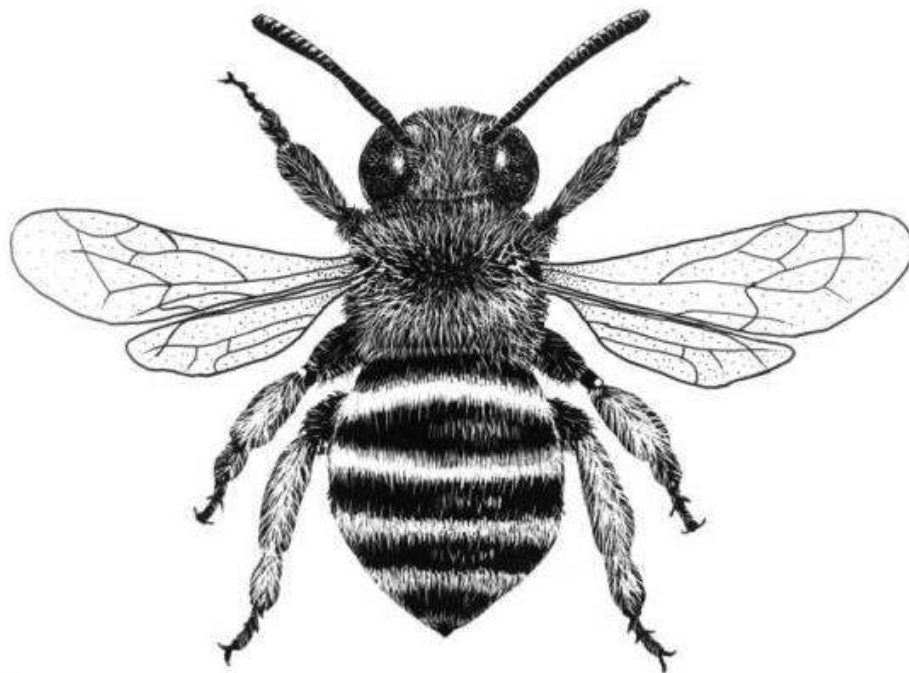


UK NEQAS

Reproductive Science

Participants' Handbook Reproductive Science Schemes



UK NEQAS

Reproductive Science

The bee pictured on the cover was adopted by the UK NEQAS Reproductive Science scheme as its logo in March 2013. As part of harmonisation within UK NEQAS it was felt that different schemes should adopt a logo to assist participants in directing follow-up 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 has its connections in reproduction in the old English language euphemism "The birds and the bees".

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

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Manchester. M13 9WL
United Kingdom

Web: <http://www.cmft.nhs.uk/ukneqasrepsci.aspx>

Tel No: +44 (0) 161 276 6437

Fax No: +44 (0) 161 276 6609

The telephone is staffed between the hours of 08:30 and 16:00 Monday to Friday with an answering machine to pick up all messages outside these times.

Callers will be asked the nature of their request or enquiry and transferred to the appropriate member of staff. Participants are requested to give their Laboratory Code Number when contacting the Centre. All calls and the actions taken are logged.

Scheme Organiser:	Dr. Diane Critchlow
Deputy Scheme Organiser:	Mrs. Helen Hunter
Scheme Manager:	Mr. Peter Goddard
Scheme Administrator	Mrs. Diane Shearden
Scheme Quality Manager	Miss. Justine Hartley
Scheme Training Officer	Mr. Mike Hooper
Scheme H&S Adviser	Mr. Peter Goddard

Email: repscience@ukneqas.org.uk
diane.critchlow@cmft.nhs.uk
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UK NEQAS

Reproductive Science

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UK NEQAS

Reproductive Science

Getting Started – Semen concentration & morphology

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



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

Store between 2-8°C when not in use.

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 (e.g. WHO laboratory manual for the examination and processing of human semen 5th edition).

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. If for any reason the samples are damaged or unsuitable for processing, please contact us at repscience@ukneqas.org.uk and request a repeat set.

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



Go to Semen analysis “Result” tab.

This will automatically bring you to the ‘latest’ distribution.

UK NEQAS

Reproductive Science

UKNEQAS
United Kingdom National External Quality Assessment Schemes

Results Entry

Laboratory: _____
 Scheme: UK NEQAS for Semen Analysis
 Distribution: 77
 Date of receipt: 13-05-2013
 Return result: 10-06-2013

Method details: Sperm concentration, Sperm morphology
 Submethod details: _____

Specimen	S305	S306	S307	S308
Sperm concentration				
Sperm morphology				

Submit Cancel

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 should take 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.

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).

UKNEQAS
United Kingdom National External Quality Assessment Schemes

Report or Results Selection

Lab: _____ Laboratory: _____

Centre: UK NEQAS Manchester

Scheme	Report	Dist	Result	Latest
UK NEQAS for Semen Analysis	Report	Dist	Result	Latest
UK NEQAS for Semen Analysis	Report	Dist	Result	Latest
UK NEQAS for Sperm Antibody Detection	Report	Dist	Result	Latest
UK NEQAS for Online Sperm Motility	Report	Dist	Result	Latest
UK NEQAS Interpretive Morphology Scheme	Report	Dist	Result	Latest

For the latest distribution results click on the 'Report' tab for Semen Analysis. This will display a pdf 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.

UKNEQAS for Semen Analysis
 Distribution: 76 Date: 11-Mar-2013
 Laboratory: _____ Page 1 of 5

Distribution Summary

Specimen	Result	Target	Specimen Value	A score	B score	C score	A	B	C	
Sperm concentration (million/mL)	S301	50	40.37	+23.8	43	+5.7	14.3	●++	●+	●++
	S302	70	67.46	+3.8						
	S303	75	75.45	+0.7						
	S304	6	6.38	-5.8						
Sperm morphology (% normal)	S301	3	-4.77	-37.1	79	-39.4	31.3	●+	●+	●++
	S302	5	5.58	-10.3						
	S303	4	5.31	-21.7						
	S304	3	-3.42	-12.3						

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

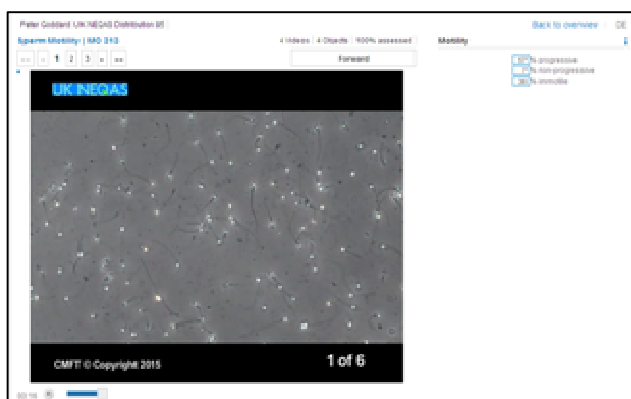
Getting Started – Sperm motility

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



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

Processing:



The first video should appear and show between 6-8 fields each around 20 seconds long.

Analyse the video as you would a patient's sample (Note: results can only be entered as per WHO manual 5th edition, i.e. Progressive, Non-progressive and Immotile sperm)

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

Select 'back to overview'

Please check that your overview '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 a week of close of distribution).

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).

UK NEQAS

Reproductive Science




For the latest distribution results click on the 'Report' tab for Sperm motility. This will display a pdf 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.

 UK NEQAS Reproductive Science		UKNEQAS for Sperm Motility						Laboratory :		
		Distribution : 76		Date : 11-Mar-2013				Page 1 of 8		
Distribution Summary										
	Specimen	Result	Target	Specimen %bias	A score	B score	C score	A	B	C
Progressive Motility (%)	MO277	64	65.47	-2.2	97	-1.5	12.7	↔	↗	↔
	MO278	67	67.90	-1.3						
	MO279	61	58.57	+4.1						
	MO280	70	67.75	+3.3						
Non Progressive (%)	MO277	13	9.78	+32.9	99	-12.8	49.8	↔	↔	↔
	MO278	6	5.59	+7.3						
	MO279	8	11.13	-28.2						
	MO280	3	5.57	-46.1						
Immotile (%)	MO277	23	24.55	-6.3	80	+3.6	17.0	↔	↘	↔
	MO278	27	26.28	+2.7						
	MO279	31	29.53	+5.0						
	MO280	27	26.19	+3.1						

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

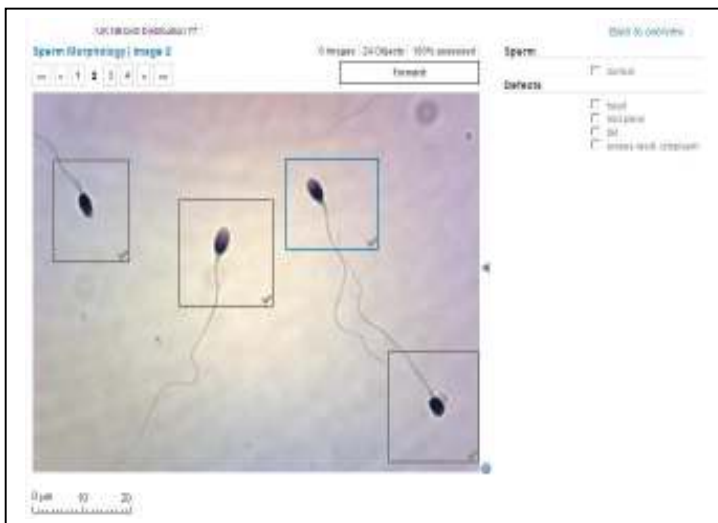
Getting Started – Interpretive morphology

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



In the Sperm motility '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.

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

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

Please check that your overview '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

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

UK NEQAS

Reproductive Science



For the latest distribution results click on the 'Report' tab for Interpretive Morphology. This will display a pdf of the report.

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

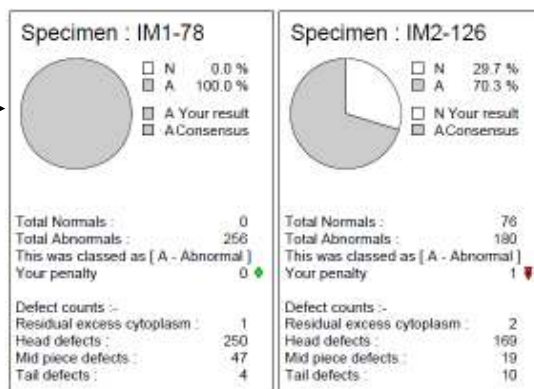
Page 1 of the report summarises the results and any penalty points gained:

UKNEQAS		Interpretive Morphology Scheme	Laboratory :	
UK NEQAS Reproductive Science		Distribution : 84	Date : 09-Mar-2015	
		Page 1 of 4		
Distribution Summary				
The Performance traffic light is calculated over a four distribution time window.				
Images with consensus of less than 60% are unclassified and therefore a target will not be listed.				
Specimen	Result	Target	Penalty	Performance
IM1-78	N	A	1	10
IM1-77	A	A	10	10
IM1-79	A	A	10	10
IM2-126	N	A	1	10
IM2-127	A	A	10	10
IM2-128	A	A	10	10
IM3-48	A	A	10	10
IM3-47	A	A	10	10
IM3-49	N	N	10	10
IM4-50	A	A	10	10
IM4-51	A	A	10	10
IM4-52	A	A	10	10
IM4-53	A	A	10	10
IM4-54	A	A	10	10
IM4-55	A	A	10	10
IM4-56	A	A	10	10
IM4-57	A	A	10	10
IM4-58	A	A	10	10
IM4-59	A	A	10	10
IM5-239	A	A	10	10
IM5-237	A	A	10	10
IM5-238	N	N	1	10
IM5-239	N	A	1	10
IM5-244	A	A	10	10
IM5-245	A	A	10	10
IM5-247	A	A	10	10
IM7-384	A	A	10	10
IM7-385	A	A	10	10
IM7-386	A	A	10	10

The Performance traffic light is calculated over a four distribution time window.

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

In this image your result agreed with the consensus (>60%) and so no penalty was given.



In this image your result disagreed with the consensus and so a one point penalty was given.

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

Getting Started – Embryo morphology

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



In the Embryos Patient 1 'box' select 'Assessment'.

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 UK NEQAS Grading Scheme – click on the 'i' for information or visit <http://www.cmft.nhs.uk/ukneqasrepsci.aspx>

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 other 'Embryo patients'.

Please check that your overview '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

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

UK NEQAS

Reproductive Science

For the latest distribution results click on the 'Report' tab for Embryology. This will display a pdf 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

Further information about performance criteria and interpretation of results can be found elsewhere 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 penalty scores represented as traffic lights

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 (i.e. quality parameters are **excluded** from this graph). A rolling average of penalties (over 4 distributions) is used.

Reproductive Science Scheme – Participants' Handbook

Schemes provided

SCHEME

Andrology (Semen analysis)

ANALYTES

Semen Concentration (practical)

Sperm Morphology (practical)

Sperm Motility (online)

Interpretive Sperm Morphology (online)

Embryology

Embryo Morphology (online)

Contacting the scheme

Details of how to get in touch with the scheme are detailed on page 2.

Scheme objectives

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.

UK NEQAS Reproductive Science is part of the Department of Reproductive Medicine, St. Mary's Hospital, Manchester. There is a close working relationship between the Reproductive Medicine laboratories and the EQA scheme.

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

Various aspects of the EQA Scheme are subcontracted to competent providers. UK NEQAS Reproductive Science is responsible for this work.

UK NEQAS Code of Practice

Please see UK NEQAS website to access the Code of Practice (www.ukneqas.org.uk).

<http://www.ukneqas.org.uk/content/PageServer.asp?S=1037777698&C=1252&Type=G&ID=65>

External Oversight of our EQA Services

CPA (UK) Ltd Accreditation

The Andrology scheme has full CPA accreditation. The Embryology scheme applied for accreditation in 2012.

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.

UK NEQAS

Reproductive Science

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 an Andrology Steering Committee (ASC) and an Embryology Steering Committee (ESC) which advises on overall policy matters and provides external scientific advice.

National Quality Assurance Advisory Panels

UK NEQAS Reproductive Science reports to the National Quality Assurance Advisory Panel (NQAAP) for Reproductive Science.

The names of ASC, ESC and Panel members are available on the

<http://www.cmft.nhs.uk/uknegasrepsci.aspx> for any participants who wish to express comments or concerns about our schemes and their operation.

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, i.e. 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 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 (fifth edition), can be found here:

<http://www.who.int/reproductivehealth/publications/infertility/9789241547789/en/>

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

All UK clinical service laboratories must agree in writing to current **Joint Working Group (JWG) Conditions of Participation** (click <http://www.rcpath.org/committees/intercollegiate-and-joint-committees/joint-working-group-for-quality-assessment-in-pathology/joint-working-group-for-quality-assessment-in-pathology> 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*.

UK NEQAS

Reproductive Science

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: <http://www.cmft.nhs.uk/uknegasrepsci.aspx> :-

- Participants' handbook
- Distribution schedules and price list
- Enrolment form

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 <http://www.cmft.nhs.uk/uknegasrepsci.aspx>

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 poor 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

UK NEQAS

Reproductive Science

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 (e.g. 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.

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 parts of the scheme a library of the images and videos analysed by participants is available.

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 must 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.

Participant objectives

The purpose of the Reproductive Science Schemes is to test a participants' 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 is not allowed. If a laboratory was suspected of collusion, the Centre would review its participation in its schemes

Andrology scheme

Analyte: Sperm Concentration

Accreditation Status: 092/0176 (CPA)

Date Scheme started: 1994

Units for Reporting: $\times 10^6/\text{ml}$

Samples Distributed: Liquid format. Human semen with a preservative (4% formaldehyde) and anti-aggregation supplement (sperm freezing medium).

Number of Distributions per year: 4

Number of Samples per Distribution: 4

Frequency of Distributions: Every three months as outlined in the Scheme Leaflet

Examination: Assessment of sperm concentration using Participants' own procedure (where practicable).

Schedule of Analysis: Data entry is via the UK NEQAS Results and Reports service for the submission of results. Data analysis is commenced 28 days after sample dispatch. Late returns are not accepted.

Data Analysis: Method Related Trimmed Mean (MRTM). All participants' methods are compared to the Improved Neubauer haemocytometer (which is the recommended method of the WHO laboratory manual for the examination and processing of human semen (fifth edition),

Performance Scoring: ABC system

Criteria of Performance: Laboratory performance is assessed over a running analytical window of 4 Distributions (12 months) See appendix 2 for details.

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

Analyte: Sperm morphology (practical)

Accreditation Status: 092/0176 (CPA)

Date Scheme started: 1994

Units for Reporting: % Normal forms

Samples Distributed: Liquid format. Human semen with a preservative (4% formaldehyde) and anti-aggregation supplement (sperm freezing medium).

Number of Distributions per year: 4

Number of Samples per Distribution: 4

Frequency of Distributions: Every three months as outlined in the Scheme Leaflet

Examination: Assessment of sperm morphology using Participants' own procedure (where practicable).

Schedule of Analysis: Data entry is via the UK NEQAS Results and Reports service for the submission of results. Data analysis is commenced 28 days after sample dispatch. Late returns are not accepted.

Data Analysis: Method Related Trimmed Mean (MRTM). All participants' methods are compared to the Strict/WHO 2010 criteria (which is the recommended method of the WHO laboratory manual for the examination and processing of human semen (fifth edition),

Performance Scoring: ABC system

Criteria of Performance: Laboratory performance is assessed over a running analytical window of 4 Distributions (12 months) See appendix 2 for details.

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

Analyte: Sperm Motility

Accreditation Status: 092/0176 (CPA)

Date Scheme started: 1995

Units for Reporting: $\times 10^6/\text{ml}$

Samples Distributed: Online videos of sperm motilities.

Number of Distributions per year: 4

Number of Samples per Distribution: 4

Frequency of Distributions: Every three months as outlined in the Scheme Leaflet

Examination: Assessment of sperm motility using Participants' own procedure (where practicable).

UK NEQAS

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Schedule of Analysis: 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: All Laboratory Trimmed Mean (ALTM).

Performance Scoring: ABC system

Criteria of Performance: Laboratory performance is assessed over a running analytical window of 4 Distributions (12 months) See appendix 2 for details.

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

Analyte: Interpretive Sperm Morphology

Accreditation Status: 092/0176 (CPA)

Date Scheme started: 2011

Units for Reporting: Normal/Abnormal

Samples Distributed: Online images of pre-stained sperm.

Number of Distributions per year: 4

Number of Samples per Distribution: 24

Frequency of Distributions: Every three months as outlined in the Scheme Leaflet

Examination: Assessment of sperm morphology using Participants' own procedure (where practicable).

Schedule of Analysis: 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: Consensus. All participants' results are compiled and must reach 60% consensus to be classified.

Performance Scoring: Penalty points system.

Criteria of Performance: Laboratory performance is assessed over a running analytical window of 4 Distributions (12 months) See appendix 2 for details.

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

Embryology scheme

Analyte: Embryo Morphology

Accreditation Status: ISO 17043 applied for.

Date Scheme started: 2011

Units for Reporting: NEQAS grading system (see Appendix 3)

Samples Distributed: Online videos of rolling embryos and time lapse videos.

Number of Distributions per year: 4

Number of Samples per Distribution: 8

Frequency of Distributions: Every three months as outlined in the Scheme Leaflet

Examination: Assessment of embryo morphology using Participants' own procedure (where practicable) in conjunction with the UK NEQAS Embryo Grading System (see Appendix 3)

Schedule of Analysis: 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: Consensus. All participants' results are compiled and must reach 50 % consensus to be classified.

Performance Scoring: Penalty points system.

Criteria of Performance: Laboratory performance is assessed over a running analytical window of 4 Distributions (12 months) See appendix 2 for details.

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

Materials

Sources of semen & embryos –

The majority of semen used by us is pooled from residual semen obtained from healthy 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.

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% aqueous formaldehyde. 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.**

Initial analysis & storage – Semen samples are stored between 2-8° 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

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, so as 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.

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Individual licences can also be purchased for online analytes to assist in the development of Internal Quality Control (IQC).

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 (valid at the time of file creation, but can be safely recreated to reflect any changes). 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 NEQAS lab numbers and that every lab has a NEQAS lab number. Where there are two identities for a NEQAS lab, these are cross checked with the Gamete-Expert "EQA assignments" spread sheet to confirm these match the two separate identity numbers allocated for Andrology and Embryology.

Due to individual IQC licences there could be many identities for a NEQAS lab number. The "EQA assignments" spread sheet provides the list of usable ID / Lab numbers. If any ID fails to find a 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 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 SQL 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 despatch and results return dates.

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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 remain open for four calendar weeks for all schemes. The schedule for the current calendar year (and the following year when finalised) is available at <http://www.cmft.nhs.uk/ukneqasrepsci.aspx> , 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 has to be expended by our staff to ensure the accuracy of method coding and updating records when these change. Participants are required to co-operate with this process by informing us when their methods change and also 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 the scheme Manager as soon as possible. Replacement samples will be sent immediately.

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. "Airsure" or "International signed for" 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 pathological material. All tubes are labelled with the scheme, analyte 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 (e.g. S401, S401, S403, S404).

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** repscience@ukneqas.org.uk.

Results documents - All schemes have distribution-specific results documents which are individual to each participant. These carry the laboratory code and in some cases method confirmation, as well as messages about sample handling and return of results. They are under constant review to make them easy to understand and use and may change from time to time to reflect improvements. The functionality of the Results document mirrors the Results return section of the online service.

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 or below, and with thorough mixing using a vortex mixer just prior to analysis. Unless instructed otherwise, participants

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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.

Embryo Morphology

The Embryo Morphology distributions contain videos of embryos from four patients for assessment. These films are taken using 'Cronus'™ or using 'Embryoscope'™ time lapsed videos. Should we leave this in?

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.

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 due date, usually 4 weeks, if they are to be included in the report. Results are reported online at <https://results.ukneqas.org.uk/scripts/scheme-select.pl> all labs will have been allocated a user name 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 <http://gamete-expert.com/>. 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 <https://results.ukneqas.org.uk/scripts/scheme-select.pl>

Embryo Morphology

Results must be entered while viewing the images/videos online at <http://gamete-expert.com/>. 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 <https://results.ukneqas.org.uk/scripts/scheme-select.pl>

Failure to return results

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

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Failure to return results will result in contact from the scheme. Failure to return results for 2 distributions within the last 4 distributions will be regarded as persistent unsatisfactory performance and the Scheme Organiser will contact the National Quality Assurance Advisory Panel (NQAAP) (see scheme website for current list of committee members <http://www.cmft.nhs.uk/ukneqasrepsci.aspx>).

Late returns

Designated values are derived from a consensus of received results; therefore late returns cannot be accepted.

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.

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.

Clearly the larger the number of data points the better the estimate, which becomes important when method-related 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)¹ 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 (Fig 1).

The MRTM taken from results of laboratories reporting the use of WHO (2010)/strict criteria is used for morphology (Fig 2).

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 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**

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'gold standard' result, and only reflects how a majority (>50%) of participating laboratories are interpreting the National Grading Scheme (Fig 5). The NEQAS embryo grading system is available via the website <http://www.cmft.nhs.uk/ukneqasrepsci.aspx>

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 poor performers to the National Quality Assurance Advisory Panel (NQAAP) for Reproductive Science. Limits for acceptable performance scores are set by the NQAAP after due deliberation and consultation with Organiser and Steering committees, 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 1.

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."

In reality, for the vast majority of 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 despatched. 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. Many scheme reports now 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

Distribution of reports: The default status for EQA report distribution is 'paper-free'. Participants may download their reports as electronic .pdf files from the secure Results and Reports website.

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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 - Results and Reports page. You will need your user name and password to access this information. 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

Firstly, participants receiving paper 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 actually received and your own, then destroy the incorrect report. A new one will be issued to both laboratories immediately. 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.

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.

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 1-3). Current performance limits are detailed in Appendix 1.

Calculation of Analytical Performance Scores for Interpretive Morphology Scheme

Laboratory Performance is not currently scored for this scheme. This is under 6 monthly review by the Andrology Steering Committee. Current suggested performance limits are detailed in Appendix 1. An example of the report format is shown below (Fig 4). The performance criteria are based on the 'sensitivity, specificity and accuracy' of results using the following formulae:

True positive (TP): Normal sperm correctly classified as Normal
False positive (FP): Abnormal sperm incorrectly classified as Normal
True negative (TN): Abnormal sperm correctly classified as Abnormal
False negative(FN): Normal sperm incorrectly classified as Abnormal

Sensitivity = $TP / (TP + FN)$
Specificity = $TN / (FP + TN)$
Accuracy = $(TP + TN) / (TP + TN + FP + FN)$

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 5 & 6). Only national grading scheme parameters i.e. cell number, evenness, 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 and for use in the 'hub and spoke' reports for comparing inter-laboratory variation. Current performance limits are detailed in Appendix 1. This is under 6 monthly review by the Embryology Steering Committee.

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 National Quality Assurance Advisory Panel (NQAAP) for Reproductive Science in consultation with the Andrology Steering Committee (ASC) and Embryology Steering Committee (ESC) 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.

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 poor performance. If a satisfactory response is made and improvement in performance ensues, no further action is taken. If poor 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 Joint Working Group may take further action.

For concentration or 'practical' morphology, if the rolling A, B or C scores break 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, 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 1) 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, the laboratory will be contacted as a persistent unsatisfactory performer.

For Interpretive Morphology this is not currently scored.

For Embryology if the overall match with the consensus target value results is less than 50% it will be noted as an unsatisfactory performance. If this happens on three distributions within the last 4 distributions, the laboratory will be contacted as a persistent unsatisfactory performer.

Annual Review of Schemes

Each year the Scheme management team reviews all aspects of the service. Results of evaluation questionnaires and comments from participants are included in this review. A report of the UK NEQAS Reproductive Science scheme results, trends in participation etc is published annually and emailed to all participants. It is also available on the website.

Communication and Comments

We take the opinions of our participants very seriously and welcome your views.

If you have any comments about any aspect of the schemes, whether scientific or operational, general or specific, please contact the Scheme Manager or Scheme Organiser as detailed on page 2. In the event of day-to-day operational matters, please have at hand your laboratory number, together with the distribution or specimen number(s). We will then endeavour to address any issues as soon as possible.

Additionally the UK NEQAS Reproductive Science Scheme operates an Annual Participants Meeting and Andrology Training Days where scheme staff are available to answer any questions.

Participants using a distributor may contact the scheme directly or through their distributor or agency.

Complaints

Definition: We define a complaint as any communication which includes the noun 'complaint' or any part of the verb 'to complain' in a way that makes it plain that a deficiency in our service has been identified, caused concern to a user of our service and requires a response from us. Formal 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.

How do participants make a formal complaint? Please study the sequence of actions indicated below and either write, fax or email the appropriate individual. Emails of complaint to repscience@ukneqas.org.uk must contain the words 'complain' or 'complaint' in the subject line in order for these to 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, fax or email) though a preliminary telephone call may assist in clarifying the issue and establishing the requisite action. All formal complaints shall be acknowledged within 5 working days of receipt. Wherever possible, a formal response is given within 3 months of the acknowledgement.

Where the complaint is about **scheme logistics**, then the **Scheme Manager** is the appropriate point of first contact. Where the matter is related to **performance assessment** and **scheme design**, the **Scheme Organiser** is more appropriate.

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

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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 appropriate **Steering Committee**.

If the issue concerns **performance assessment**, the **Chairman of the Advisory Panel** may also be contacted. Where lack of compliance with **CPA (EQA) Standards** is suspected by the complainant, then the **Chief Executive of CPA (EQA)** may be contacted. Similarly, 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.

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 repscience@ukneqas.org.uk 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. We are grateful for the work of the Central Manchester University Hospitals Foundation Trust Andrology & Embryology laboratories and the Central Manchester University Hospitals Foundation Trust Finance Department. The continued loyalty of all participants, which has enabled us to develop and expand to meet the challenges of the new EQA environment, is also warmly acknowledged.

FURTHER COPIES OF THIS HANDBOOK

The current definitive version of the Participants Handbook may be downloaded (from <http://www.cmft.nhs.uk/ukneqasrepsci.aspx>) 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 – Sperm concentration (millions/ml)

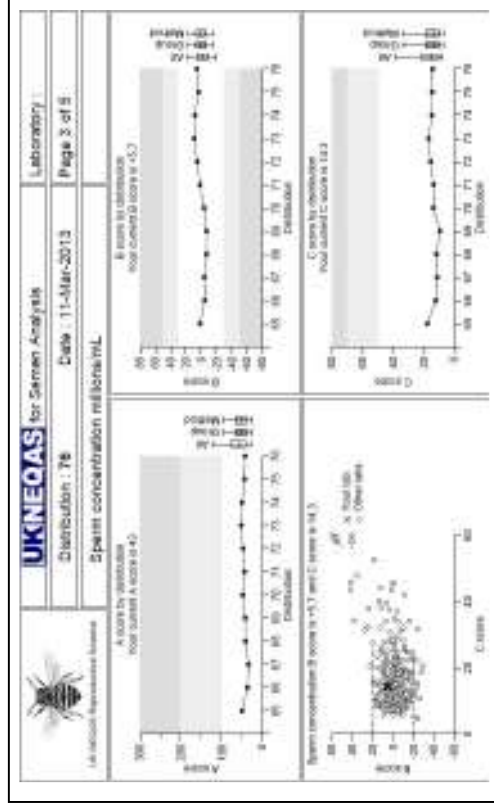
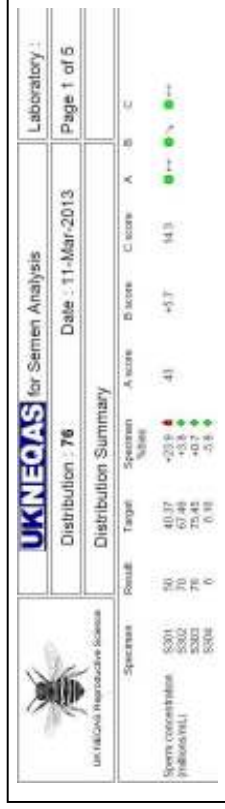
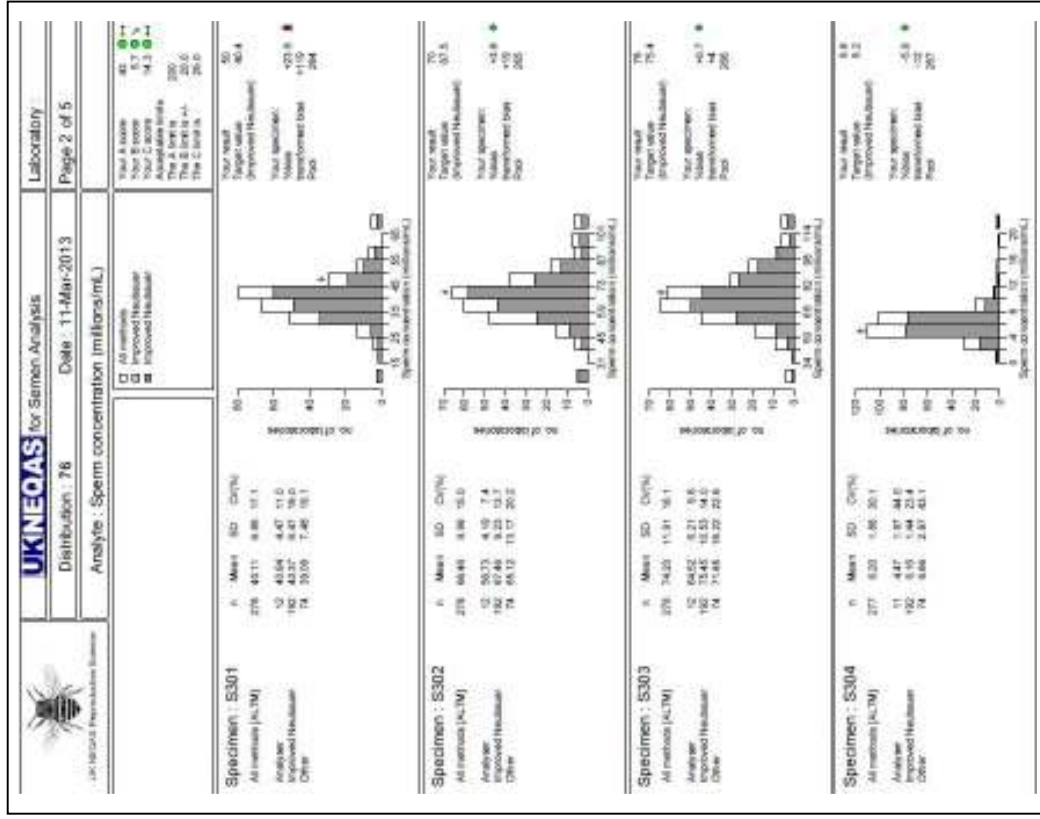


Figure 2 – Sperm Morphology (% normal)

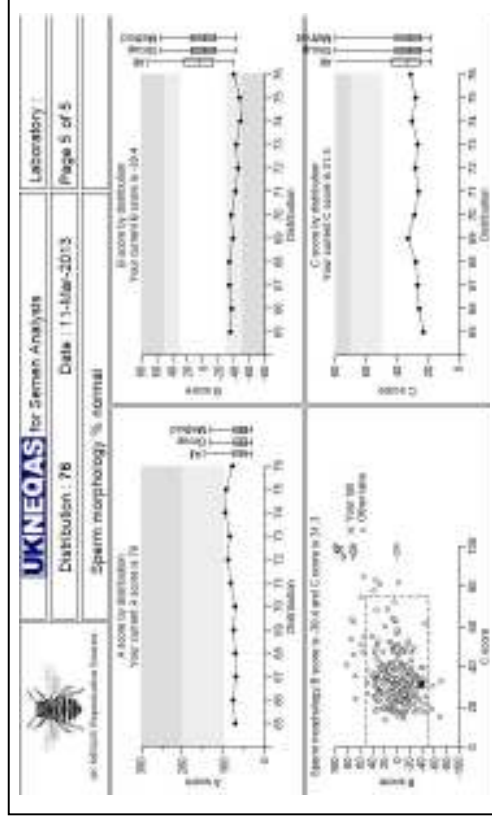
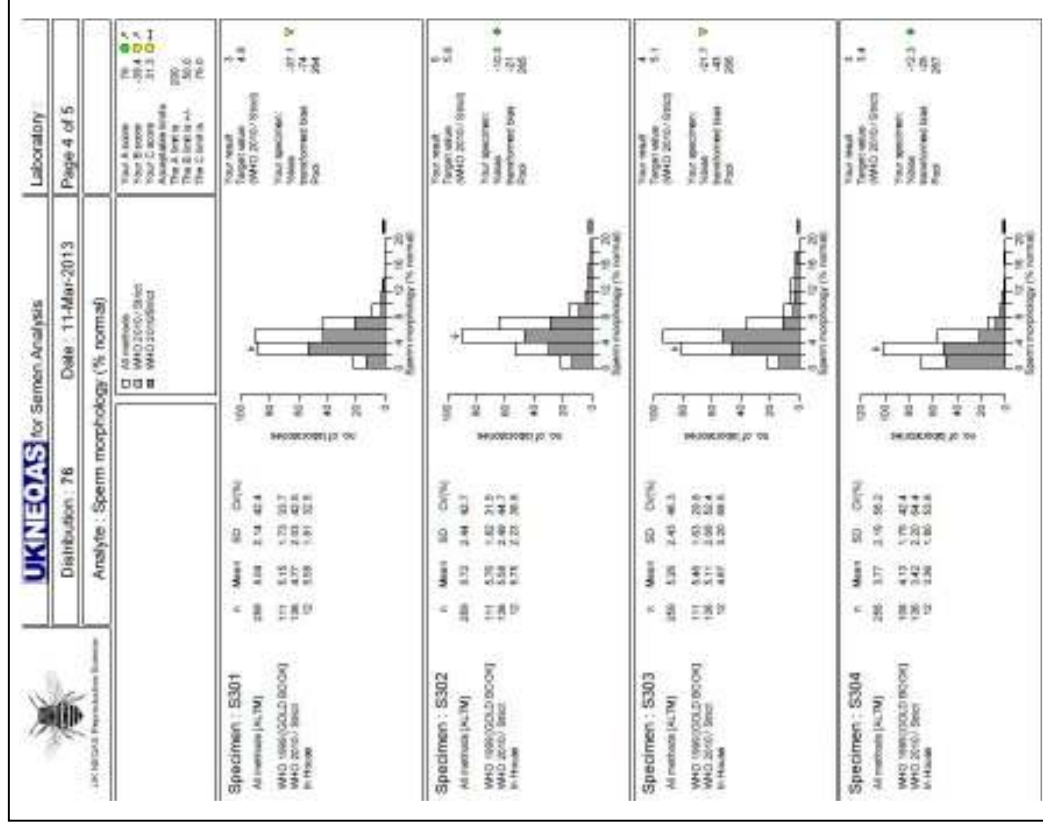


Figure 3 – Sperm Motility

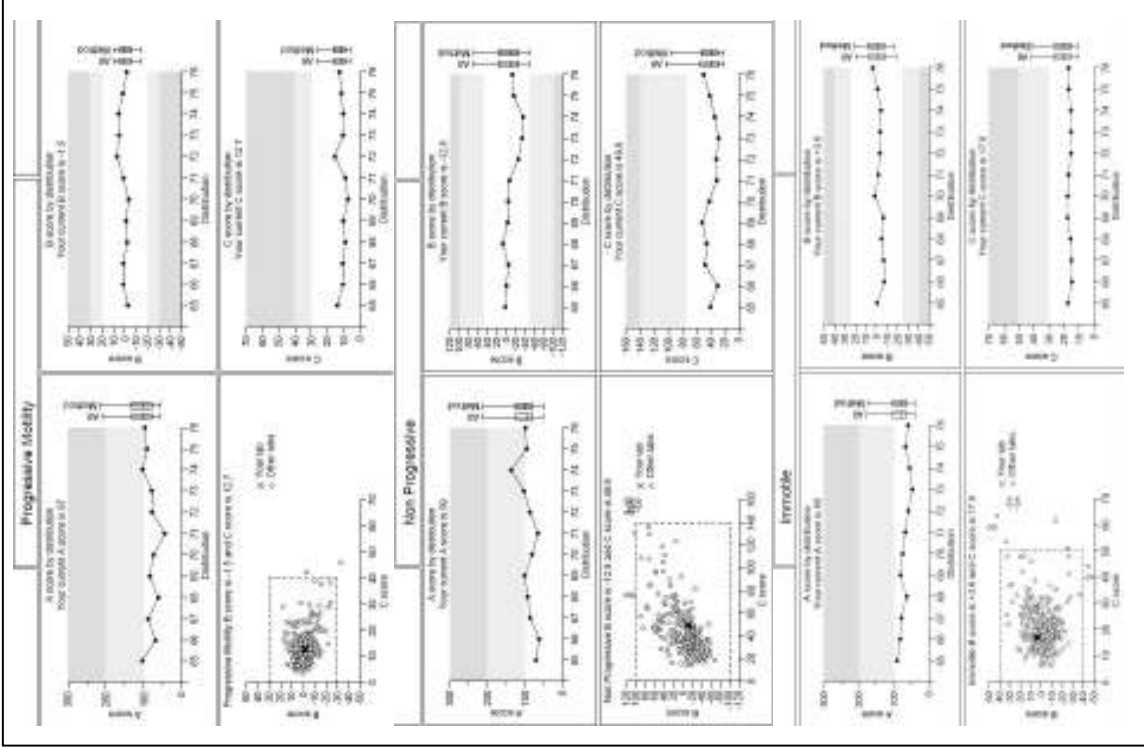
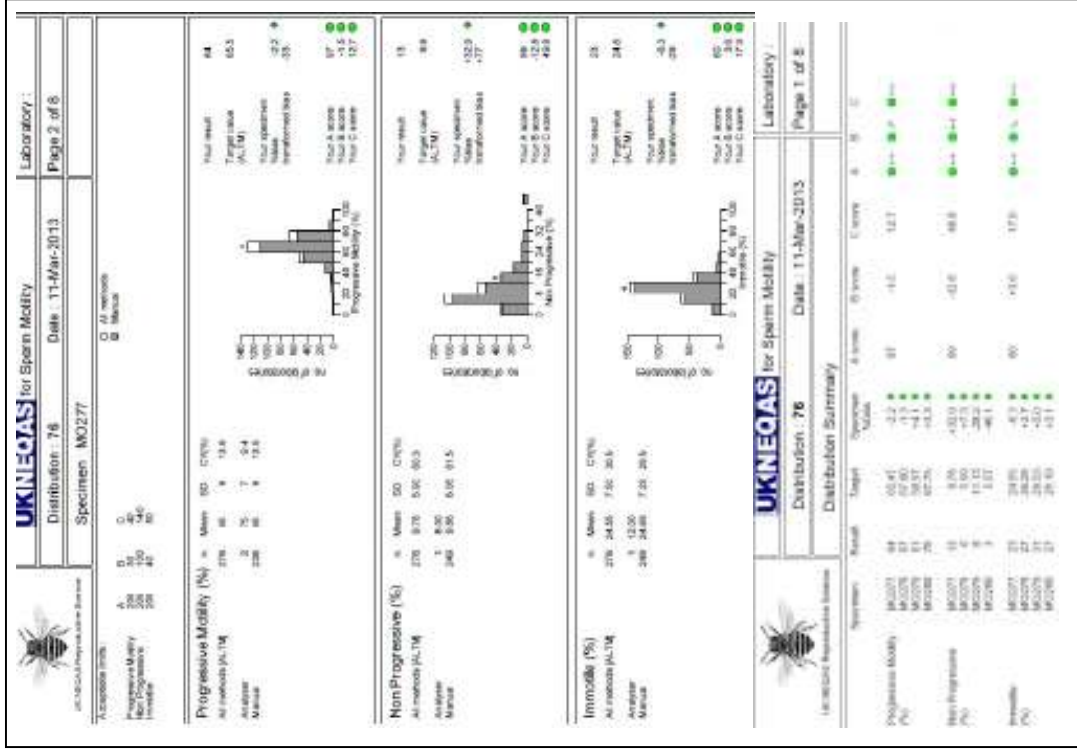



Figure 4 – Interpretive Morphology Report

 UK NEQAS Reproductive Science		UK NEQAS Interpretive Morphology Scheme Distribution : 84 Date : 09-Mar-2015 Laboratory : Page 1 of 4		
Distribution Summary				
The Performance target is calculated over a four distribution time window. Images with consensus of less than 60% are unclassified and therefore a target will not be listed.				
Specimen	Result	Target	Penalty	Performance
IM1-76	N	A	1	10
IM1-77	A	A	0	10
IM1-78	A	A	0	10
IM2-126	N	A	1	10
IM2-127	A	A	0	10
IM2-128	A	A	0	10
IM3-47	A	A	0	10
IM3-48	N	N	0	10
IM3-49	N	N	0	10
IM3-50	A	A	0	10
IM3-51	A	A	0	10
IM3-52	A	A	0	10
IM3-53	N	A	0	10
IM3-54	N	A	1	10
IM3-55	A	A	0	10
IM3-56	A	A	0	10
IM3-57	A	A	0	10
IM3-58	A	A	0	10
IM3-59	A	A	0	10
IM3-60	A	A	0	10
IM3-61	A	A	0	10
IM3-62	A	A	0	10
IM3-63	A	A	0	10
IM3-64	A	A	0	10
IM3-65	A	A	0	10
IM3-66	A	A	0	10
IM3-67	A	A	0	10
IM3-68	A	A	0	10
IM3-69	A	A	0	10
IM3-70	A	A	0	10


 UK NEQAS Reproductive Science		UK NEQAS Interpretive Morphology Scheme Distribution : 84 Date : 09-Mar-2015 Laboratory : Page 2 of 4	
Analyte : Sperm classification			
Your rating this window: Sensitivity is 67% (best 50%) Your rating this window: Specificity is 81% (best 70%) Your rating this window: Accuracy is 69% (best 60%)			
Specimen : IM1-76 Total Normals : 15 Total Abnormals : 241 This was classified as [A - Abnormal] Your penalty : 1	Specimen : IM1-77 Total Normals : 73 Total Abnormals : 183 This was classified as [A - Abnormal] Your penalty : 0	Specimen : IM1-78 Total Normals : 0 Total Abnormals : 256 This was classified as [A - Abnormal] Your penalty : 0	Specimen : IM2-126 Total Normals : 76 Total Abnormals : 180 This was classified as [A - Abnormal] Your penalty : 1
Specimen : IM2-127 Total Normals : 125 Total Abnormals : 121 This was classified as [Unclassified] Your penalty : 0	Specimen : IM2-128 Total Normals : 20 Total Abnormals : 236 This was classified as [A - Abnormal] Your penalty : 0	Specimen : IM3-47 Total Normals : 4 Total Abnormals : 252 This was classified as [A - Abnormal] Your penalty : 0	Specimen : IM3-48 Total Normals : 200 Total Abnormals : 53 This was classified as [N - Normal] Your penalty : 0
Specimen : IM3-49 Total Normals : 21 Total Abnormals : 223 This was classified as [A - Abnormal] Your penalty : 0	Specimen : IM3-50 Total Normals : 26 Total Abnormals : 255 This was classified as [A - Abnormal] Your penalty : 0	Specimen : IM3-51 Total Normals : 7 Total Abnormals : 242 This was classified as [A - Abnormal] Your penalty : 0	Specimen : IM3-52 Total Normals : 4 Total Abnormals : 252 This was classified as [A - Abnormal] Your penalty : 0
Specimen : IM3-53 Total Normals : 200 Total Abnormals : 53 This was classified as [N - Normal] Your penalty : 0	Specimen : IM3-54 Total Normals : 40 Total Abnormals : 206 This was classified as [A - Abnormal] Your penalty : 0	Specimen : IM3-55 Total Normals : 7 Total Abnormals : 242 This was classified as [A - Abnormal] Your penalty : 0	Specimen : IM3-56 Total Normals : 4 Total Abnormals : 252 This was classified as [A - Abnormal] Your penalty : 0
Specimen : IM3-57 Total Normals : 200 Total Abnormals : 53 This was classified as [N - Normal] Your penalty : 0	Specimen : IM3-58 Total Normals : 7 Total Abnormals : 242 This was classified as [A - Abnormal] Your penalty : 0	Specimen : IM3-59 Total Normals : 4 Total Abnormals : 252 This was classified as [A - Abnormal] Your penalty : 0	Specimen : IM3-60 Total Normals : 4 Total Abnormals : 252 This was classified as [A - Abnormal] Your penalty : 0
Specimen : IM3-61 Total Normals : 4 Total Abnormals : 252 This was classified as [A - Abnormal] Your penalty : 0	Specimen : IM3-62 Total Normals : 4 Total Abnormals : 252 This was classified as [A - Abnormal] Your penalty : 0	Specimen : IM3-63 Total Normals : 4 Total Abnormals : 252 This was classified as [A - Abnormal] Your penalty : 0	Specimen : IM3-64 Total Normals : 4 Total Abnormals : 252 This was classified as [A - Abnormal] Your penalty : 0
Specimen : IM3-65 Total Normals : 4 Total Abnormals : 252 This was classified as [A - Abnormal] Your penalty : 0	Specimen : IM3-66 Total Normals : 4 Total Abnormals : 252 This was classified as [A - Abnormal] Your penalty : 0	Specimen : IM3-67 Total Normals : 4 Total Abnormals : 252 This was classified as [A - Abnormal] Your penalty : 0	Specimen : IM3-68 Total Normals : 4 Total Abnormals : 252 This was classified as [A - Abnormal] Your penalty : 0
Specimen : IM3-69 Total Normals : 4 Total Abnormals : 252 This was classified as [A - Abnormal] Your penalty : 0	Specimen : IM3-70 Total Normals : 4 Total Abnormals : 252 This was classified as [A - Abnormal] Your penalty : 0	Specimen : IM4-57 Total Normals : 4 Total Abnormals : 252 This was classified as [A - Abnormal] Your penalty : 0	Specimen : IM4-58 Total Normals : 4 Total Abnormals : 252 This was classified as [A - Abnormal] Your penalty : 0
Specimen : IM4-59 Total Normals : 4 Total Abnormals : 252 This was classified as [A - Abnormal] Your penalty : 0	Specimen : IM4-60 Total Normals : 4 Total Abnormals : 252 This was classified as [A - Abnormal] Your penalty : 0	Specimen : IM4-61 Total Normals : 4 Total Abnormals : 252 This was classified as [A - Abnormal] Your penalty : 0	Specimen : IM4-62 Total Normals : 4 Total Abnormals : 252 This was classified as [A - Abnormal] Your penalty : 0

Figure 5 – Embryology Scheme Report (part 1)



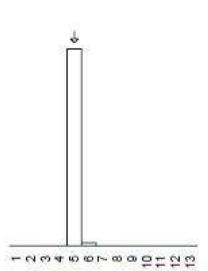
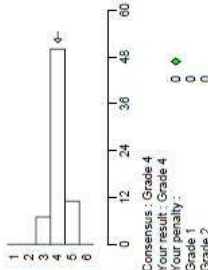
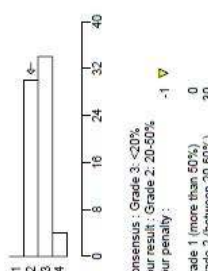
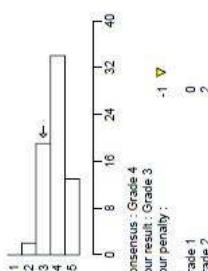
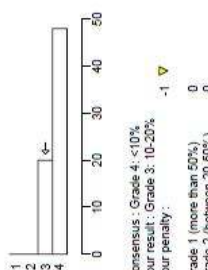
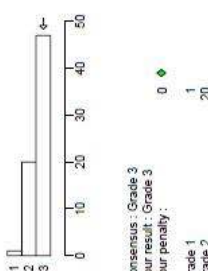
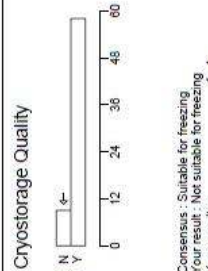
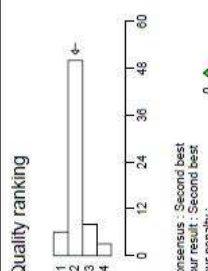
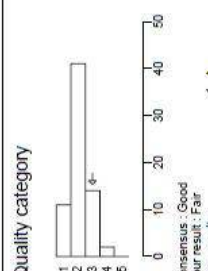
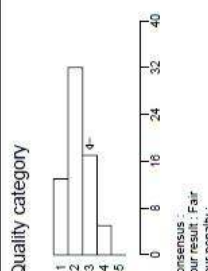
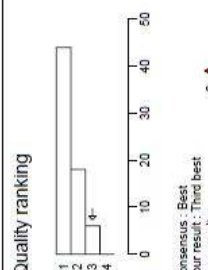
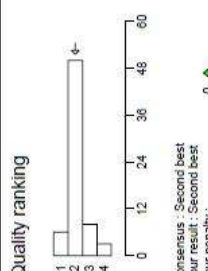
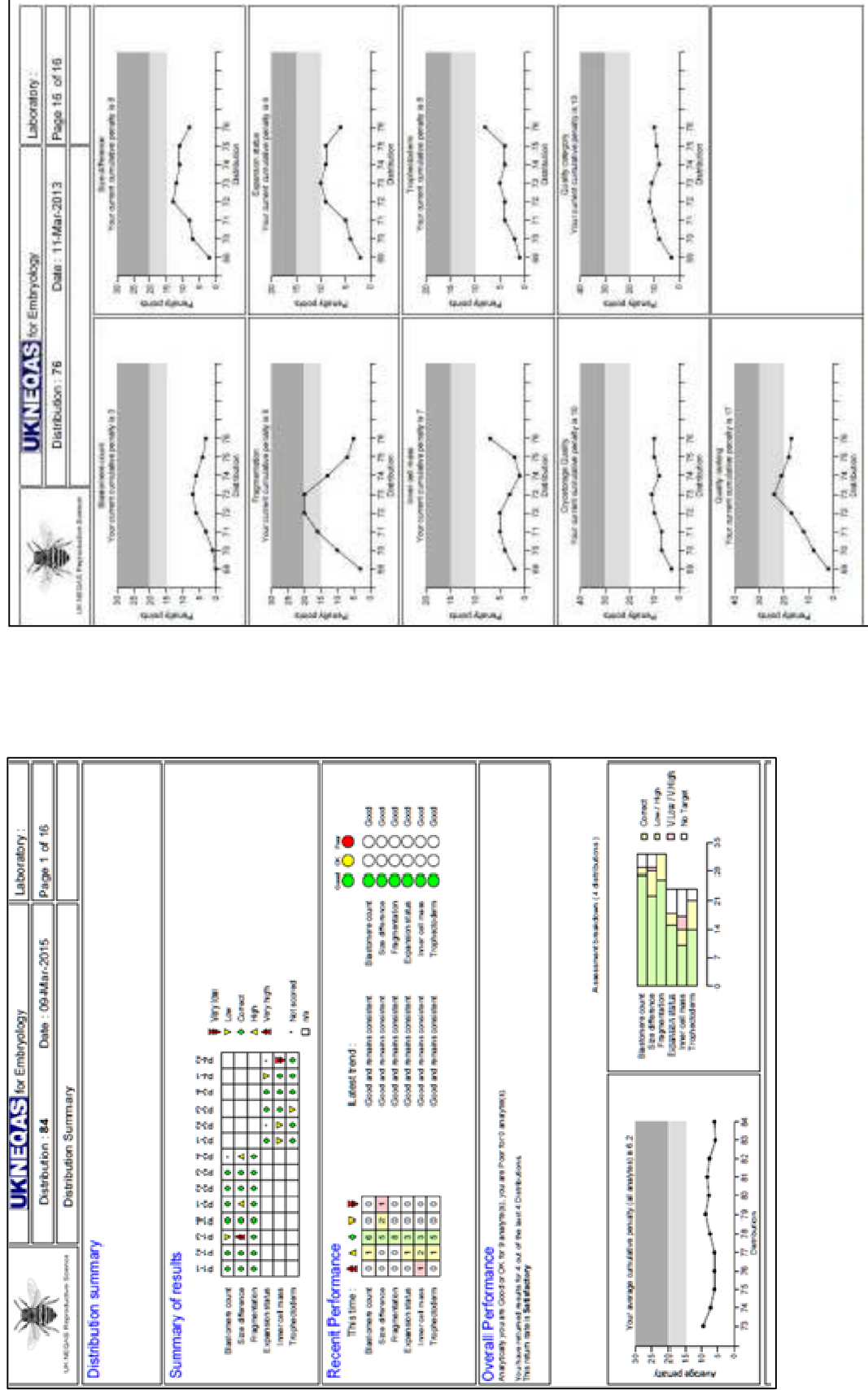
 UK NEQAS for Embryology Distribution : 76 Date : 11-Mar-2013 Specimen : P1-1		 UK NEQAS for Embryology Distribution : 76 Date : 11-Mar-2013 Specimen : P3-1	
Embryo 1 Day 2 48h		Embryo 1 Day 5 120h	
Blastomere count  <p>Consensus : 3 Your result : 5 Your penalty : 0</p>		Expansion status  <p>Consensus : Grade 4 Your result : Grade 4 Your penalty : 0</p>	
Size difference  <p>Consensus : Grade 3: <20% Your result : Grade 2: 20-50% Your penalty : -1</p>		Inner cell mass  <p>Consensus : Grade 4 Your result : Grade 3 Your penalty : -1</p>	
Fragmentation  <p>Consensus : Grade 4: <10% Your result : Grade 3: 10-20% Your penalty : -1</p>		Trophectoderm  <p>Consensus : Grade 3 Your result : Grade 3 Your penalty : 0</p>	
Cryostorage Quality  <p>Consensus : Suitable for freezing Your result : Not suitable for freezing Your penalty : 1</p>		Quality ranking  <p>Consensus : Second best Your result : Second best Your penalty : 0</p>	
Quality category  <p>Consensus : Good Your result : Fair Your penalty : 1</p>		Quality category  <p>Consensus : Fair Your result : Fair Your penalty : 0</p>	
Quality ranking  <p>Consensus : Best Your result : Third best Your penalty : 2</p>		Quality ranking  <p>Consensus : Second best Your result : Second best Your penalty : 0</p>	

Figure 6 – Embryology Scheme Report (part 2)



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

From April 2013 the report format will change for the above analytes. The change will harmonise the Andrology scheme into line with other UK NEQAS schemes which already use this system. Here is an explanation of the new system from Birmingham Quality:

The '**ABC of EQA**' is an *ISO Guide 43 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 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 **A**ccuracy (total error)

B is for **B**ias

C is for **C**onsistency 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 'timewindow'.

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.

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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:

$$\text{specimen \% bias} = \frac{(\text{result} - \text{target})}{\text{target}} \times 100$$

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**', (ie 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 timewindow.

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.

Example reports:

Summary page (concentration & morphology)

	Specimen	Result	Target	Specimen %bias	A score	B score	C score	A	B	C
Sperm concentration (millions/mL)	S289	56	56.09	-0.2 ◆	52	+9.3	16.8	● ↔	● ↘	● ↔
	S290	72	59.79	+20.4 ▲						
	S291	52	40.77	+27.5 ▲						
	S292	16	14.35	+8.0 ◆						
Sperm morphology (% normal)	S289	2	5.60	-64.3 ▼	85	-42.7	26.7	● ↔	● ↔	● ↔
	S290	3	6.00	-50.0 ▼						
	S291	3	5.50	-45.4 ▼						
	S292	5	4.67	+7.1 ◆						

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

Results page (concentration & morphology)

Specimen : S289	n	Mean	SD	CV(%)
All methods	266	54.44	8.75	16.1
Analysed	8	46.55	1.43	3.1
Improved Neubauer	193	58.09	7.56	13.5
Other	65	52.04	12.63	24.3

Your result	56
Target value (OGLTM)	56.1
Your specimen: %bias	-0.2 ◆
transformed bias	-1
Your A score	52 ●
Your B score	9 ●
Your C score	16 ●

Specimen : S289	n	Mean	SD	CV(%)
All methods	231	5.91	2.37	40.1
WHO 1999 [GOLD BOOK]	111	6.25	2.44	39.0
WHO 2010 / Strict	109	5.60	2.30	41.2
In House	11	5.53	1.85	33.5

Your result	2
Target value (OGLTM)	5.6
Your specimen: %bias	-64.3 ▼
transformed bias	-129
Your A score	85 ●
Your B score	-42 ●
Your C score	26 ●

Summary page (motility)

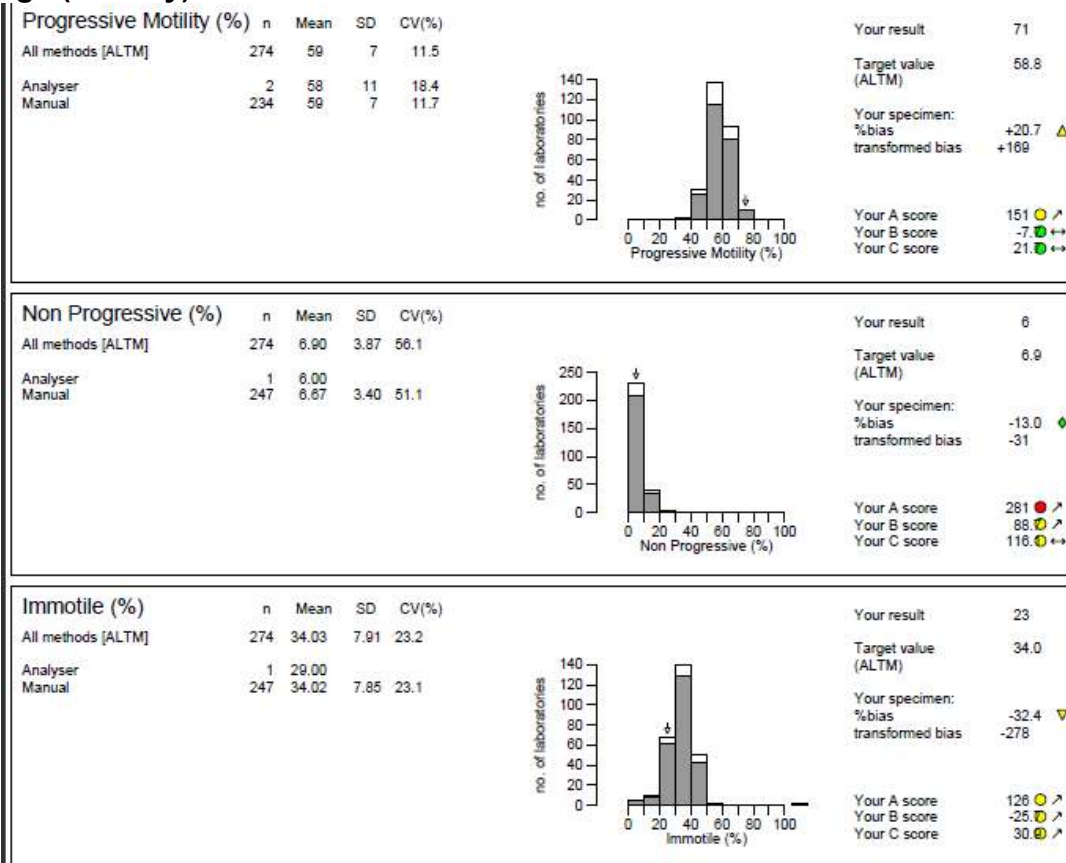
	Specimen	Result	Target	Specimen %bias	A score	B score	C score	A	B	C
Progressive Motility (%)	MO273	71	58.81	+20.7 ▲	151	-7.7	21.7	● ↗	● ↔	● ↔
	MO274	18	18.99	-15.7 ◆						
	MO275	62	62.68	-1.1 ◆						
	MO276	73	71.62	+1.9 ◆						
Non Progressive (%)	MO273	8	6.90	-13.0 ◆	281	+88.7	116.1	● ↗	● ↗	● ↔
	MO274	13	11.03	+17.8 ◆						
	MO275	5	9.90	-49.5 ◆						
	MO276	3	5.47	-45.2 ◆						
Immotile (%)	MO273	23	34.03	-32.4 ▼	126	-25.7	30.9	● ↗	● ↗	● ↗
	MO274	71	69.90	+1.6 ◆						
	MO275	33	27.71	+19.1 ◆						
	MO276	24	22.72	+5.6 ◆						

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

Results page (motility)



'A' scores

The 'A' scores for samples is a 'transformed bias' similar to the old 'Bias Index Score (BIS)' on our previous system (although calculated from a different algorithm). UK NEQAS normalise ABC data so that the median 'A' score at 1st January 2000 is 100 (setting the Chosen Co-efficient of Variation to achieve this).

'B' & 'C' scores

We have plotted the data and looked at the 5th/95th 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.

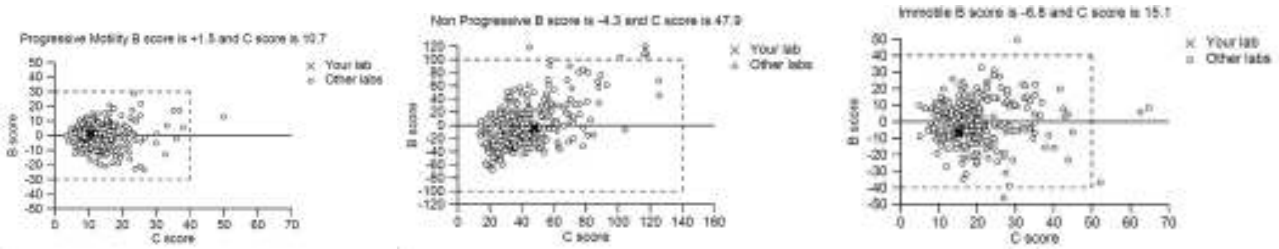
The allowance of % BIAS (B score) or (C score) is (where Green = satisfactory, Yellow = warning and Red = unsatisfactory):

Motility

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

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B scores:

	Green	Yellow	Red
Progressive:	0 to +/- 15	+/-15 to +/-30	>+/-30
Non Progressive:	0 to +/- 75	+/-75 to +/-100	>+/-100
Immotile:	0 to +/- 25	+/-25 to +/-40	>+/-40

C scores:

	Green	Yellow	Red
Progressive:	0 to 20	20 to 40	>40
Non Progressive:	0 to 100	100 to 140	>140
Immotile:	0 to 30	30 to 50	>50

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

The concentration dependent degree of difficulty is reflected in the A score (rolling) and Specimen Accuracy Index (SAI) c.f. your BIS values.

Morphology (practical)

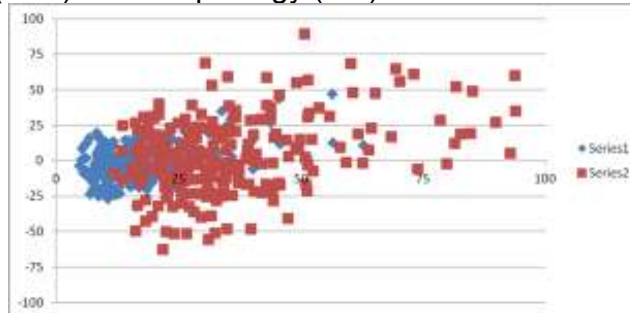
B scores:

	Green	Yellow	Red
Morphology	0 to +/-20	+/-20 to +/- 50	>+/-50

C scores:

	Green	Yellow	Red
Morphology	0 to 25	25 to 75	>75

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



Performance assessment

With the old report format performance assessment was done manually on a distribution by distribution basis. If results were out of limits in >50% of the samples, labs would receive one unsatisfactory performance event. Three unsatisfactory performance events within 8 distributions would change a lab status from 'GREEN' to 'AMBER'. A fourth event would change status to 'RED'.

In essence, an A score of >200 (i.e. red) for two consecutive distributions would raise a poor perf 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 new format is designed so that the performance is determined automatically over a four distribution period. 'Red' labs only would then be contacted. (ie labs 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 National Quality Assurance Advisory Panel (NQAAP) for Reproductive Science, on recommendation from the relevant UK NEQAS Steering Committee, are shown in **green**

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

Below are the performance limits for each scheme in the four distribution timewindow. Participants whose scores go above these limits may be contacted about their performance.

Andrology (Semen Analysis) Scheme

The 'ABC of EQA'	A score limit	B score limit (+/-)	C score limit
Semen concentration	200	20	25
Sperm morphology	200	50	75
Sperm motility – progressive	200	30	40
Sperm motility – non-progressive	200	100	140
Sperm motility – Immotile	200	40	50
	Penalty limit		
Interpretive morphology	30		

Embryology scheme

Embryo grading	Penalty limit* 20
----------------	-----------------------------

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

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

Appendix 3: Embryo Morphology Scheme Grading System

Cleavage stage embryo grading system

Blastomere Number		
Blastomere Size	4 =	Regular, even division
	3 =	<20% difference (blastomere diameter)
	2 =	20-50% difference
	1 =	>50% difference <i>Hardarson et al 2001</i>
Fragmentation	4 =	10% fragmentation by volume
	3 =	10-20%
	2 =	20-50%
	1 =	>50% <i>van Royen et al 2003</i>

Blastocyst grading system

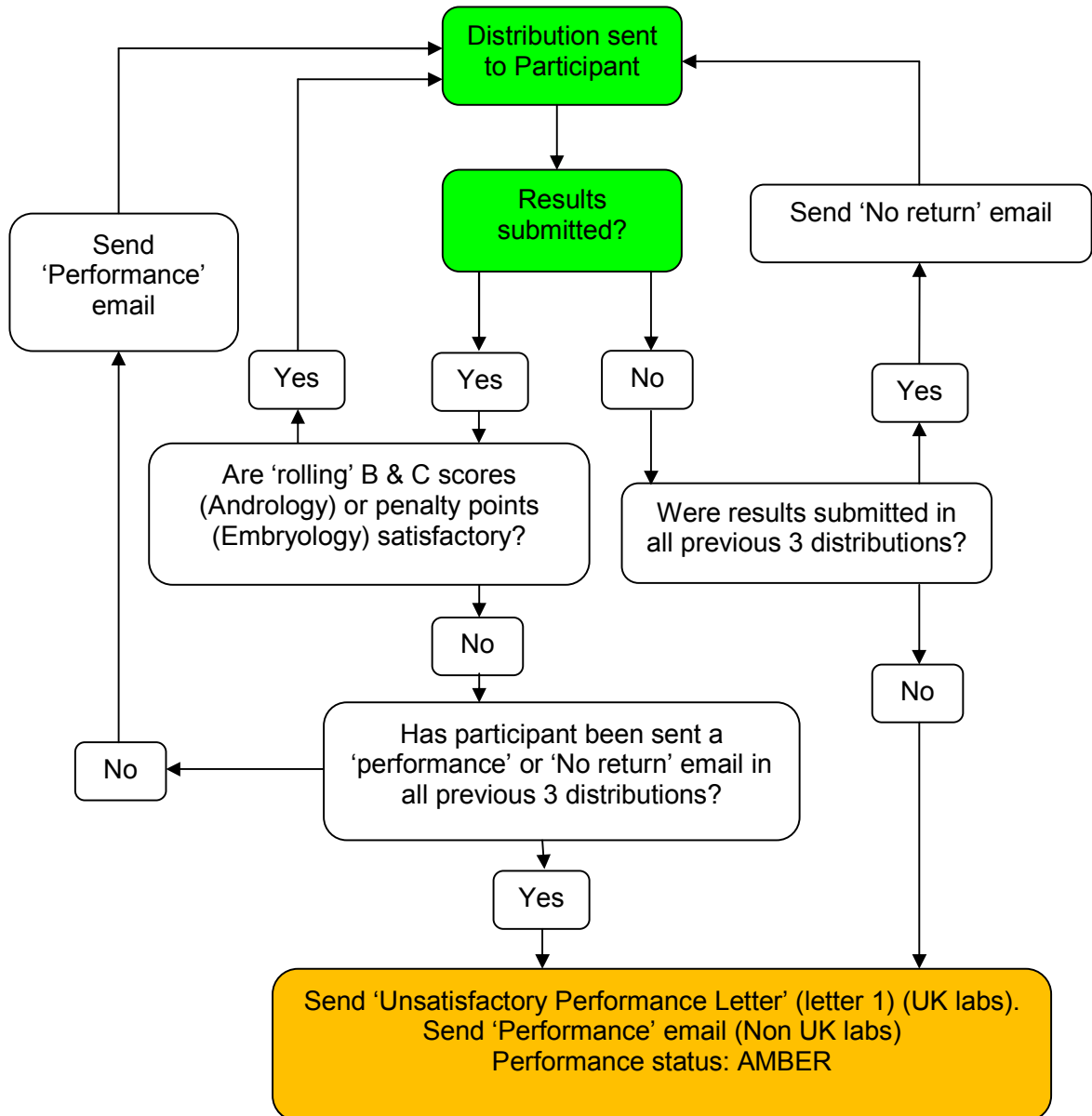
Expansion Status	6 =	Hatched blastocyst; the blastocyst has evacuated the ZP.
	5 =	Hatching blastocyst; trophectoderm has started to herniate through the ZP.
	4 =	Expanded blastocyst: blastocoele volume now larger than that of the early embryo, ZP very thin.
	3 =	Full blastocyst; blastocoele completely fills the embryo.
	2 =	Blastocyst; blastocoele more than half the volume of the embryo, some expansion in overall size, ZP beginning to thin.
	1 =	Early blastocyst; blastocoele less than half the volume of the embryo, little or no expansion in overall size, <i>zona pellucida</i> (ZP) still thick.
ICM Grading	5 =	ICM prominent, easily discernible and consisting of many cells, cells compacted and tightly adhered together.
	4 =	Cells less compacted so larger in size, cells loosely adhered together; some individual cells may be visible.
	3 =	Very few cells visible; either compacted or loose, may be difficult to completely distinguish from trophectoderm.
	2 =	Cells of the ICM appear degenerate or necrotic.
	1 =	No ICM cells discernible in any focal plane.
Trophectoderm	3 =	Many small identical cells forming a continuous trophectoderm layer.
	2 =	Fewer larger cells; may not form a completely continuous layer.
	1 =	Sparse cells; may be very large, very flat or appear degenerate.

(Modified for UK NEQAS Embryo Morphology Scheme 2010 from Cutting et al, *Elective Single Embryo Transfer: Guidelines for Practice*. British Fertility Society and Association of clinical Embryologists. *Human Fertility*, September 2008; 11(3): 131–146)

Version 1 17/02/2012

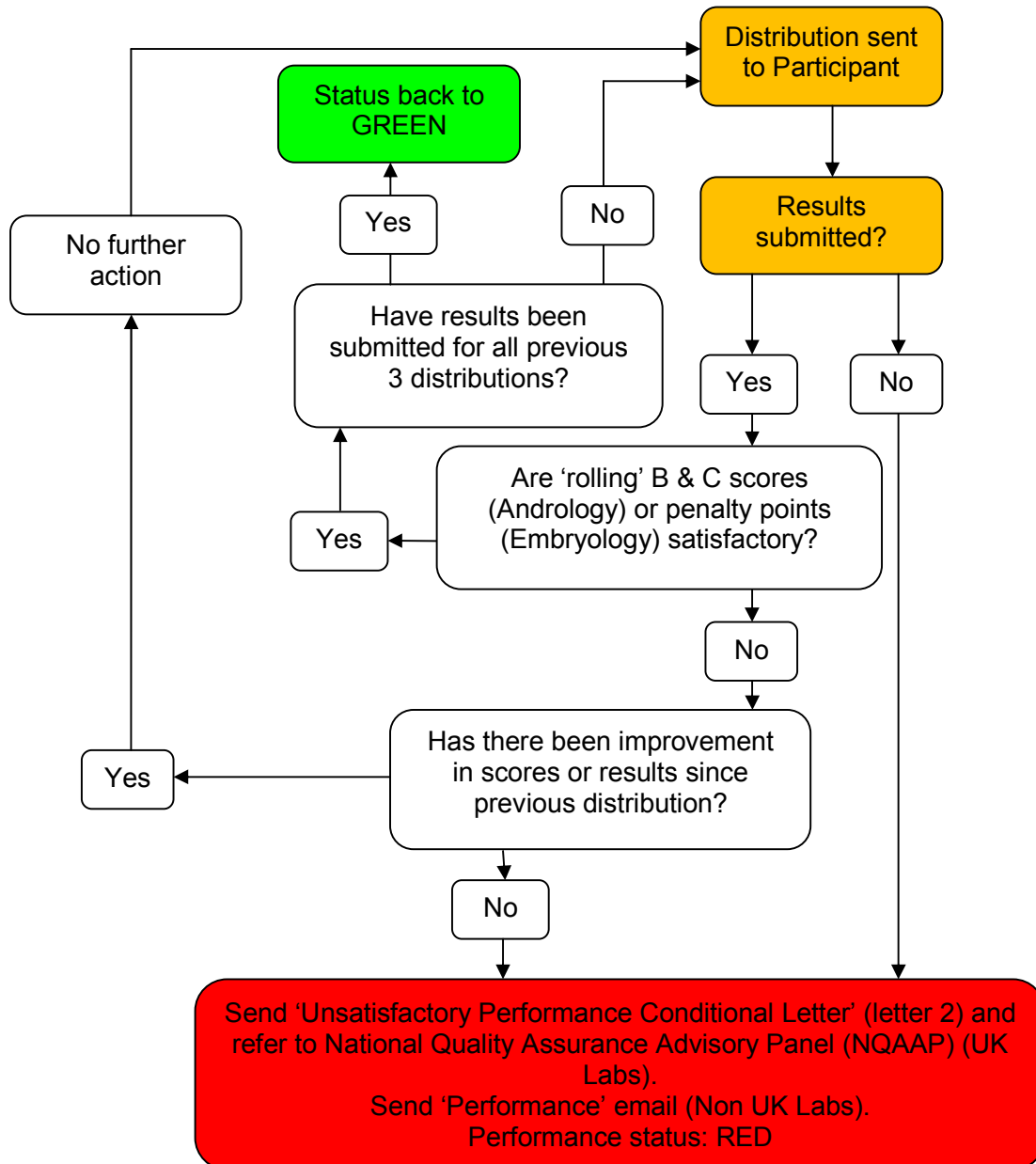
Appendix 4: Performance in UK NEQAS Reproductive Science Schemes

GREEN to AMBER

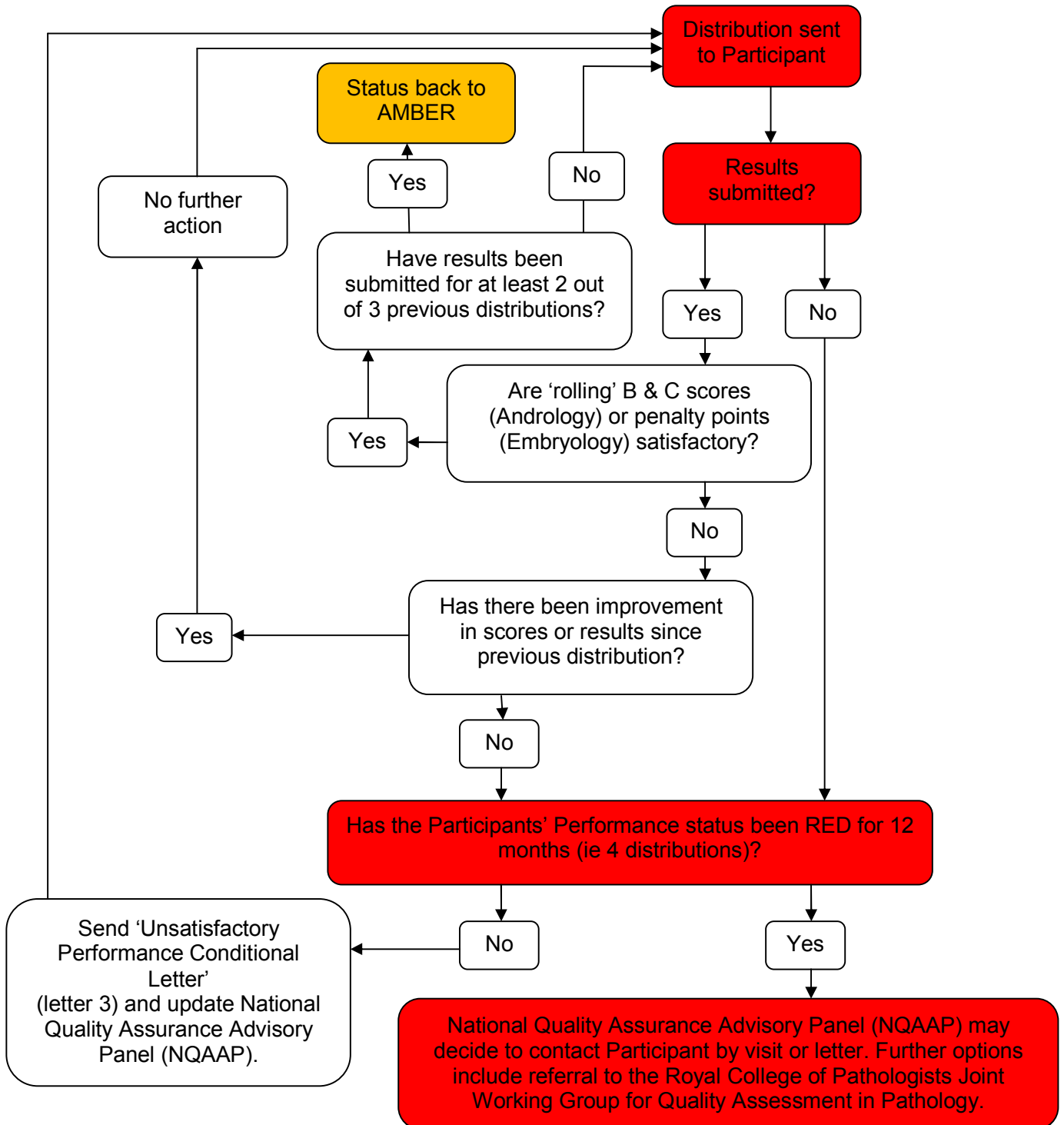


Performance in UK NEQAS Reproductive Science Schemes

AMBER to RED



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



Appendix 5: 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: <http://www.cmft.nhs.uk/ukneqasrepsci.aspx>

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 repscience@ukneqas.org.uk 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 repscience@ukneqas.org.uk or +44 (0) 161 276 6437 to request a repeat sample. You will need to give 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 repscience@ukneqas.org.uk. If you are not the main contact, your email request will need to be copied to the main contact, in order for us to 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 <http://gamete-expert.com/morphology/login-password-forgotten.html> and enter your email address. If you do not receive contact within 24 hours email repscience@ukneqas.org.uk.

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 40 years of experience in offering EQA schemes. Our Semen analysis scheme is fully accredited by Clinical Pathology Accreditation (CPA) UK Ltd and our Embryology scheme uses video clips of rolling embryos and time lapse videos from the 'Embryoscope'™

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 complements this by asking participants to assess the same images of sperm. Over time this should make morphology reporting more consistent. Currently, only the 'practical' morphology is assessed for performance.

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 become an unsatisfactory performer which you will have to justify to your institution and regulatory body (e.g. CPA, 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@ukneqas.org.uk or phone +44 (0) 161 276 6437 quoting your lab ID number.

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@ukneqas.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 fifth 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. non return of results, 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. non return of results, input error)?
- Were 'practical' 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 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. non return of results, input error)?
- Were embryos assessed using the recognised UK NEQAS/ACE criteria (available for download <http://www.cmft.nhs.uk/media/327850/neqasgradingsystem.pdf>)?

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