribution date, you should contact the Scheme for advice. For overseas participants it is difficult to predict how long it will take to arrive by post. If overseas labs have difficulties, it may be worth considering using a courier service.

#### Q: What do I do if I miss the closing date?

A: Unfortunately, we are unable to accept late results. Please email the scheme at <a href="repscience@ukneqas.org.uk">repscience@ukneqas.org.uk</a> giving an explanation as to why the materials were not processed in time (please quote your UK NEQAS ID number).

#### Q: What do I do if the sample quality is unsatisfactory or if I break the samples?

A: Contact the Scheme on <a href="repscience@ukneqas.org.uk">repscience@ukneqas.org.uk</a> or +44 (0) 161 276 6437 to request a repeat sample. You will need to give for your ID number and the reason for your request.

#### Q: What do I do if I cannot find or have forgotten my UK NEQAS ID or password?

A: Email the Scheme at <a href="mailto:repscience@ukneqas.org.uk">repscience@ukneqas.org.uk</a> . If you are not the main contact, your email request will need to be copied to the main contact, so we can release an ID or password.

#### Q: What do I do if I cannot find or have forgotten my gamete-expert.com password?

A: Go to the <a href="http://gamete-expert.com/morphology/login-password-forgotten.html">http://gamete-expert.com/morphology/login-password-forgotten.html</a> and enter your email address. If you do not receive contact within 24 hours email <a href="mailto:repscience@ukneqas.org.uk">repscience@ukneqas.org.uk</a>.

#### Q: Can I change my password details?

A: You are supplied with a randomly generated password; you may change this on request, however there are some restrictions, e.g. the password must be at least 7 characters long and contain a mixture of alpha and numeric characters.

#### Q: Other EQA schemes are available. Why should I participate in UK NEQAS?

A: UK NEQAS has over 50 years of experience in offering EQA schemes. Our Semen analysis and Embryology schemes are accredited by UKAS to ISO 17043:2010 standards.

# Q: The method/sub method I am using for concentration/morphology is not on the list on the 'results and reports' website. What do I do?

A: Contact us at repscience@ukneqas.org.uk and give us the details of the method. We can then update our lists.

#### Q: Why do we have two morphology schemes?

A: The 'practical' morphology scheme mimics the processing, analysing and reporting for morphology that you do in the laboratory. The interpretive morphology scheme compliments this by asking participants to assess the same images of sperm. Over time this should make morphology reporting more consistent.

#### Q: We do not report morphology, can we opt out of this analyte?

A: No. The WHO guidelines define Semen Analysis as including concentration, motility and morphology so it is an important part of the test. UK NEQAS cannot give an 'opt out'. If you do not return results you will have to justify to your institution and regulatory body (e.g. UKAS, HFEA)

#### Q: At what stage of the time lapse should I grade my blastocyst?

A: During the time lapse video the required Day and hours required for assessment will be displayed on screen.

#### Q: What support is available if results fall below expected values?

A: Scheme staff can offer advice on all aspects of the schemes. Please read the below section on troubleshooting and if you can't find an answer email repscience@uknegas.org.uk or phone +44 (0) 161 276 6437 quoting your lab ID number.

#### Q: There is aggregation in my UK NEQAS semen sample, will it affect my results?

A: All UK NEQAS samples should be mixed on a vortex mixer for up to a minute before analysing. If aggregation persists it should be ignored and testing performed as normal. Ongoing studies show that it is an artefact and does not adversely affect results. Repeat sets are available if participants are concerned.



# **Performance troubleshooting:**

#### Q: My performance in Semen concentration is unsatisfactory, what can I do?

A: First you need to establish if this is a one-off event or an ongoing problem. To do this you need to look at your 'rolling time window' results. It would then be worth considering:

- Were unsatisfactory results due to non-analytical problems (e.g. non return of results, input error, dilution error)?
- Were the samples mixed thoroughly using a vortex mixer (recommended)?
- Were the samples stored at 2-8°C when not in use?
- Were the counting chambers calibrated recently (where applicable)?
- Were the dilution pipettes calibrated recently (where applicable)?
- Were positive displacement pipettes used (where applicable)?

If further assistance is required, contact repscience@uknegas.org.uk quoting your UK NEQAS ID number.

#### Q: My performance in practical morphology is unsatisfactory, what can I do?

A: First you need to establish if this is a one-off event or an ongoing problem. To do this you need to look at your 'rolling time window' results. It would then be worth considering:

- Were unsatisfactory results due to non-analytical problems (e.g. non return of results, input error, reporting of 'Abnormal' forms)?
- Were the samples mixed thoroughly using a vortex mixer (recommended)?
- Were the slides stained using a recognised staining method for morphology?
- Were the slides assessed using a recognised method (e.g. WHO 6th edition)?
- Did the microscope have an integral graticule for measuring sperm?
- Were 'interpretive morphology' results also unsatisfactory (this may pinpoint a problem in assessment)?

If further assistance required contact repscience@ukneqas.org.uk quoting your ID number

#### Q: My performance in Sperm motility is unsatisfactory, what can I do?

A: First you need to establish if this is a one-off event or an ongoing problem. To do this you need to look at your 'rolling time window' results. It would then be worth considering:

- Were unsatisfactory results due to non-analytical problems (e.g. input error)?
- Were videos assessed using WHO criteria?

If further assistance required contact repscience@ukneqas.org.uk quoting your ID number

#### Q: My performance in Interpretive morphology is unsatisfactory, what can I do?

A: First you need to establish if this is a one-off event or an ongoing problem. To do this you need to look at your 'rolling time window' results. It would then be worth considering:

- Were unsatisfactory results due to non-analytical problems (e.g. input error)?
- Were 'practical' morphology results also unsatisfactory (this may pinpoint a problem in assessment)?

If further assistance required contact repscience@uknegas.org.uk quoting your ID number

#### Q: My performance in Embryology is unsatisfactory, what can I do?

A: First you need to establish if this is a one-off event or an ongoing problem. To do this you need to look at your 'rolling time window' results. It would then be worth considering:

- Were unsatisfactory results due to non-analytical problems (e.g. input error)?
- Were embryos assessed using the recognised UK NEQAS/ARCS criteria (see appendix 3)?

If further assistance required contact <a href="mailto:repscience@ukneqas.org.uk">repscience@ukneqas.org.uk</a> quoting your ID number



#### Appendix 7: Embryo time-lapse annotation analyte

This part of the Embryology scheme was launched April 2016 and is an extension to the time-lapse images used for Patient 4 blastocyst grade assessment.

For 'Schedule of Analytes, see Participants' Handbook, page 21.

#### **Time Lapse Annotation**

Taken from: Proposed guidelines on the nomenclature and annotation of dynamic human embryo monitoring by a time-lapse user group H. Nadir Ciray1, †, \*, Alison Campbell2, †, Inge Errebo Agerholm3, Jesu's Aguilar4, Sandrine Chamayou5, Marga Esbert6, and Shabana Sayed7, for The Time-Lapse User Group. Human Reproduction, Vol.29, No.12 pp. 2650–2660, 2014

- 1. **tPNf:** The time when both (or the last) PN disappear. This annotation is made at the first frame whereby the embryo is still at the 1-cell stage but pronuclei can no longer be visualized.
- **2. t2:** The time of the first cell cleavage, or mitosis. t2 is the first frame at which the two blastomeres are completely separated by individual cell membranes.
- **3. t3:** The first observation of three discrete cells. The three cells stage marks initiation of the second round of cleavage.
- 4. T4: The first observation of four discrete cells.
- **5. T5:** The first observation of five discrete cells.
- **6. T8:** The first observation of eight discrete cells.
- 7. tSC (From distribution 97): The first frame in which evidence of compaction is present; the initial frame that any (two) cells start to compact is observed. (The precise timing of initiation of compaction may be difficult to observe due to the increased number of cells and the type of compaction (partial or complete).
  - N.B Previously tM (April 2017- March 2018): This marks the end of the compaction process; when observable compaction is complete. The morula may be fully or partially compacted, where f is full and p is partial; the morula has excluded material.
- 8. tSB ¼ initiation/start of blastulation. The first frame when initiation of a cavity formation is observed.
- 9. tB full blastocyst. The last frame before the zona pellucida starts to thin.



#### Appendix 8: Standard Distribution Letters for D121 to D124

Distribution letters are no longer be printed. A QR code link for this information will be attached to the semen samples each distribution and a copy of the below letter emailed to the named contact.

Department of Reproductive Medicine

Saint Mary's Hospital

Oxford Road Manchester M13 9WL United Kingdom

Telephone: 0161 276 6437

e-mail: repscience@ukneqas.org.uk

Dear Participants Please note date samples received below:

#### **Andrology Scheme - Distribution**

Distribution 121 consists of:

- Semen samples S481, S482, S483 and S484 for Concentration and Morphology assessment.
- Sperm Motility (four video samples) hosted online by <a href="http://gamete-expert.com">http://gamete-expert.com</a> .
- Interpretive Morphology (images of 24 sperm) hosted online by <a href="http://gamete-expert.com">http://gamete-expert.com</a>.

Please submit results for ALL these components.

Samples and images should be processed as soon as possible after receipt using the same methods used for your patient samples (where possible). Methods used should be referenced to current recognised guidelines (e.g. WHO laboratory manual for the examination and processing of human semen 6th edition (2021).

Check samples on receipt to be sure that the correct samples are in the pack and there is no damage to the ampoules. Please inform us if your package appears to have been damaged in transit. Contact <a href="mailto:repscience@ukneqas.org.uk">repscience@ukneqas.org.uk</a> immediately for replacement samples.

If you are not aware of your online Motility/Morphology Username and password or have trouble viewing the distribution, please contact us at <a href="mailto:repscience@ukneqas.org.uk">repscience@ukneqas.org.uk</a> immediately.

Closing date for result entry is 10<sup>th</sup> June 2024.

All semen samples should be well mixed (vortexed for up to a minute) before analysis as specimen may have settled in transit.

All semen samples contain 10% formalin, added as a preservative. When performing the concentration this inclusion of formalin should be ignored and treated as neat semen. You should employ all your usual safety measures and dispose of the specimens in accordance with your usual clinical waste disposal procedure.

#### Result entry and reporting

Concentration results should be reported to 2 significant figures and motility and 'practical' morphology results should be reported to the nearest whole number (as stated in WHO manual 2021).

The statistics package can only view numbers, and so it is not possible to enter, for example, a result shown as <2 million. In this case your result should be entered as 2 million.

Concentration and Morphology - online at <a href="https://results.ukneqas.org.uk">https://results.ukneqas.org.uk</a> (or alternatively via <a href="https://results.ukneqas.org.uk">https://results.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukne

**Online Motility and Morphology** – view online and input results at <a href="http://gamete-expert.com">http://gamete-expert.com</a> , results entered can be altered up until the deadline. All labs have been allocated a username and can request a password from the website login page. After the distribution closes UK NEQAS reports can be viewed at <a href="https://results.ukneqas.org.uk">https://results.ukneqas.org.uk</a>

Links to both these websites can be found on the Reproductive Science pages via http://www.uknegas.org.uk

Yours sincerely

Mr Peter Goddard Reproductive Science EQA Scheme Manager 13<sup>th</sup> May 2024



Telephone: 0161 276 6437

e-mail: <a href="mailto:repscience@ukneqas.org.uk">repscience@ukneqas.org.uk</a>

Department of Reproductive Medicine Saint Mary's Hospital Oxford Road Manchester M13 9WL United Kingdom

Dear Participants

Please note date samples received below:

#### Andrology Scheme - Distribution

Distribution 122 consists of:

- Semen samples S485, S486, S487 and S488 for Concentration and Morphology assessment.
- Sperm Motility (four video samples) hosted online by <a href="http://gamete-expert.com">http://gamete-expert.com</a> .
- Interpretive Morphology (images of 24 sperm) hosted online by <a href="http://gamete-expert.com">http://gamete-expert.com</a>.

Please submit results for ALL these components.

Samples and images should be processed as soon as possible after receipt using the same methods used for your patient samples (where possible). Methods used should be referenced to current recognised guidelines (e.g. WHO laboratory manual for the examination and processing of human semen 6th edition (2021).

Check samples on receipt to be sure that the correct samples are in the pack and there is no damage to the ampoules. Please inform us if your package appears to have been damaged in transit. Contact <a href="mailto:repscience@ukneqas.org.uk">repscience@ukneqas.org.uk</a> immediately for replacement samples.

If you are not aware of your online Motility/Morphology Username and password or have trouble viewing the distribution, please contact us at <a href="mailto:repscience@ukneqas.org.uk">repscience@ukneqas.org.uk</a> immediately.

Closing date for result entry is 09th September 2024.

All semen samples should be well mixed (vortexed for up to a minute) before analysis as specimen may have settled in transit.

All semen samples contain 10% formalin, added as a preservative. When performing the concentration this inclusion of formalin should be ignored and treated as neat semen. You should employ all your usual safety measures and dispose of the specimens in accordance with your usual clinical waste disposal procedure.

#### Result entry and reporting

Concentration results should be reported to 2 significant figures and motility and 'practical' morphology results should be reported to the nearest whole number (as stated in WHO manual 2021).

The statistics package can only view numbers, and so it is not possible to enter, for example, a result shown as <2 million. In this case your result should be entered as 2 million.

**Concentration and Morphology** - online at <a href="https://results.ukneqas.org.uk">https://results.ukneqas.org.uk</a> (or alternatively via <a href="https://results.ukneqas.org.uk">https://results.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.uk

Online Motility and Morphology – view online and input results at <a href="http://gamete-expert.com">http://gamete-expert.com</a>, results entered can be altered up until the deadline. All labs have been allocated a username and can request a password from the website login page. After the distribution closes UK NEQAS reports can be viewed at <a href="https://results.ukneqas.org.uk">https://results.ukneqas.org.uk</a>

Links to both these websites can be found on the Reproductive Science pages via http://www.uknegas.org.uk

Yours sincerely

Mr Peter Goddard

Reproductive Science EQA Scheme Manager

12th August 2024

V18.0 23/05/2024



Telephone: 0161 276 6437

e-mail: repscience@ukneqas.org.uk

Department of Reproductive Medicine Saint Mary's Hospital Oxford Road Manchester M13 9WL United Kingdom

Please note date samples received below:

Dear Participants

#### **Andrology Scheme - Distribution**

Distribution 123 consists of:

- Semen samples S489, S490, S491 and S492 for Concentration and Morphology assessment.
- Sperm Motility (four video samples) hosted online by <a href="http://gamete-expert.com">http://gamete-expert.com</a>
- Interpretive Morphology (images of 24 sperm) hosted online by <a href="http://gamete-expert.com">http://gamete-expert.com</a>.

Please submit results for ALL these components.

Samples and images should be processed as soon as possible after receipt using the same methods used for your patient samples (where possible). Methods used should be referenced to current recognised guidelines (e.g. WHO laboratory manual for the examination and processing of human semen 6th edition (2021).

Check samples on receipt to be sure that the correct samples are in the pack and there is no damage to the ampoules. Please inform us if your package appears to have been damaged in transit. Contact <a href="mailto:repscience@ukneqas.org.uk">repscience@ukneqas.org.uk</a> immediately for replacement samples.

If you are not aware of your online Motility/Morphology Username and password or have trouble viewing the distribution, please contact us at <a href="mailto:repscience@ukneqas.org.uk">repscience@ukneqas.org.uk</a> immediately.

Closing date for result entry is 02nd December 2024.

All semen samples should be well mixed (vortexed for up to a minute) before analysis as specimen may have settled in transit.

All semen samples contain 10% formalin, added as a preservative. When performing the concentration this inclusion of formalin should be ignored and treated as neat semen. You should employ all your usual safety measures and dispose of the specimens in accordance with your usual clinical waste disposal procedure.

#### Result entry and reporting

Concentration results should be reported to 2 significant figures and motility and 'practical' morphology results should be reported to the nearest whole number (as stated in WHO manual 2021).

The statistics package can only view numbers, and so it is not possible to enter, for example, a result shown as <2 million. In this case your result should be entered as 2 million.

Concentration and Morphology - online at <a href="https://results.ukneqas.org.uk">https://results.ukneqas.org.uk</a> (or alternatively via <a href="https://results.ukneqas.org.uk">https://results.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukneqas.org.ukne

**Online Motility and Morphology** – view online and input results at <a href="http://gamete-expert.com">http://gamete-expert.com</a> , results entered can be altered up until the deadline. All labs have been allocated a username and can request a password from the website login page. After the distribution closes UK NEQAS reports can be viewed at <a href="https://results.ukneqas.org.uk">https://results.ukneqas.org.uk</a>

Links to both these websites can be found on the Reproductive Science pages via http://www.uknegas.org.uk

Yours sincerely

Mr Peter Goddard

Reproductive Science EQA Scheme Manager

04<sup>th</sup> November 2024

V18.0 23/05/2024



Telephone: 0161 276 6437

e-mail: repscience@uknegas.org.uk Department of Reproductive Medicine Saint Mary's Hospital Oxford Road Manchester M13 9WL United Kingdom

| ear Participants   | Please note date samples received below: |
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| and the second of the second o | / /                                      |

#### Andrology Scheme - Distribution

Distribution 124 consists of:

Dear Participants

- Semen samples S493, S494, S495 and S496 for Concentration and Morphology assessment.
- Sperm Motility (four video samples) hosted online by <a href="http://gamete-expert.com">http://gamete-expert.com</a> .
- Interpretive Morphology (images of 24 sperm) hosted online by http://gamete-expert.com .

Please submit results for ALL these components.

Samples and images should be processed as soon as possible after receipt using the same methods used for your patient samples (where possible). Methods used should be referenced to current recognised guidelines (e.g. WHO laboratory manual for the examination and processing of human semen 6th edition (2021).

Check samples on receipt to be sure that the correct samples are in the pack and there is no damage to the ampoules. Please inform us if your package appears to have been damaged in transit. Contact repscience@uknegas.org.uk immediately for replacement samples.

If you are not aware of your online Motility/Morphology Username and password or have trouble viewing the distribution, please contact us at repscience@ukneqas.org.uk immediately.

Closing date for result entry is 03rd March 2025.

All semen samples should be well mixed (vortexed for up to a minute) before analysis as specimen may have settled in transit.

All semen samples contain 10% formalin, added as a preservative. When performing the concentration this inclusion of formalin should be ignored and treated as neat semen. You should employ all your usual safety measures and dispose of the specimens in accordance with your usual clinical waste disposal procedure.

#### Result entry and reporting

Concentration results should be reported to 2 significant figures and motility and 'practical' morphology results should be reported to the nearest whole number (as stated in WHO manual 2021).

The statistics package can only view numbers, and so it is not possible to enter, for example, a result shown as <2 million. In this case your result should be entered as 2 million.

Concentration and Morphology online at https://results.uknegas.org.uk (or alternatively via http://www.birminghamquality.org.uk) all labs will have been allocated a user name and password. When entering results please ensure you click the submit button after both motility and concentration/morphology. A printable confirmation of submission will appear.

Online Motility and Morphology - view online and input results at <a href="http://gamete-expert.com">http://gamete-expert.com</a>, results entered can be altered up until the deadline. All labs have been allocated a username and can request a password from the website login page. After the distribution closes UK NEQAS reports can be viewed at https://results.ukneqas.org.uk

Links to both these websites can be found on the Reproductive Science pages via http://www.uknegas.org.uk

Yours sincerely

Mr Peter Goddard

Reproductive Science EQA Scheme Manager

03rd February 2025

V18.0 23/05/2024