

Participants' Handbook

Reproductive Science Schemes



Changes for version 15:

- More information on Time-lapse analyte including relevant photographs from Gamete Expert and associated reports.
- Replacement of Andrology and Embryology Steering Committees with Reproductive Science Steering Committee.
- Inclusion of ratification of embryology grading scheme by ARCS.
- Change to Interpretive Morphology performance limit from D109.
- Change to Embryo Morphology performance limit from D110
- Monitoring of Embryology time-lapse performance from D109.
- Instructions to view Enrolment Certificate.



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

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

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

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Contacting the Scheme:

UK NEQAS Reproductive Science Manchester University NHS Foundation Trust Department of Reproductive Medicine Old St Mary's Hospital Oxford Road Manchester. M13 9WL United Kingdom	Scheme Organiser: Deputy Scheme Organiser: Scheme Manager: Scheme Administrator Scheme Administrator Scheme Quality Manager Deputy Scheme Quality Manager Scheme Training Officer Scheme H&S Adviser	Gregory Horne Annette Lloyd Peter Goddard Karen Brackley Diane Shearden Justine Hartley Laura Kiely Genette Lloyd Peter Goddard
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Email: repscience@ukneqas.org.uk
gregory.horne@mft.nhs.uk
pete.goddard@mft.nhs.uk

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

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

The telephone is staffed between the hours of 08:30 and 16:00 Monday to Friday. Email to repscience@ukneqas.org.uk is the preferred method of contact.

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.

How to join the Scheme:

Details on how to join the schemes and our enrolment form are available on the website.

Additional equipment:

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

Andrology: vortex mixer, computer with Internet connection is required. For the screen we recommend a width ≥ 1200 pixels and a height ≥ 600 pixels with a diagonal ≥ 15 inch (381mm). Consequently, tablets and smartphones are not recommended for assessment.

Embryology: computer with Internet connection is required. For the screen we recommend a width ≥ 1200 pixels and a height ≥ 600 pixels with a diagonal ≥ 15 inch (381mm). Consequently, tablets and smartphones are not recommended for assessment.

COVID-19 UK NEQAS Response

We are adapting our operations in response to this rapidly changing and exceptional situation. We will update you if anything changes relevant to your participation in the scheme.

Any recent updates will be posted via the UK NEQAS consortium website <https://ukneqas.org.uk/>.

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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, note the date of receipt (you will need to enter this date with your results).
Store between 2-8°C when not in use.

Receipt: Check samples on receipt to be sure that the correct samples are in the pack and there is no damage to the ampoules. Contact repscience@ukneqas.org.uk immediately if replacement samples are required.

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 (do not over-mix). 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 the Sperm concentration & Morphology “Result” tab.
This will automatically bring you to the ‘latest’ distribution.

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Scheme: **Andrology - Sperm Concentration & Morphology**
 Distribution: **97**
 Dispatch date: **14-05-2018**
 Return results: **11-06-2018**

Method details: Submethod details:
 Sperm concentration: Improved Neubauer
 Sperm morphology: WHO 2010 / Strict

S385 S386 S387 S388
 Sperm concentration: millions/mL
 Sperm morphology: % normal

* indicates analyte for which you are not registered
 Specimen received: (dd/mm/yy)
 Analysis (start) date: (dd/mm/yy)

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).

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Results and Reports

UK NEQAS Reproductive Science (Manchester) [Homepage]

Andrology - Sperm Motility	Report <input type="button" value="95"/>	Dist	Result	Latest
Andrology - Sperm Concentration & Morphology	Report <input type="button" value="96"/>	Dist	Result	Latest
Andrology - Interpretive Sperm Morphology	Report <input type="button" value="95"/>	Dist	Result	Latest
Embryology - Embryo Morphology	Report <input type="button" value="96"/>	Dist	Result	Latest

For the latest distribution results click on the 'Report' tab for Semen Analysis. This will display a 'pdf' copy of the report. For older reports amend the distribution number in the 'drop down box'

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

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

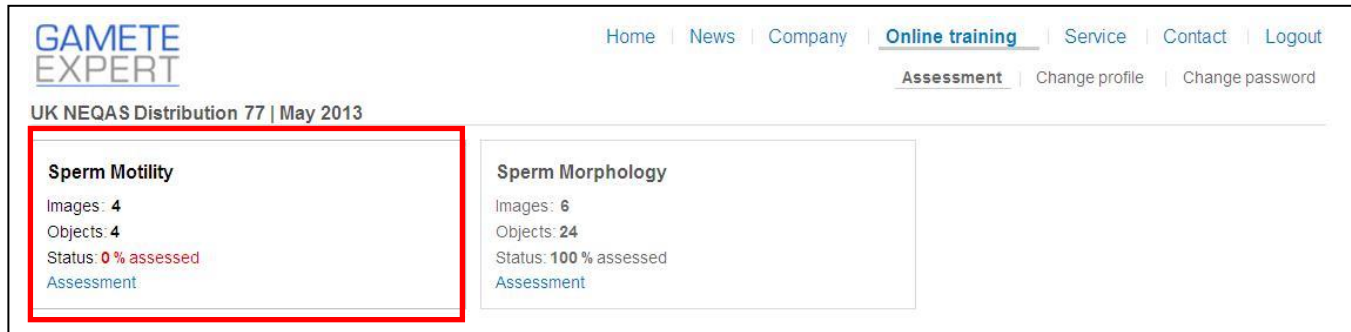
UK NEQAS Reproductive Science		Andrology - Sperm Concentration & Morphology					Laboratory :			
		Distribution : 92		Date : 06-Mar-2017		Page 1 of 5				
Distribution Summary										
	Specimen	Result	Target	Specimen %bias	A score	B score	C score	A	B	C
Sperm concentration (millions/mL)	S365	57.4	59.04	-2.8	24	-3.2	5.6	↔	↔	↔
	S366	11.9	12.25	-2.8						
	S367	39.2	41.84	-6.3						
	S368	40.6	42.40	-4.3						
Sperm morphology (% normal)	S365	4	4.19	-4.6	57	-5.3	43.1	↔	↔	↘
	S366	2	3.30	-39.4						
	S367	3	4.21	-28.7						
	S368	2	4.18	-52.2						

- Very low
- Low
- Correct
- High
- Very high

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

Getting Started – Sperm motility

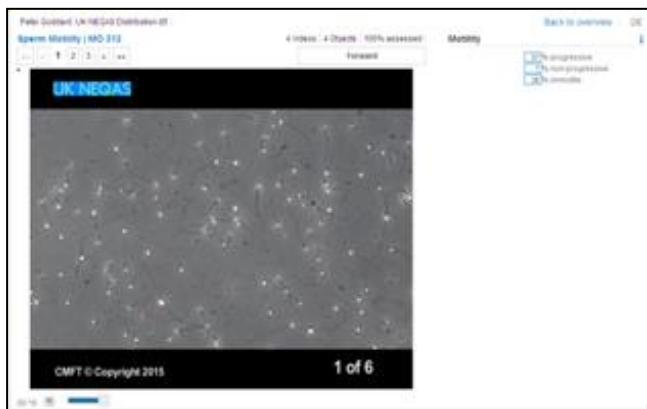
Notification: Participants should receive an email shortly after the distribution opens from UK NEQAS and the host website (gamete-expert.com). Log onto <http://gamete-expert.com> using your username and password



The screenshot shows the GAMETE EXPERT website interface. At the top, there is a navigation menu with links for Home, News, Company, Online training, Service, Contact, and Logout. Below the navigation, there is a sub-menu with Assessment, Change profile, and Change password. The main content area displays two assessment boxes. The first box, titled 'Sperm Motility', is highlighted with a red border and contains the following information: Images: 4, Objects: 4, Status: 0% assessed, and a link for Assessment. The second box, titled 'Sperm Morphology', contains: Images: 6, Objects: 24, Status: 100% assessed, and a link for Assessment.

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'

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

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).

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Centre Contact

Andrology - Sperm Motility	Report 96 95	Dist	Result	Latest
Andrology - Sperm Concentration & Morphology	96 95	Dist	Result	Latest
Andrology - Interpretive Sperm Morphology	Report 96 95	Dist	Result	Latest
Embryology - Embryo Morphology	Report 96 95	Dist	Result	Latest

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

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

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

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

	Andrology - Sperm Motility							Laboratory :		
	Distribution : 92				Date : 06-Mar-2017			Page 1 of 8		
	Distribution Summary									
	Specimen	Result	Target	Specimen %bias	A score	B score	C score	A	B	C
Progressive Motility (%)	MO341	85	78.54	+8.2	103	+9.1	9.2			
	MO342	48	34.79	+38.0						
	MO343	51	43.88	+16.2						
	MO344	52	43.32	+20.0						
Non Progressive (%)	MO341	6	4.37	+37.2	67	-25.8	16.9			
	MO342	7	9.14	-23.4						
	MO343	5	6.80	-26.4						
	MO344	3	7.00	-57.1						
Immotile (%)	MO341	9	16.77	-46.3	62	-4.7	8.0			
	MO342	45	55.86	-19.4						
	MO343	44	49.08	-10.4						
	MO344	45	49.41	-8.9						

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

	Very low
	Low
	Correct
	High
	Very high

Getting Started – Interpretive morphology

Notification: Participants should receive an email shortly after the distribution opens from UK NEQAS and the host website (gamete-expert.com). Log onto <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).

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Centre Contact

Andrology - Sperm Motility	Report	96	95	Dist	Result	Latest
Andrology - Sperm Concentration & Morphology	Report	96	95	Dist	Result	Latest
Andrology - Interpretive Sperm Morphology	Report	96	95	Dist	Result	Latest
Embryology - Embryo Morphology	Report	96	95	Dist	Result	Latest

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

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

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

	Andrology - Interpretive Sperm Morphology		Laboratory
	Distribution : 92	Date : 06-Mar-2017	Page 1 of 4
	Distribution Summary		

Specimen	Result	Target	Penalty	Performance
Sperm classification				
IM1-390	A	A	0	7 ● ↔
IM1-391	A	A	0	
IM1-392	A	A	0	
IM1-393	A	A	0	
IM1-394	A	A	0	
IM2-384	A	A	0	
IM2-385	A	A	0	
IM2-386	A	A	0	
IM3-367	A	A	0	
IM3-368	N	A	1	
IM3-370	A	A	0	
IM4-295	N	N	0	
IM4-296	A	A	0	
IM4-298	A	A	0	
IM5-229	A	A	0	
IM5-230	A	A	0	
IM5-231	A	A	0	
IM5-232	A	A	0	
IM5-233	N	N	0	
IM5-234	A	A	0	
IM5-235	A	A	0	
IM6-73	A	A	0	
IM6-74	N	A	0	
IM6-75	A	A	0	

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

Agree with UK NEQAS consensus
 Disagree with UK NEQAS consensus, 1 penalty point

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.

Specimen : IM1-78

N 0.0 %
 A 100.0 %
 A Your result
 A Consensus

Total Normals : 0
 Total Abnormals : 256
 This was classed as [A - Abnormal]
 Your penalty 0

Defect counts :-
 Residual excess cytoplasm : 1
 Head defects : 250
 Mid piece defects : 47
 Tail defects : 4

Specimen : IM2-126

N 29.7 %
 A 70.3 %
 N Your result
 A Consensus

Total Normals : 76
 Total Abnormals : 180
 This was classed as [A - Abnormal]
 Your penalty 1

Defect counts :-
 Residual excess cytoplasm : 2
 Head defects : 169
 Mid piece defects : 19
 Tail defects : 10

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

Getting Started – Embryo morphology

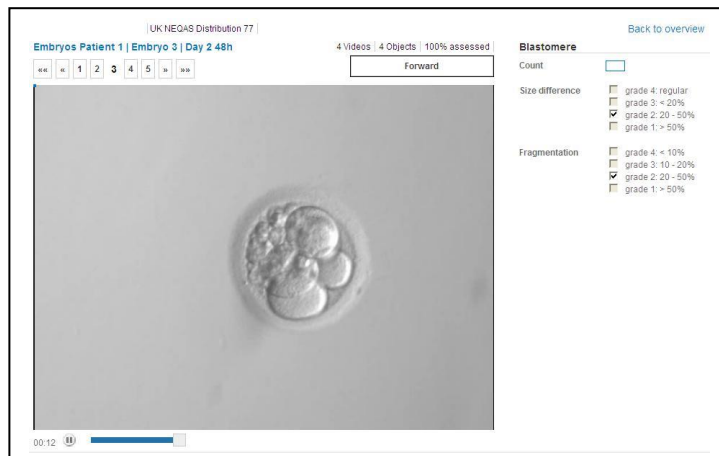
Notification: Participants should receive an email shortly after the distribution opens from UK NEQAS and the host website (gamete-expert.com). Log onto <http://gamete-expert.com> using your username and password

UK NEQAS Distribution 109 | May 2021

<p>Sperm Motility</p> <p>Images: 4 Objects: 4 Status: 0 % assessed Assessment</p>	<p>Sperm Morphology</p> <p>Images: 9 Objects: 24 Status: 100 % assessed Assessment</p>	<p>Embryos Patient 1</p> <p>Images: 4 Objects: 4 Status: 100 % assessed Assessment</p>	<p>Embryos Patient 2</p> <p>Images: 4 Objects: 4 Status: 100 % assessed Assessment</p>
<p>Embryos Patient 3</p> <p>Images: 4 Objects: 4 Status: 100 % assessed Assessment</p>	<p>Embryos Patient 4</p> <p>Images: 4 Objects: 4 Status: 100 % assessed Assessment</p>	<p>Embryos Patient 4_TL</p> <p>Images: 5 Objects: 5 Status: 100 % assessed Assessment</p>	

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 see Appendix 3).

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

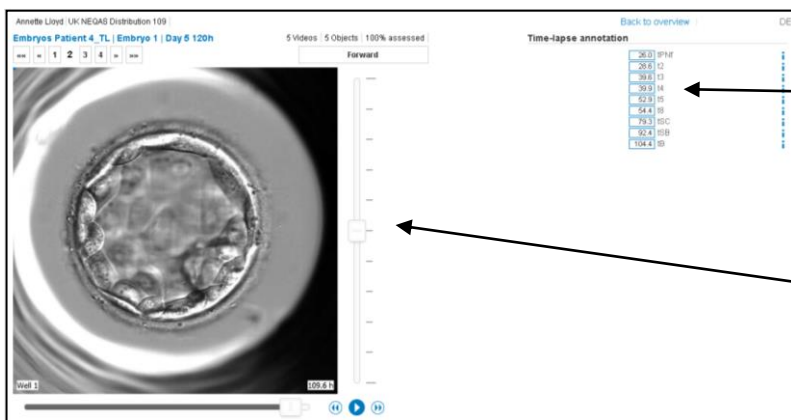
Select 'back to overview' and repeat on other 'Embryo patients'.

To enlarge video screen press 'Ctrl' and rotate the scroll wheel of your mouse anticlockwise. To reset, press Ctrl 0. To use the slider backwards and forwards: Please start the video. Go on the slider (while running video). Click left mouse button and keep it down (do not click back). The video stops. Move the slider with the down clicked mouse button. After release of the left mouse button the video starts again. For the time-lapse annotation analyse with Patient 4 – please see appendix 7 for instructions.



Patient 4 Time-lapse:
Please mark box to state whether you routinely use or don't use Time-lapse annotations in your clinical setting.

Even if not used clinically you are welcome to use for training and information purposes.



Enter Time-lapse annotations time point to 1 decimal place for each of the time points listed from tPNf to tB. Use the blue information button for further information. Complete for all 4 videos

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

Please check that 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).

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Centre: Contact:

Andrology - Sperm Motility	Report: 96 95	Dist: <input type="text"/>	Result: <input type="text"/>	Latest
Andrology - Sperm Concentration & Morphology	Report: 96 95	Dist: <input type="text"/>	Result: <input type="text"/>	Latest
Andrology - Interpretive Sperm Morphology	Report: 96 95	Dist: <input type="text"/>	Result: <input type="text"/>	Latest
Embryology - Embryo Morphology	Report: 96 95	Dist: <input type="text"/>	Result: <input type="text"/>	Latest

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

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

Page 1 of the report is a summary of the results

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

UK NEQAS Reproductive Science

Embryology - Embryo Morphology Laboratory : 11698

Distribution : 92 Date : 06-Mar-2017 Page 1 of 18

Distribution Summary

Summary of results

	P1-1	P1-2	P1-3	P1-4	P2-1	P2-2	P2-3	P2-4	P3-1	P3-2	P3-3	P3-4	P4-1	P4-2	P4-3	P4-4
Blastomere count	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Size difference	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲
Fragmentation	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲
Expansion status	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Inner cell mass	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Trophoctoderm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Legend:
 ▼ Very low
 ▲ Low
 ◆ Correct
 ▲ High
 ▲ Very high
 * Not scored
 □ n/a

Recent Performance

This time : ▲ ▲ ▲ ▲ ▲ ▲ ▲

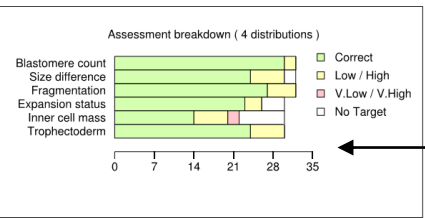
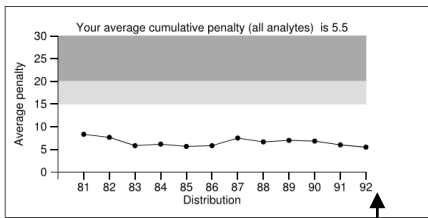
Blastomere count	0	1	7	0	0	Good and remains consistent	Good	OK	Poor	Blastomere count	●	○	○	Good
Size difference	0	0	7	1	0	Good and remains consistent	Good	OK	Poor	Size difference	●	○	○	Good
Fragmentation	0	0	7	1	0	Good and remains consistent	Good	OK	Poor	Fragmentation	●	○	○	Good
Expansion status	0	0	7	0	0	Good and remains consistent	Good	OK	Poor	Expansion status	●	○	○	Good
Inner cell mass	0	0	4	0	0	Good and remains consistent	Good	OK	Poor	Inner cell mass	●	○	○	Good
Trophoctoderm	0	0	7	1	0	Good and remains consistent	Good	OK	Poor	Trophoctoderm	●	○	○	Good

Overall Performance

Analytically you are Good or OK for 10 analyte(s), you are Poor for 0 analyte(s).
 You have returned results for 4 out of the last 4 Distributions.
 This return rate is **Satisfactory**

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.

Getting Started – Embryo morphology Hub and Spoke reports

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

Go to <https://results.ukneqas.org.uk>

Enter Hub Number (HBnnnn) and password (if you do not have these details, contact repscience@ukneqas.org.uk). Hub login screen (username of the form HBnnnn where 'n' is a single digit).

Results and Reports

HB

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[Centre](#) [Contact](#)

[UK NEQAS for Embryology \(Hubs\)](#) [Report](#) [Dist](#) [Network](#) [Latest](#)

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

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

Each spoke will be listed with its SPnnnnnn number and any mnemonic (e.g. users' initials)
The Hub coordinator can view the reports for individual spokes.

Results and Reports

HB

[Scheme](#) UK NEQAS for Embryology (Hubs)

[Dist](#) 2014-08-11 (82)

SP 0001	AB	Report	Result
SP 0002	CD	Report	Result
SP 0003	EF	Report	Result
SP 0004	GH	Report	Result
SP 0005	JK	Report	Result
SP 0006	LM	Report	Result

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

Access to spoke reports by individuals is available on request from repscience@ukneqas.org.uk.

Reports:

Key to code shapes:

- ◆ Green diamond - match with UK NEQAS consensus
- ▼ Yellow triangle - one step up or down away from UK NEQAS consensus
- ▲ Red triangles - two or more steps up or down from UK NEQAS consensus
- No symbol - no UK NEQAS consensus

Specimen	UKNEQAS Consensus	SP200379 Result	SP200637 Result	SP200661 Result	SP200648 Result	SP200746 Result	SP200790 Result	SP200839 Result	SP200940 Result	SP200941 Result
Blastomere count										
P1-1	4	3 ▼	3 ▼	3 ▼	4 ◆				3 ▼	3 ▼
P1-2	5	5 ◆	5 ◆	5 ◆	5 ◆				5 ◆	5 ◆
P1-3	4	4 ◆	4 ◆	4 ◆	4 ◆				4 ◆	4 ◆
P1-4	4	4 ◆	4 ◆	4 ◆	4 ◆				4 ◆	4 ◆
P2-1	7	7 ◆	7 ◆	7 ◆	7 ◆				8 ▲	8 ▲
P2-2	12	12 ◆	12 ◆	10 ▼	11 ▼				11 ▼	12 ◆
P2-3	6	6 ◆	6 ◆	6 ◆	6 ◆				6 ◆	6 ◆
P2-4	7	6 ▼	7 ◆	6 ▼	7 ◆				7 ◆	7 ◆
Size difference (blastomere evenness)										
P1-1		3	3	3	2				3	3
P1-2		3	2	3	3				2	2
P1-3	3	2 ▼	2 ▼	3 ◆	3 ◆				3 ◆	3 ◆
P1-4	3	3	3	3	3				3	3
P2-1	3	2 ▼	2 ▼	3 ◆	3 ◆				3 ◆	3 ◆
P2-2	3	3 ◆	3 ◆	4 ▲	3 ◆				3 ◆	3 ◆
P2-3	2	2	2	4	3				2	2
P2-4	3	2 ▼	3 ◆	4 ▲	3 ◆				3 ◆	3 ◆
Fragmentation										
P1-1	4	3 ▼	3 ▼	3 ▼	4 ◆				3 ▼	3 ▼
P1-2	4	4 ◆	4 ◆	4 ◆	4 ◆				4 ◆	4 ◆
P1-3	3	3	4 ▲	4 ▲	3				4 ▲	4 ▲
P1-4	4	4 ◆	3 ▼	3 ▼	3 ▼				4 ◆	4 ◆
P2-1	3	3	2	3	3				3	3
P2-2	4	4 ◆	4 ◆	4 ◆	4 ◆				4 ◆	4 ◆
P2-3	4	4 ◆	4 ◆	4 ◆	4 ◆				4 ◆	4 ◆
P2-4	2	2	2	2	2				2	2
Expansion status										
P3-1	5	5 ◆	5 ◆	5 ◆	5 ◆				5 ◆	5 ◆
P3-2	5	5 ◆	5 ◆	5 ◆	5 ◆				4 ▼	5 ◆
P3-3	5	5 ◆	5 ◆	5 ◆	5 ◆				5 ◆	5 ◆
P3-4	5	5 ◆	5 ◆	5 ◆	5 ◆				5 ◆	5 ◆
P4-1	4	4 ◆	4 ◆	4 ◆	4 ◆				4 ◆	4 ◆
P4-2	4	4 ◆	4 ◆	4 ◆	4 ◆				3 ▼	4 ◆
Inner cell mass										
P3-1	5	4 ▼	5 ◆	5 ◆	5 ◆				4 ▼	5 ◆
P3-2	5	5 ◆	5 ◆	5 ◆	2				5 ◆	4
P3-3	3	3	3	3	1 ▼				3 ◆	3 ◆
P3-4	4	3 ▼	4 ◆	4 ◆	3 ▼				4 ◆	4 ◆
P4-1	2	2	2	3	2				2	2
P4-2	4	4 ◆	4 ◆	4 ◆	4 ◆				4 ◆	4 ◆
Trophectoderm										
P3-1	3	2 ▼	2 ▼	2 ▼	3 ◆				2 ▼	3 ◆
P3-2	3	2 ▼	2 ▼	2 ▼	2 ▼				2 ▼	2 ▼
P3-3	2	1 ▼	1 ▼	2 ◆	1 ▼				2 ◆	2 ◆
P3-4	2	1 ▼	2 ◆	2 ◆	2 ◆				2 ◆	2 ◆
P4-1	2	1 ▼	2 ◆	2 ◆	2 ◆				2 ◆	2 ◆
P4-2	2	1 ▼	2 ◆	2 ◆	2 ◆				2 ◆	2 ◆

Spokes are individual licence/login holders and will be identified by initials or a unique spoke number. The report allows comparison between embryologists within your laboratory for IQC purposes.

These 3 people (spokes) did not submit results.

▼	Very low
▼	Low
◆	Correct
▲	High
▲	Very high

Continued on next page:

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

Key to code shapes:

- ◆ Green diamond - match with UK NEQAS consensus
- ▼ Yellow triangle - one step up or down away from UK NEQAS consensus
- ▲ Red triangles - two or more steps up or down from UK NEQAS consensus
- No symbol - no UK NEQAS consensus

	Specimen	UKNEQAS Consensus	SP200379 Result	SP200637 Result	SP200661 Result	SP200649 Result	SP200746 Result	SP200790 Result	SP200939 Result	SP200940 Result	SP200941 Result	
Quality (suitability for cryostorage)	P1-1	N	Y	Y	N	Y	N			Y	Y	
	P1-2	Y	Y ◆	N ▲	Y ◆	Y ◆				N ▲	Y ◆	
	P1-3	Y	N ▲	N ▲	Y ◆	Y ◆				Y ◆	Y ◆	
	P1-4	Y	Y ◆	Y ◆	Y ◆	Y ◆				Y ◆	Y ◆	
	P2-1	Y	N ▲	N ▲	Y ◆	Y ◆				Y ◆	Y ◆	
	P2-2	Y	Y ◆	Y ◆	Y ◆	N ▲				N ▲	Y ◆	
	P2-3	Y	N ▲	N ▲	Y ◆	Y ◆				N ▲	N ▲	
	P2-4	N	N ▲	N ▲	N ▲	N ▲				N ▲	N ▲	
	P3-1	Y	Y ◆	Y ◆	Y ◆	Y ◆				Y ◆	Y ◆	
	P3-2	Y	Y ◆	Y ◆	Y ◆	N ▲				Y ◆	Y ◆	
	P3-3	N	N ▲	N ▲	N ▲	N ▲				N ▲	N ▲	
	P3-4	Y	N ▲	Y ◆	Y ◆	Y ◆				Y ◆	Y ◆	
	P4-1	Y	N ▲	N ▲	N ▲	N ▲				N ▲	N ▲	
	P4-2	Y	N ▲	Y ◆	Y ◆	Y ◆				Y ◆	Y ◆	
	Quality category	P1-1	3	2	2	3	4				3	2
		P1-2	2	1 ▲	3 ▼	1 ▲	2				2 ▼	2 ◆
P1-3		2	3	2	2	3				2 ◆	2 ◆	
P1-4			N	2	2	2				2	2	
P2-1			2	3	2	2				3	2	
P2-2			1	2	2	4				4	2	
P2-3		2	3 ▼	3 ▼	1 ▲	2				3 ▼	3 ▼	
P2-4		4	5 ▼	4 ◆	4 ◆	4 ◆				3 ▲	3 ▲	
P3-1		1	2 ▼	1 ◆	1 ◆	2 ▼				2 ▼	1 ◆	
P3-2			1	2	1	4				2	2	
P3-3			3	4	3	4				4	3	
P3-4			4	3	2	3				2	2	
P4-1			5	4	3	4				5	3	
P4-2		2	3 ▼	2 ◆	1 ▲	2 ◆				3 ▼	2 ◆	
Quality ranking		P1-1	4	3	3	4	4				4	4
		P1-2		1	4	1	1				3	1
	P1-3		4	2	2	2				1	2	
	P1-4		2	1	3	3				2	3	
	P2-1		2	3	2	4				1	1	
	P2-2		1	1	3	1				4	2	
	P2-3		3	2	1	2				2	4	
	P2-4	4	4 ◆	4 ◆	4 ◆	4 ◆				3 ▲	3 ▲	
	P3-1	1	2 ▼	1 ◆	1 ◆	1 ◆				2 ▼	1 ◆	
	P3-2	2	1 ▲	2 ◆	2 ◆	3 ▼				1 ▲	2 ◆	
	P3-3	4	3	4	4	4				4	4	
	P3-4	3	4 ▼	3	3	2 ▲				3	3	
	P4-1	2	2	2	2	2				2	2	
	P4-2	1	2 ▼	1 ◆	1 ◆	1 ◆				1	1	

Suitability for cryostorage:
Are your embryologists adhering to your clinic's cryostorage policy?

Quality category:
How do your embryologists define top quality or poor-quality embryos?

Quality ranking:
Would your embryologists choose the same embryo for transfer?

Reproductive Science Scheme – Participants’ Handbook

Schemes provided

SCHEME

Andrology (Semen analysis)

ANALYTES

Sperm Concentration (practical)

Sperm Morphology (practical)

Sperm Motility (online)

Interpretive Sperm Morphology (online)

Embryology

Embryo Morphology (online)

Time lapse annotation (online)

Contacting the scheme

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

Aims

The UK NEQAS Reproductive Science Scheme aims to:

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

Organisation

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

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

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

Changes to the scheme

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

Deviations from Contract

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

External Oversight of our EQA Services

Accreditation to ISO/IEC 17043:2010

UK NEQAS Reproductive Science is accredited by UKAS against the requirements of ISO/IEC 17043:2010 – Conformity Assessment – General requirements for proficiency testing. The scope of accreditation can be viewed on the UKAS website: [Scope of Accreditation](#). UKAS number for UK NEQAS Reproductive Science is 8228.

UK NEQAS Consortium

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

Steering Committees

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

RCPATH National Quality Assurance Advisory Panel

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

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

Ethics

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

Other Links

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

Terms and Conditions of Participation

Eligibility - Our services are designed principally for UK public and private sector clinical laboratories serving clinicians and patients. Non-UK clinical laboratories, those with purely research or industrial roles, manufacturers of diagnostic instruments and reagents and other laboratories are also welcome to participate. Manufacturers may do so on an 'information only' basis, 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 postal transport system.

Andrology scheme – The latest recommended World Health Organisation (WHO) guidelines for processing semen - WHO laboratory manual for the examination and processing of human semen (fifth edition), can be found here: <https://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) and ratified by the Association of Clinical Reproductive scientists (ARCS) in 2020.

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

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

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

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

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

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

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

Please quote your laboratory code number in all communications.

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

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

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

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

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

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

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

Performance scores (and some raw data) may be shared with the relevant NQAAP under defined circumstances as part of the routine reporting of persistent unsatisfactory performance. This data may be shared with local management, regional QA officers, accrediting bodies and suppliers of equipment and reagents where appropriate and necessary, but the participant shall be informed. UK NEQAS Reproductive science reports are copyright and may not be copied, distributed, published or used for publicity and promotion in any form without the written consent of the relevant scheme Organiser on each and every occasion, though performance data may be shared with individual clients (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 schemes a library of the images and videos analysed by participants is available (this function is unavailable during an open distribution).

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

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

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

Participant objectives

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

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

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

Scheme Design

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

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

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

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

Schedule of analytes

Andrology scheme

Analyte: Sperm Concentration

Accreditation Status: accredited by UKAS against the requirements of ISO/IEC 17043:2010

Date Scheme started: 1994

Units for Reporting: x10⁶/ml

Proficiency testing materials: Human semen containing preservative (10% neutral buffered formalin).

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: accredited by UKAS against the requirements of ISO/IEC 17043:2010

Date Scheme started: 1994

Units for Reporting: Percentage (%) Normal forms

Proficiency testing materials: Human semen containing preservative (10% neutral buffered formalin).

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: accredited by UKAS against the requirements of ISO/IEC 17043:2010

Date Scheme started: 1995

Units for Reporting: Percentage (%) for Progressive Motility (PR), Non-Progressive (NP) and Immotile (IM) sperm.

Proficiency testing materials: Video clips of fresh semen.

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).

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: accredited by UKAS against the requirements of ISO/IEC 17043:2010

Date Scheme started: 2011

Units for Reporting: Normal/Abnormal

Proficiency testing materials: Images of Papanicolau stained spermatozoa.

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: accredited by UKAS against the requirements of ISO/IEC 17043:2010

Date Scheme started: 2011

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

Proficiency testing materials: Video clips of embryos.

Number of Distributions per year: 4

Number of Samples per Distribution: 16

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, except for time lapse annotation which is an expert derived target.

Performance Scoring: Penalty points system for embryo morphology.

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: Embryo Time Lapse Annotation

Accreditation Status: accredited by UKAS against the requirements of ISO/IEC 17043:2010

Date Scheme started: 2016

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

Proficiency testing materials: time-lapse video clips of embryos.

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 time-lapse annotations in conjunction with the Ciray et al (2014) Embryo annotation timing System.

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: Expert derived consensus. A minimum of 3 expert assessors results are used.

Performance Scoring: Rolling B score (ABC system).

Criteria of Performance: Laboratory performance is assessed over a running analytical window of 4 Distributions (12 months). Formal monitoring for assessment purposes from May 2021. For full details of the time-lapse annotation analyte please see Appendix 7.

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

Materials

Sources of semen & embryos –

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

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% neutral buffered formalin. Please handle EQA semen specimens with the same precautions as are normally adopted in the handling of patient specimens in accordance with your departmental safety arrangements. **Appropriate procedures should be used to minimise contact with samples and for their disposal.**

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

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

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

Online services

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

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

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

Individual logins

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

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

These reports do not represent a proficiency testing report from UK NEQAS Reproductive Science and they are not accredited to ISO17043:2010.

Hub and Spoke Reports

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

Transfer of Data

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

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

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

The web service does not permit the user to independently add or modify the validation or associated setups. This ensures it fully replicates the manual data entry options and result validation as defined in the Wolfson software. The participants are responsible for accurately entering their results. Results entered online are thus pre-validated and can be imported directly into the Wolfson EQA software (again by file transfer).

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

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

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

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

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

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

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

Operations

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

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

Distribution dates – Once distributions go live, they usually remain open for four calendar weeks for all schemes (this can be extended in certain circumstances). The schedule for the current calendar year (and the following year when finalised) is available at <https://mft.nhs.uk/saint-marys/services/gynaecology/reproductive-medicine/uknegasreproductive-science/>, 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 for errors, omissions or changes at the earliest opportunity.

If semen specimens and email notification of the online schemes do not arrive on time or are incorrect it is essential that participants inform 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. "International tracked and 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 'Human Exempt Specimens'. All tubes are labelled with the scheme name and sample number. The naming convention for the latter is a sequential numeric sample identifier plus a letter where there are multiple specimens in a distribution (e.g. S401, S402, S403, S404).

Receipt of samples: Check samples on receipt to be sure that the correct samples are in the pack and there is no damage to the ampoules. Contact repscience@ukneqas.org.uk immediately if replacement samples are required.

If your samples do not arrive within an appropriate time frame (5 working days for most participants, may take longer for overseas post) **please contact** repscience@ukneqas.org.uk.

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

- **Semen specimens**

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

- **Sperm Motility and Interpretive Morphology (online)**

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

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

- **Embryo Morphology**

The Embryo Morphology distributions contain videos of embryos (rolling and 'time-lapse') from patients for assessment. Please note: videos used for assessment purpose may be longer than the time taken to grade embryos in a clinical setting, to allow participants to have sufficient time to assess.

Processing UK NEQAS samples in your laboratory

- **Receipt and analysis**

UK NEQAS distributions are intended to monitor your performance on routine patient specimens.

Please process them through your normal reception, analytical and reporting procedure.

Result reporting procedure

Results should be entered in the units shown onto the correct results document (or online service form), taking care to match sample numbers and avoid transcription or transposition errors. In the numerical analytes, concentration results should be reported to 2 significant figures and motility and 'practical' morphology results should be reported to the nearest whole number (as stated in WHO manual 2010).

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://mft.nhs.uk/saint-marys/services/gynaecology/reproductive-medicine/ukneqasreproductive-science/>

Embryo Morphology including time-lapse annotation

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://mft.nhs.uk/saint-marys/services/gynaecology/reproductive-medicine/ukneqasreproductive-science/>

- **Failure to return results**

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

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

- **Late returns**

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

- **Input errors**

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

- **Amendments to results prior to reporting deadline**

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

- **UK NEQAS errors**

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

Data processing

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

Calculation of target values - Target values are crucial to scheme design and usefulness and are the basis for accurate performance scores. In all cases, a robust estimator of the central tendency of the data set and its dispersion are calculated.

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 (See section 'Example Reports' - 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 'gold standard' result**, and only reflects how a majority (>50%) of participating laboratories are interpreting the National Grading Scheme (Fig 5 &6). The 'correct answer' displayed on the Gamete Expert website is a consensus result for all participating laboratories (UK NEQAS target value) or for all participating individuals with personal logins (Gamete Expert target value). For time-lapse annotation an expert derived Target Value is used with minimum input from three members of the expert panel. This is currently under review as time-lapse annotation becomes routine in the clinical setting. The embryo grading scheme is available via the website <https://mft.nhs.uk/saint-marys/services/gynaecology/reproductive-medicine/ukneqasreproductive-science/>

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

Acceptable performance criteria - Schemes are required to provide information on persistent unsatisfactory performers to the 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 committee, to reflect the state of the art of analysis and encourage improvement. Special procedures are used to identify those laboratories which have breached these limits on a set number of occasions within the cumulative reporting period. Current limits for our schemes are outlined in Appendix 2.

Reports and Report interpretation

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

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

For 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 dispatched. Once again, these dates are recorded.

Reports - Schemes' reports are the main interface with participants, and a great deal of effort has gone into making these informative and easy to interpret. All scheme reports are generated as A4 format PDF files, which display the data in a number of discrete tabular and graphic formats shared across related schemes. 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
- Standard Uncertainty measurement (numerical schemes only)

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.

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 username 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.

Standard Uncertainty

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

$$\text{Standard Uncertainty} = \frac{1.25 \times \text{SD}}{\text{SQRT (NTRIM)}}$$

Where:

SD = Standard deviation

SQRT = Square root

NTRIM = Number of Participants remaining once outliers are trimmed.

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

Rolling Time Window performance scores

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

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

- When interpreting performance scores, participants should look first for atypical results in a single isolated distribution (as above) and relate these to IQC data on the day of analysis, and then for shifts or trends over a number of distributions which might indicate a method related problem. Note that the C score always increases when the B score changes in either direction, so that this will occur when bias shifts and again if a correction is made. Only after a full period of stable performance (with or without a change in bias) will the C score decrease to low levels. The graphical elements of cumulative reports show this clearly in relation to acceptable limits of performance (not all schemes) and the overall behaviour of different method groups. Attempts should be made to correlate trends and/or shifts in bias with IQC data, which in turn should indicate whether changes in personnel, data reduction, procedures, calibration or instruments are implicated.

- **Calculation of Analytical Performance Scores for Concentration, morphology & motility**

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

- **Calculation of Analytical Performance Scores for Interpretive Morphology Scheme**

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

• Calculation of Analytical Performance Scores for Embryology Scheme

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

Time-lapse annotation analyte (introduced April 2016): 9 annotations for assessment: Laboratory performance is **now being formally assessed from May 2021** after a trial period following the pilot scheme and UKAS accreditation (which was gained in March 2019). Target values (TVs) for each of the 9 annotations are given and are derived by 'Expert' consensus. A minimum of 3 expert assessors are used for each distribution. Rolling performance is reported on page 20 of the report. This part of the scheme gained UKAS accreditation (ISO17043:2010) in March 2019.

Coincidence Monitoring

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

Enrolment Certificates

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

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

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

The screenshot shows the UK NEQAS website interface. At the top, it says 'UK NEQAS United Kingdom National External Quality Assessment Schemes'. Below this are links for 'UK NEQAS Website', 'Switch Lab/ID', 'Change password', and 'Help'. The main heading is 'Results and Reports'. A button labeled 'Lab' is circled in red. Below this is a link for 'UK NEQAS Reproductive Science (Manchester) [Homepage]'. There are two buttons: 'Centre' and 'Contact'. A table lists various schemes with their respective report scores and result dropdown menus.

Scheme	Report	Dist	Result
Andrology - Sperm Motility	96 95		Latest
Andrology - Sperm Concentration & Morphology	96 95		Latest
Andrology - Interpretive Sperm Morphology	96 95		Latest
Embryology - Embryo Morphology	96 95		Latest

Performance Problems

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

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

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

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

Performance surveillance and Advisory Panel liaison –

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

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

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

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

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

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

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

Complaints & Appeals

Definition

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

Types of Complaint and How to make a Complaint

Please study the sequence of actions indicated below and either write or email the appropriate individual. Emails of complaint to repscience@ukneqas.org.uk should 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 or email) though a preliminary telephone call may assist in clarifying the issue and establishing the requisite action. All 17043:2010 complaints shall be acknowledged within 5 working days of receipt. Wherever possible, a final response is given within 3 months of the acknowledgement.

- Where the complaint is about **scheme logistics**, then the **Scheme Manager** 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 contacted.
- If matters remain unresolved, or the action taken by us is not satisfactory to the complainant, the next step is to refer the complaint to the Chairman of the **Steering Committee**.
- If the issue concerns **performance assessment**, the **Chairman of the Advisory Panel** may also be contacted.
- Where lack of compliance with **ISO 17043:2010 Standards** is suspected by the complainant, then (in the first instance), contact our **Quality Manager**. If the complaint is not resolved to the satisfaction of the complainant then the **Executive Chair of UKAS** may be contacted.
- Where the **UK NEQAS Code of Practice** itself is the issue of concern, the **President of UK NEQAS** may be appropriate.

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

Appeals Against the Evaluation of Your Performance and erroneous results.

If you wish to appeal against the evaluation of your performance, or if there are erroneous results, please contact us using the details on page 2 of this document.

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

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

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

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 Manchester University Foundation Trust Andrology & Embryology laboratories, the Manchester University Foundation Trust's Finance Department, and our subcontractors. The continued loyalty of all participants, which has enabled 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 <https://mft.nhs.uk/saint-marys/services/gynaecology/reproductive-medicine/ukneqasreproductive-science/>) or printed by UK NEQAS Reproductive Science Scheme participants for their personal use.

REFERENCES


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Example Reports

Figure 1 – Address and Comments page

	Andrology - Sperm Concentration & Morphology	Laboratory :	
	Distribution : 95	Date : 04-Dec-2017	Page 1 of 6
	Address and Comments		

Quality Manager
Pathology Laboratory
Biochemistry Department
Hospital
Town
County
Country

Current contact person and address details we have for your laboratory.

Current email address details we have for your laboratory.

This Scheme is essentially web-based. We can alert you to information regarding the Scheme via email. The e-mail address (or addresses) we are currently using to contact your laboratory is shown below in red . If no e-mail address is displayed or the information shown is incorrect, please email us with an appropriate contact e-mail address as soon as possible, using the word 'feedback' in the title line and stating your UK NEQAS lab number.

Transit and analysis times (Sperm Concentration & Morphology only).

Based on the date information you have provided, the transit time from specimen dispatch [] to receipt [] was day(s), and the laboratory was day(s). (Missing values indicate dates not provided. "0 days" represents same day receipt/analysis).

Any comments you made to us are shown below and have been acted upon where necessary

Comments received from your laboratory and any response from UK NEQAS.

Any specific comments applicable only to laboratory are shown below

Any general comments applicable to all laboratories are shown below

General comments from UK NEQAS specific to this distribution. Authorisation signature, date and report type.

The homogeneity and stability assessment for this distribution was satisfactory.

For further details on the design, operation and statistical analysis of this scheme, please see the Participants' Handbook (available to download from <http://www.cmfh.nhs.uk/ukneqasrepsci.aspx>)

Please note: Performance limits amended from Distribution 93 onwards, see Participants' Handbook for details

Final Report, authorised on Monday 18th December 2017 by
Diane Critchlow
Scheme Organiser, UK NEQAS for Reproductive Science



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

UK NEQAS
International Quality Expertise

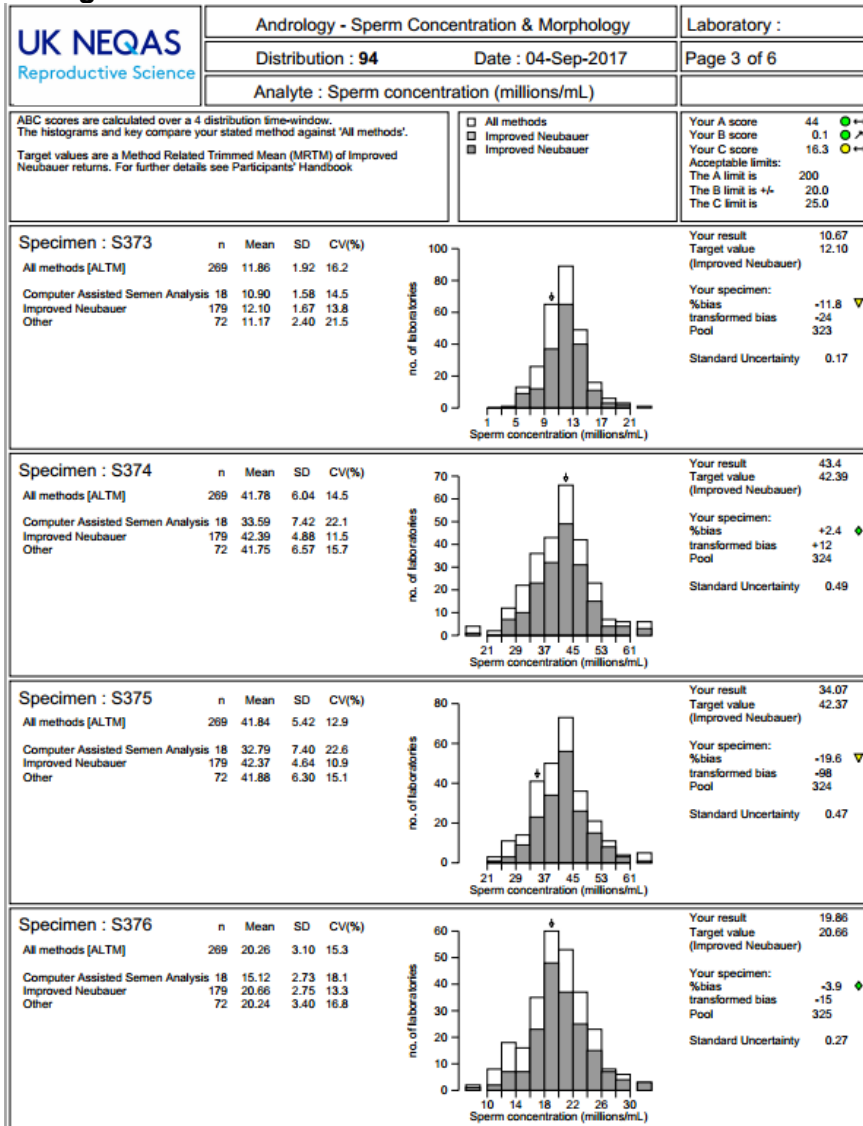
UK NEQAS Reproductive Science is proud to offer EQA services that adhere to the code of practice and have the badge of quality of UK NEQAS

UK NEQAS Reproductive Science is part of Manchester University Hospitals NHS Foundation Trust and provides this UK NEQAS service from Andrology Laboratories, St Mary's Hospital, Oxford Rd, Manchester, M13 9WL, UK.
To contact us email repsci@ukneqas.org.uk or Tel +44 (0)161 276 6437
Please return results for Semen Concentration and Morphology via the Online Results and Reports Service.
Semen collection is currently subcontracted to other UKAS accredited laboratories.

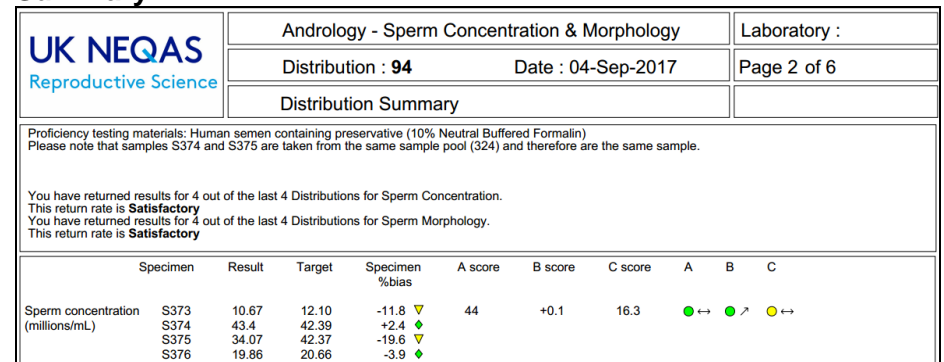
© Data UK NEQAS report is confidential
For this scheme the Organiser is Diane Critchlow

UK NEQAS Reproductive Science is a UKAS accredited proficiency testing provider, No. 8228.
Published at 8:32 on Monday 15 January 2018

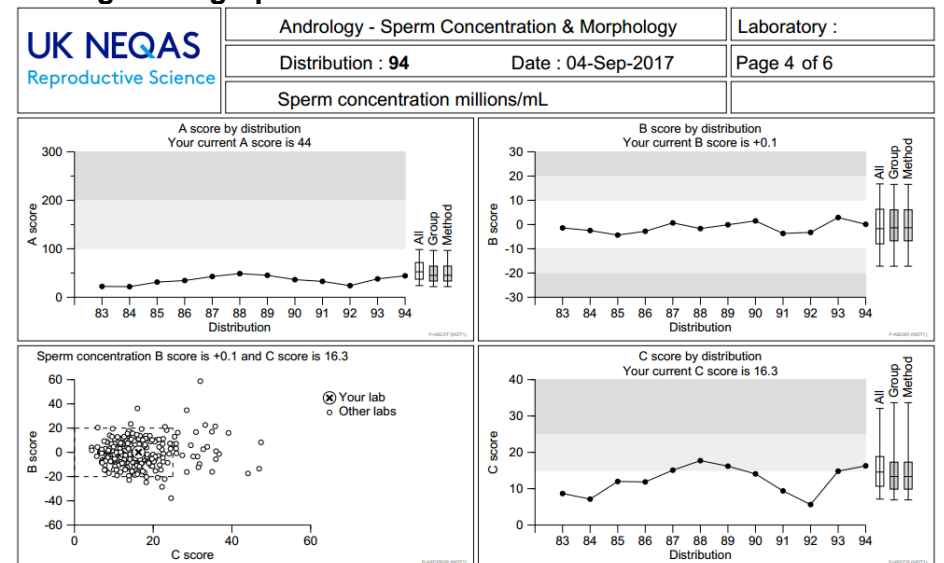
Example reports
Figure 2 – Sperm concentration (millions/ml)
Histograms



Summary

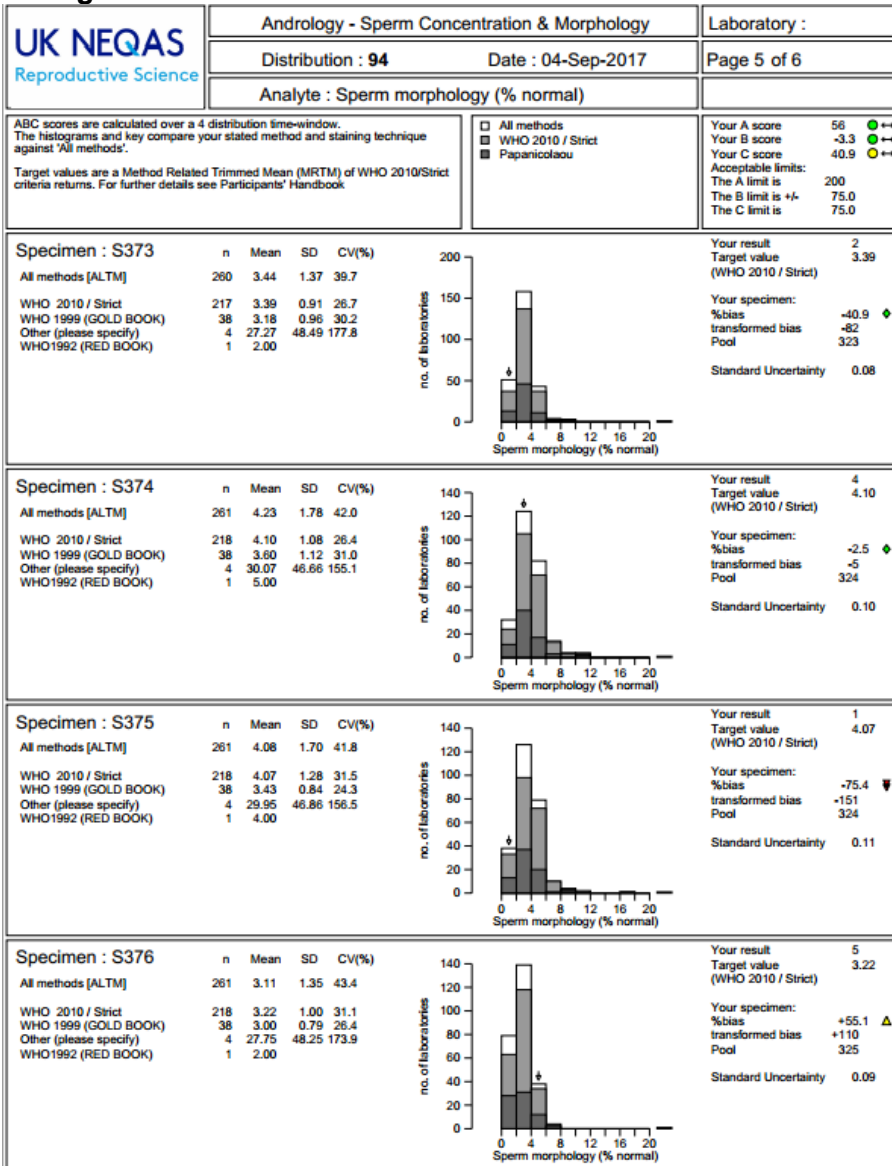


Rolling score graphs

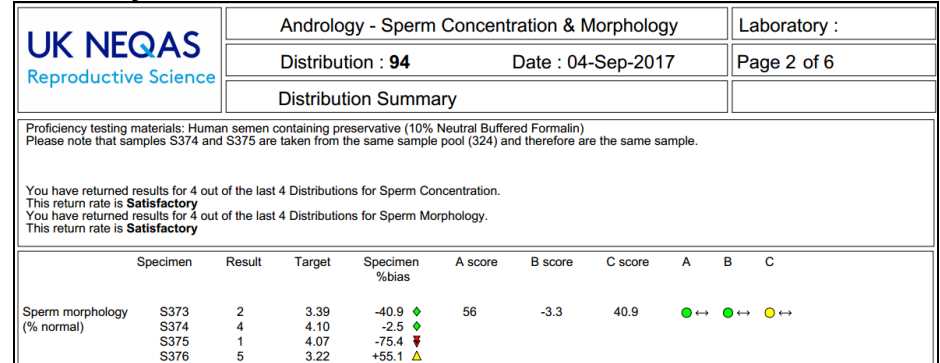


For current performance limits, see appendix 2.

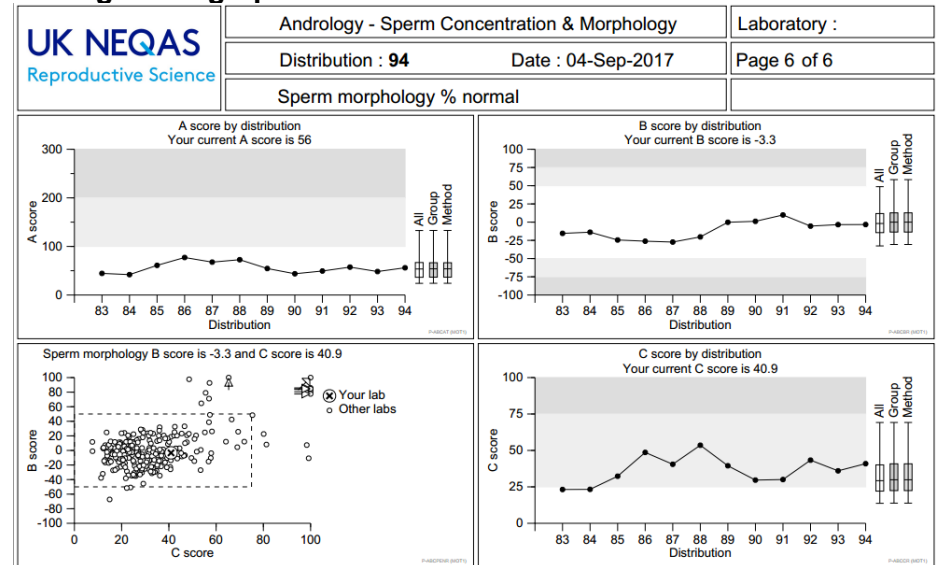
Figure 3 – Sperm Morphology (% normal) Histograms



Summary

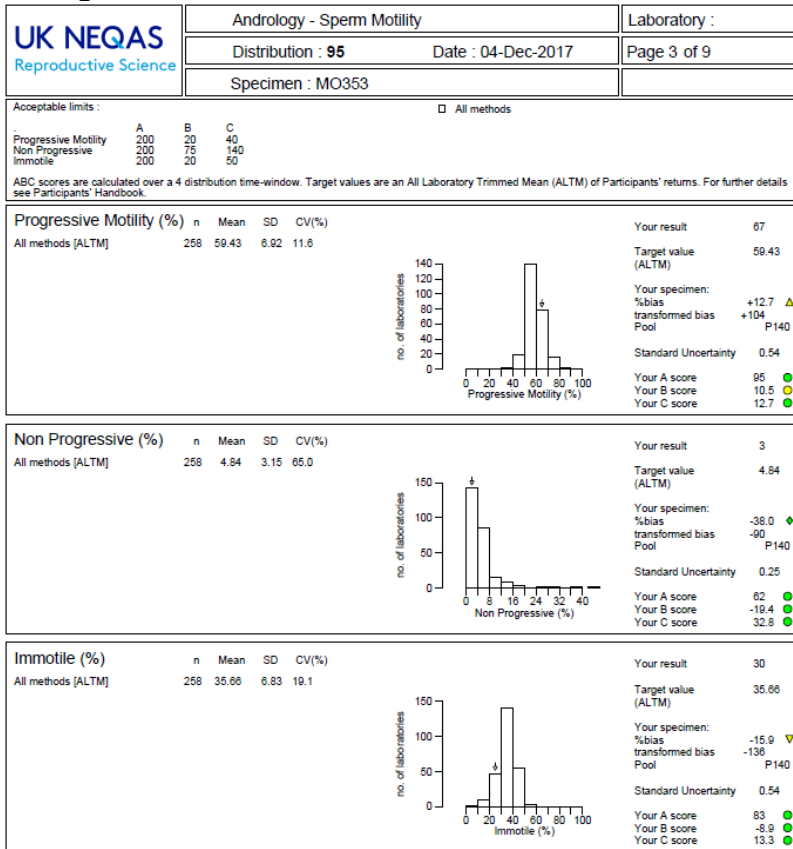


Rolling score graphs



For current performance limits, see appendix 2.

Figure 4 – Sperm Motility Histograms



Summary

Proficiency testing materials: video clips of fresh semen.

You have returned results for 4 out of the last 4 Distributions.
This return rate is **Satisfactory**.

Specimen	Result	Target	Specimen %bias	A score	B score	C score	A	B	C	
Progressive Motility (%)	MO353	67	59.43	+12.7 ▲	95	+10.5	12.7	●	●	●
	MO354	73	67.73	+7.8 ▲			●	●	●	
	MO355	45	32.58	+38.1 ▲						
	MO356	54	49.63	+8.8 ▲						
Non Progressive (%)	MO353	3	4.84	-38.0 ●	62	-19.4	32.8	●	●	●
	MO354	6	5.97	+0.5 ●						
	MO355	13	11.04	+17.8 ●						
	MO356	7	6.10	+14.8 ●						
Immotile (%)	MO353	30	35.66	-15.9 ▼	83	-8.9	13.3	●	●	●
	MO354	21	25.69	-18.2 ▼						
	MO355	42	56.40	-25.5 ▼						
	MO356	39	44.29	-11.9 ▼						

For current performance limits, see appendix 2.

Rolling score graphs

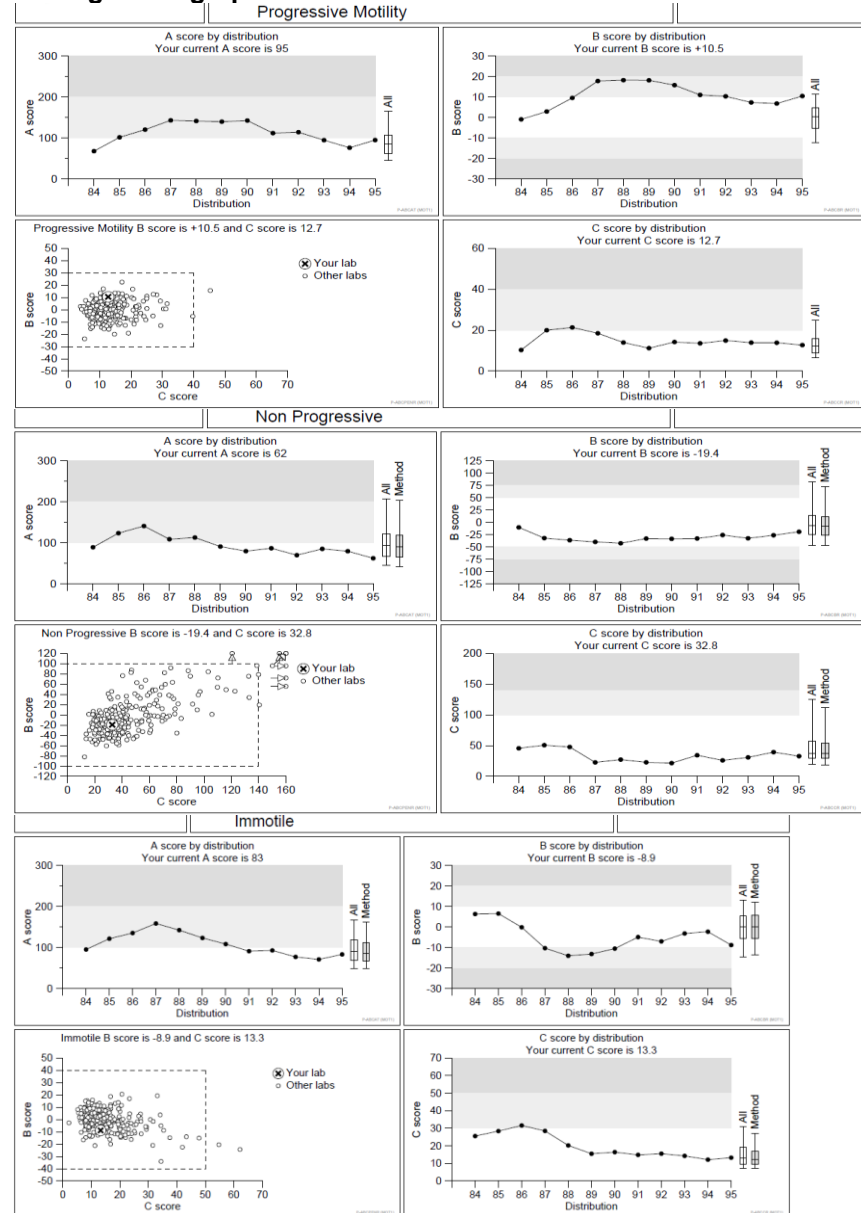


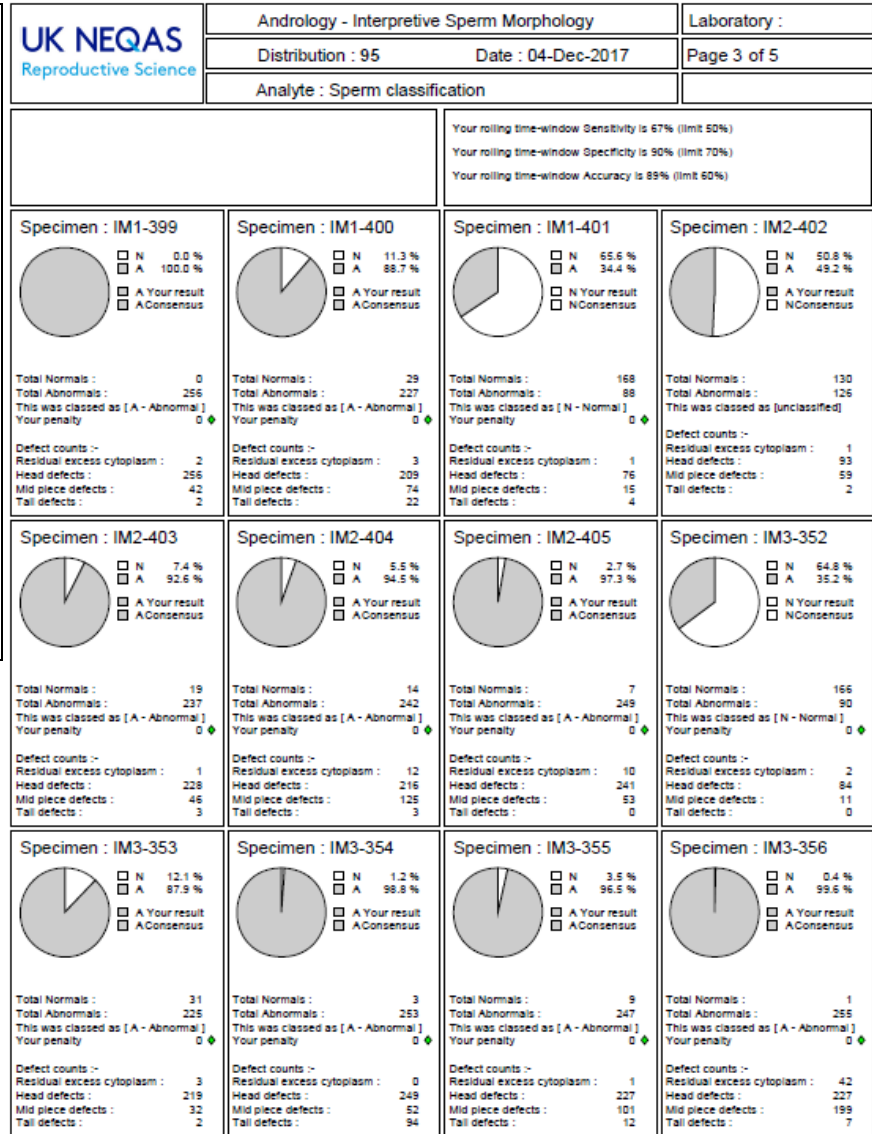
Figure 5 – Interpretive Morphology Report Summary

UK NEQAS Reproductive Science	Andrology - Interpretive Sperm Morphology	Laboratory :
	Distribution : 95 Date : 04-Dec-2017	Page 2 of 5
	Distribution Summary	

Proficiency testing materials: images of Papanicolaou stained spermatazoa.
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.

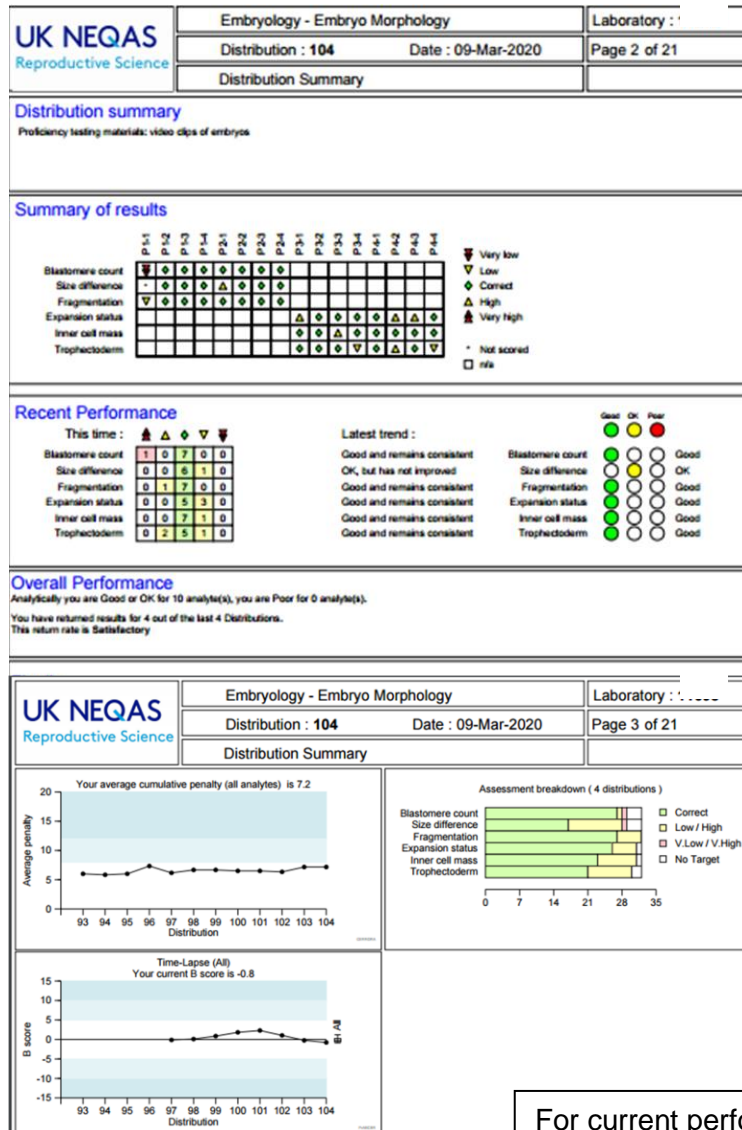
Specimen	Result	Target	Penalty	Performance
Sperm classification				10 ● ● ●
IM1-399	A	A	0	●
IM1-400	A	A	0	●
IM1-401	N	N	0	●
IM2-402	A	A	0	●
IM2-403	A	A	0	●
IM2-404	A	A	0	●
IM2-405	A	A	0	●
IM3-352	N	N	0	●
IM3-353	A	A	0	●
IM3-354	A	A	0	●
IM3-355	A	A	0	●
IM3-356	A	A	0	●
IM4-214	A	A	0	●
IM4-215	A	A	0	●
IM4-216	A	A	0	●
IM5-357	A	A	0	●
IM5-358	A	A	0	●
IM5-359	A	A	0	●
IM6-79	A	A	0	●
IM6-80	A	A	0	●
IM6-81	A	A	0	●
IM6-82	A	A	0	●
IM6-83	A	A	0	●
IM6-84	A	A	0	●

Pie Charts

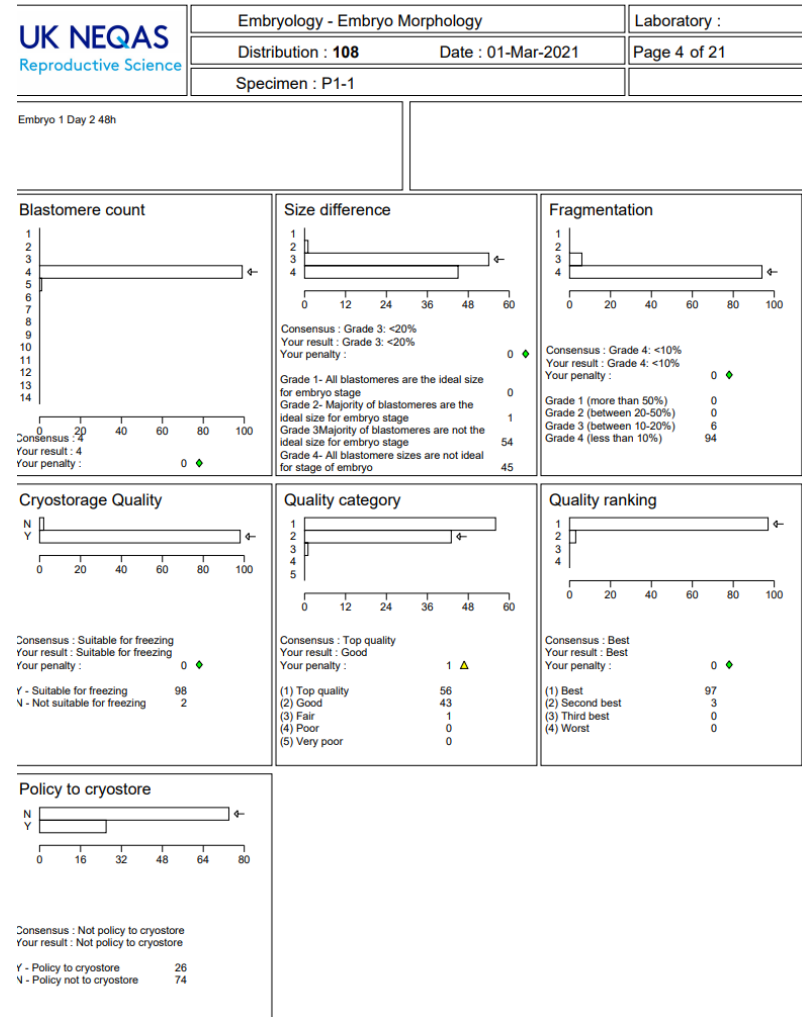


For current performance limits, see appendix 2.

Figure 6 – Embryology Scheme Report (part 1) Summary



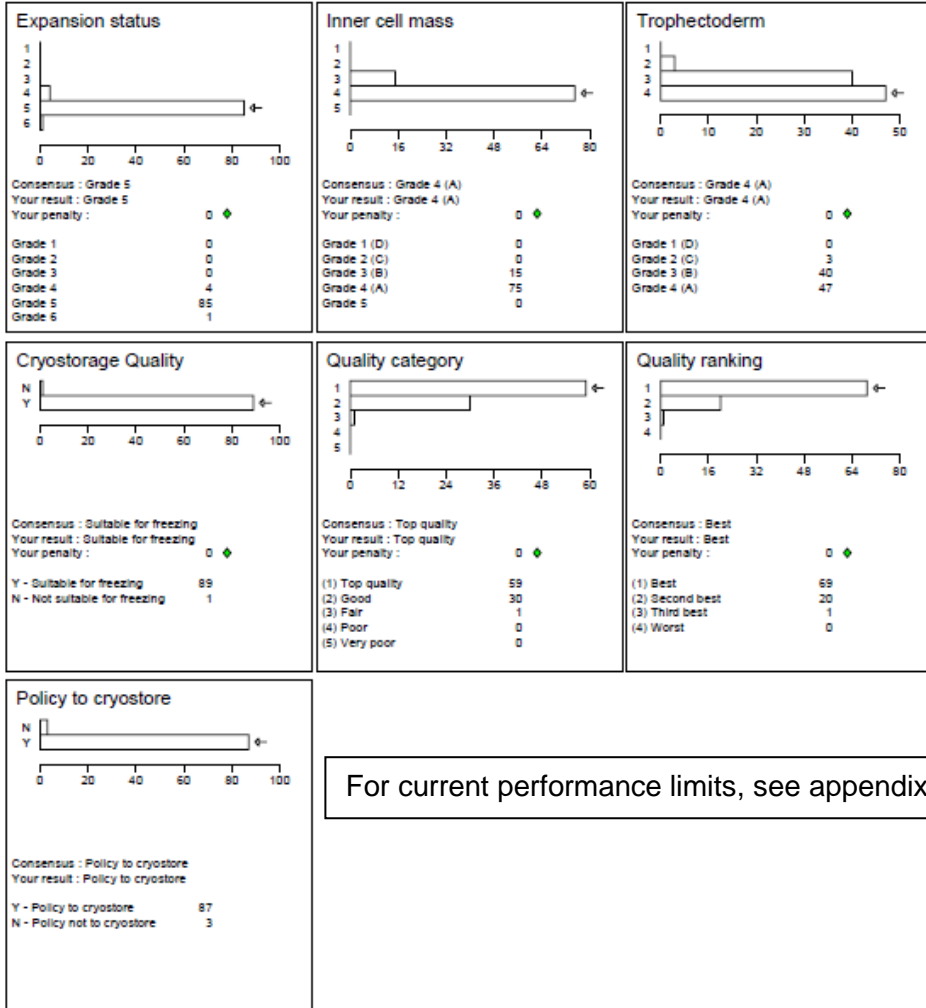
Histograms



For current performance limits, see appendix 2.

Figure 6 – Embryology Scheme Report (part 2)
Histograms

UK NEQAS Reproductive Science	Embryology - Embryo Morphology	Laboratory :
	Distribution : 95 Date : 04-Dec-2017	Page 11 of 19
	Specimen : P3-1	



For current performance limits, see appendix 2.

Time Lapse Annotation Histograms

UK NEQAS Reproductive Science	Embryology - Embryo Morphology	Laboratory : 11698
	Distribution : 104 Date : 09-Mar-2020	Page 19 of 21
	Specimen : P4-4	

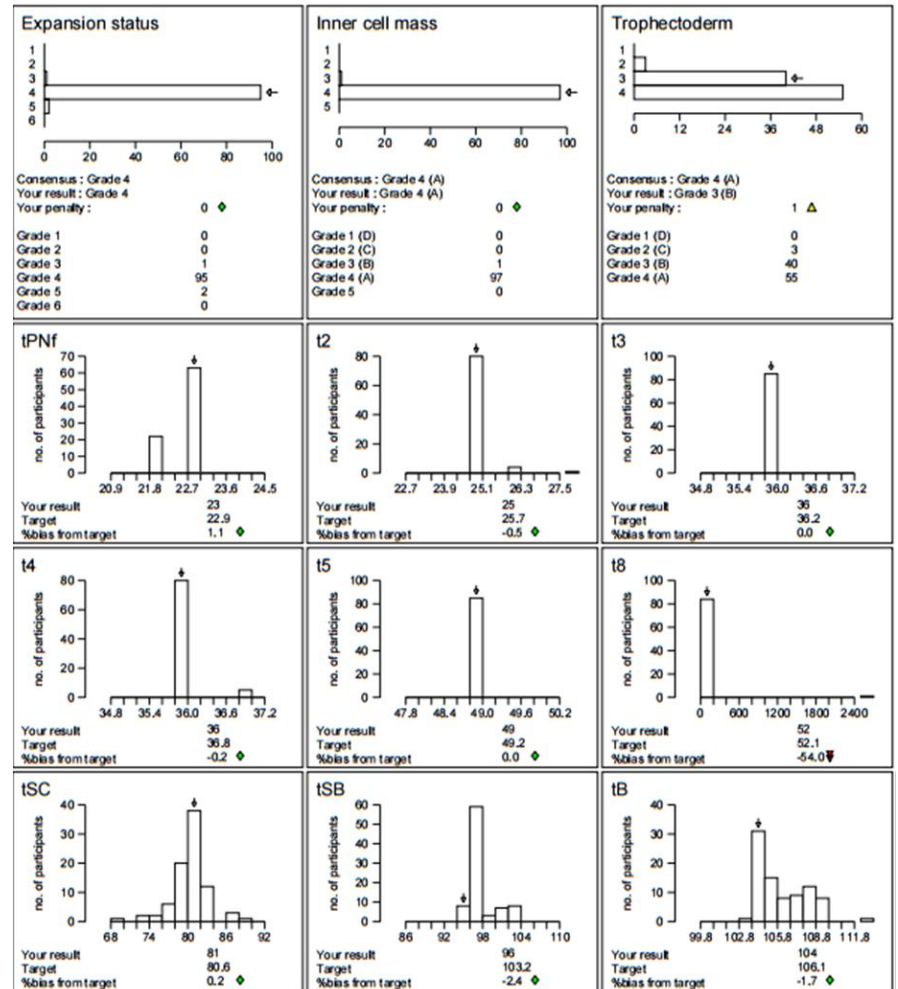
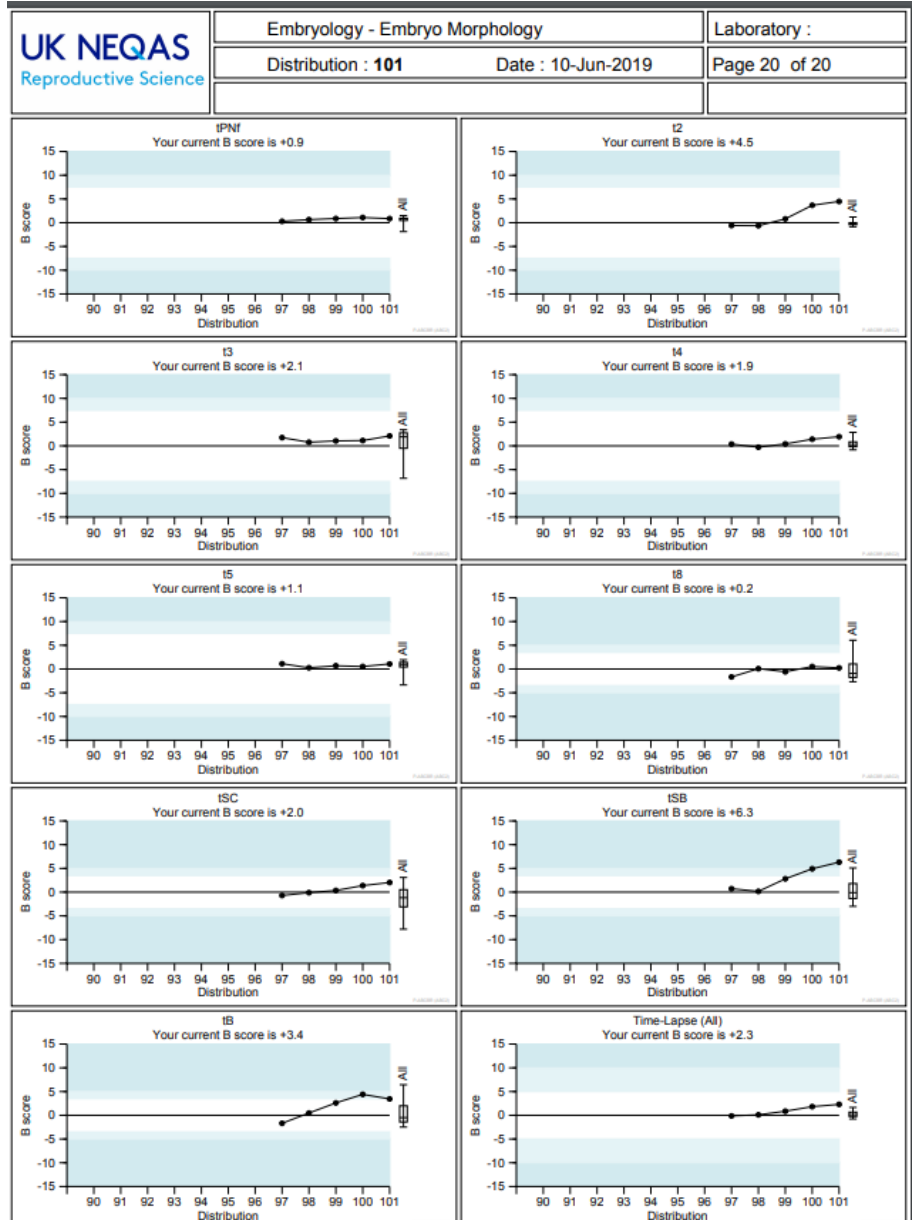
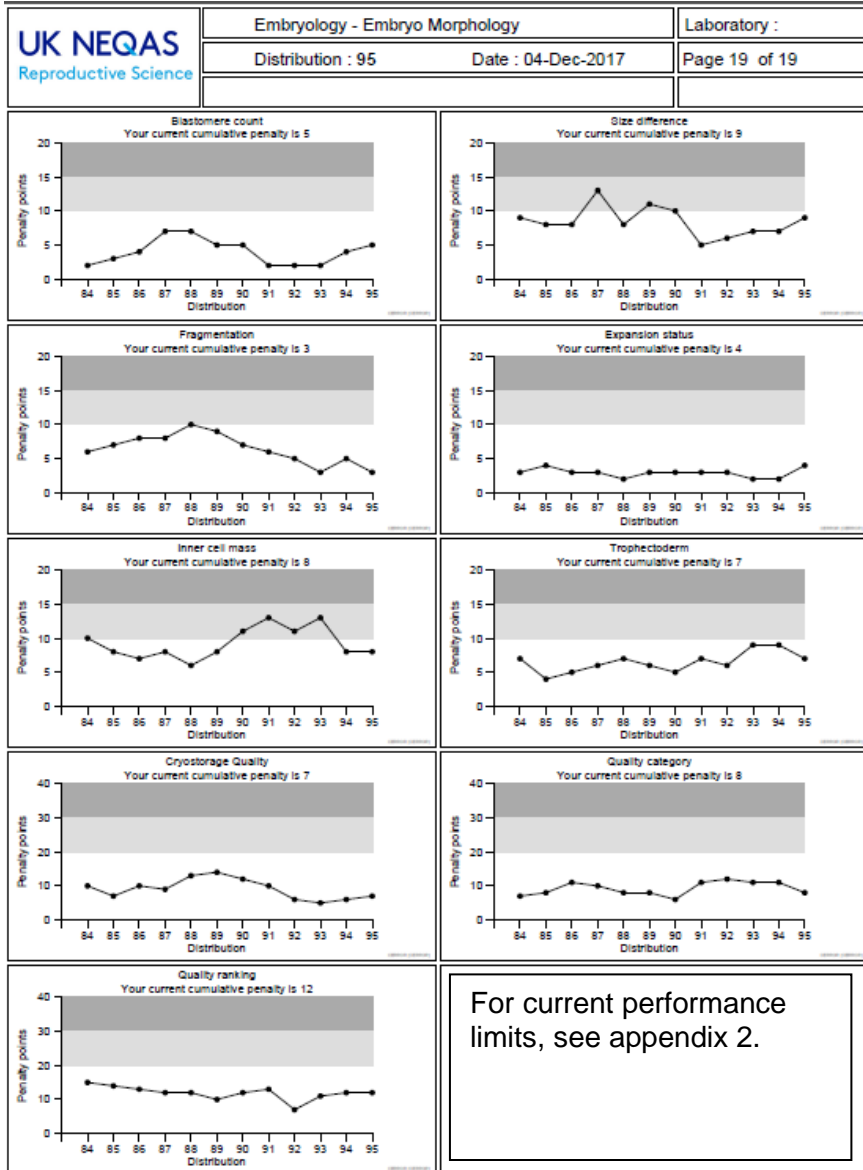


Figure 6 – Embryology Scheme Report (part 3)



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

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

The '**ABC of EQA**' is an *ISO 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 'time-window'.

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

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

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

A, B and C score calculation

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

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

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 time-window.

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

Example reports:

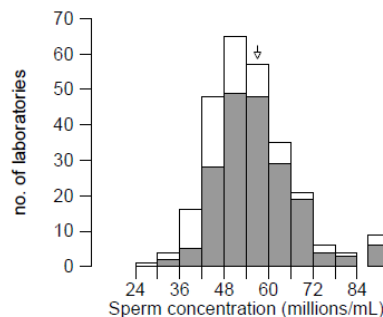
Summary page (concentration & morphology)

	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.

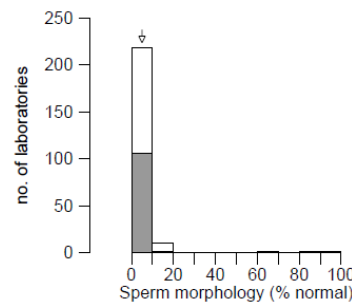
Results page (concentration & morphology)

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	56.09	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



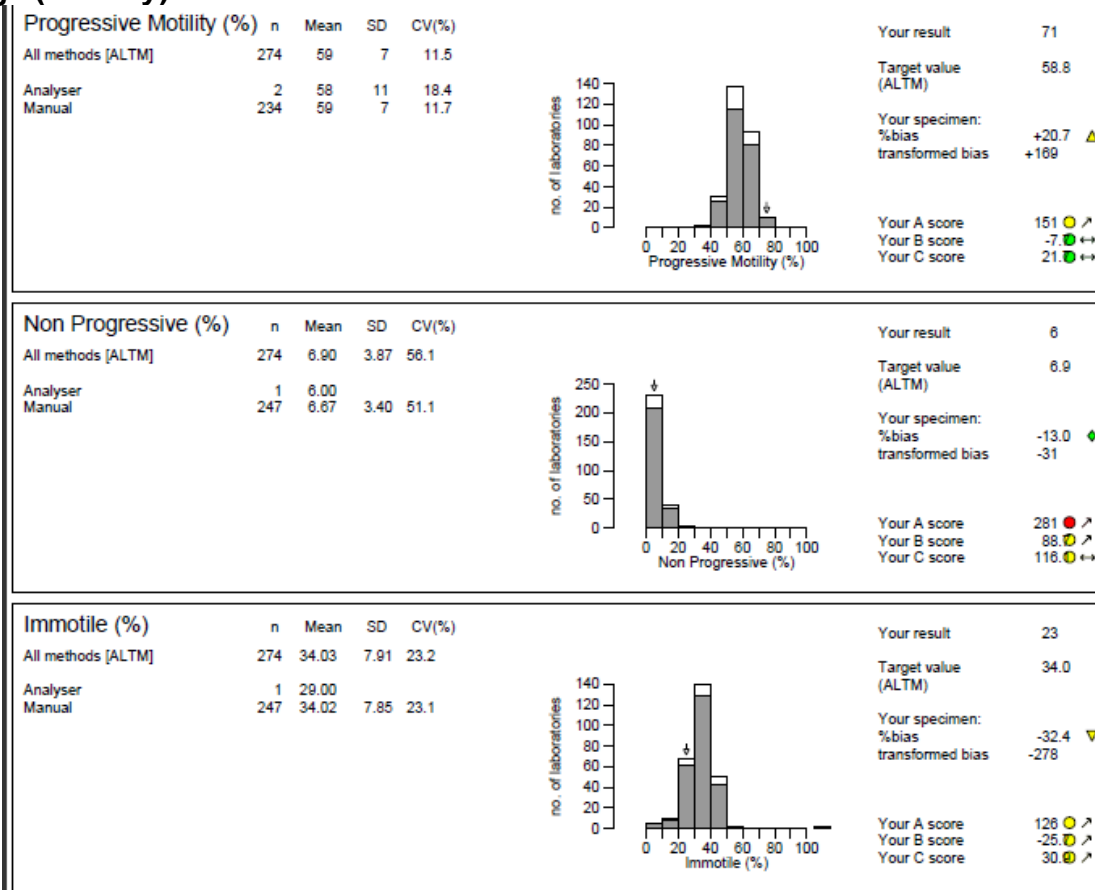
Your result	2
Target value (OGLTM)	5.6
Your specimen: %bias	-64.3 ▼
transformed bias	-129
Your A score	85 ●
Your B score	-42 ●
Your C score	26 ●

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	16	18.99	-15.7 ◆						
	MO275	62	62.68	-1.1 ◆						
	MO276	73	71.62	+1.9 ◆						
Non Progressive (%)	MO273	6	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 ◆						

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

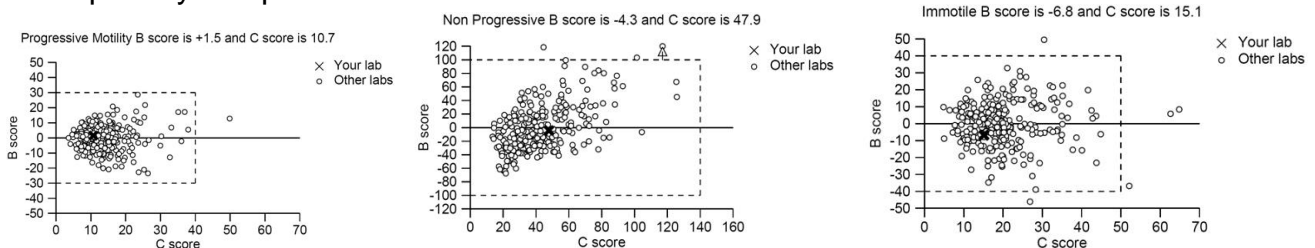
‘B’ & ‘C’ scores

We have plotted the data and looked at the 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:



B scores:

	Green	Yellow	Red
Progressive:	0 to +/- 10	+/-10 to +/-20	>+/-20
Non-Progressive:	0 to +/- 50	+/-50 to +/-75	>+/-75
Immotile:	0 to +/- 10	+/-10 to +/-20	>+/-20

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

Morphology (practical)

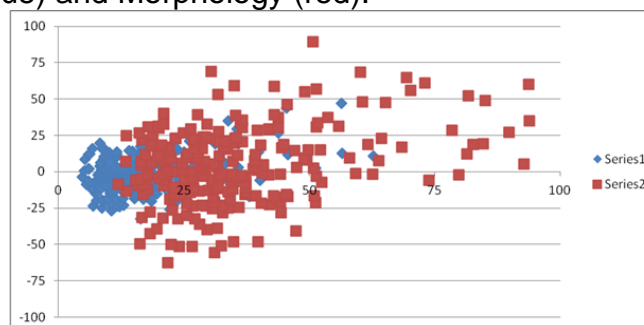
B scores:

	Green	Yellow	Red
Morphology	0 to +/-50	+/-50 to +/- 75	>+/-75

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

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

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

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

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

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

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

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

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

Andrology (Semen Analysis) Scheme

The 'ABC of EQA'

	Penalty limit	B score limit (+/-)	C score limit
Semen concentration		20	25
Sperm morphology		75	75
Sperm motility – progressive		20	40
Sperm motility – non-progressive		75	140
Sperm motility – Immotile		20	50
Interpretive morphology	16		

Embryology scheme

	Penalty limit*	B score limit (+/-)
Embryo grading (until 31/07/2021)	12	
Embryo grading (from 01/08/2021)	10	
Time-lapse annotation		5

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

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

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

UK NEQAS Embryology Scheme

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

Cleavage stage embryo grading system

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

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

*Please see figure 1

Blastocyst stage embryo grading system

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

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

** see Figure 2

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

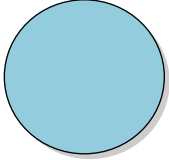
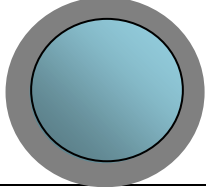
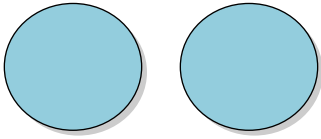
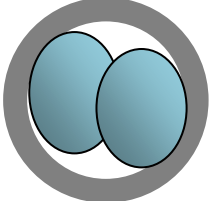
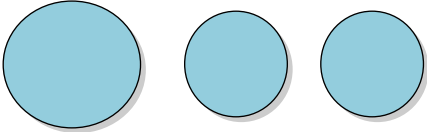
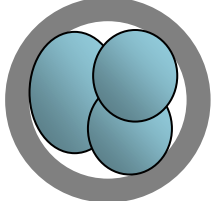
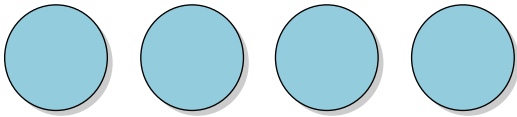
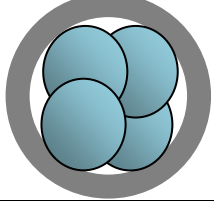
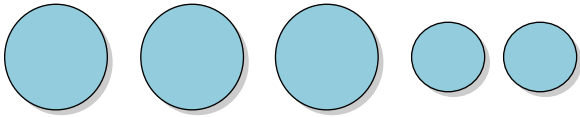
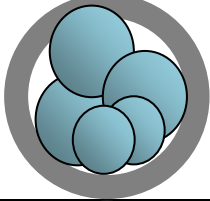
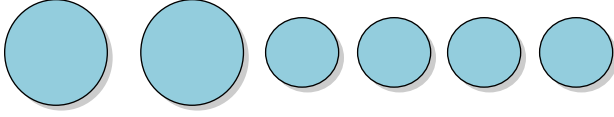
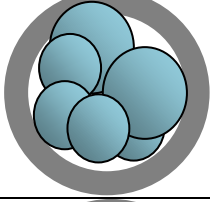
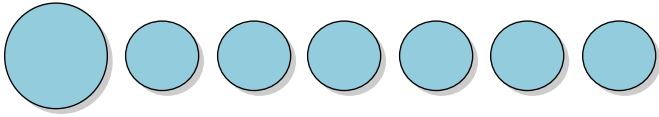
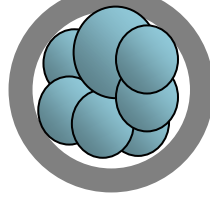
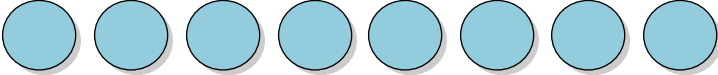
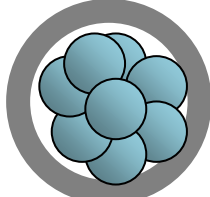
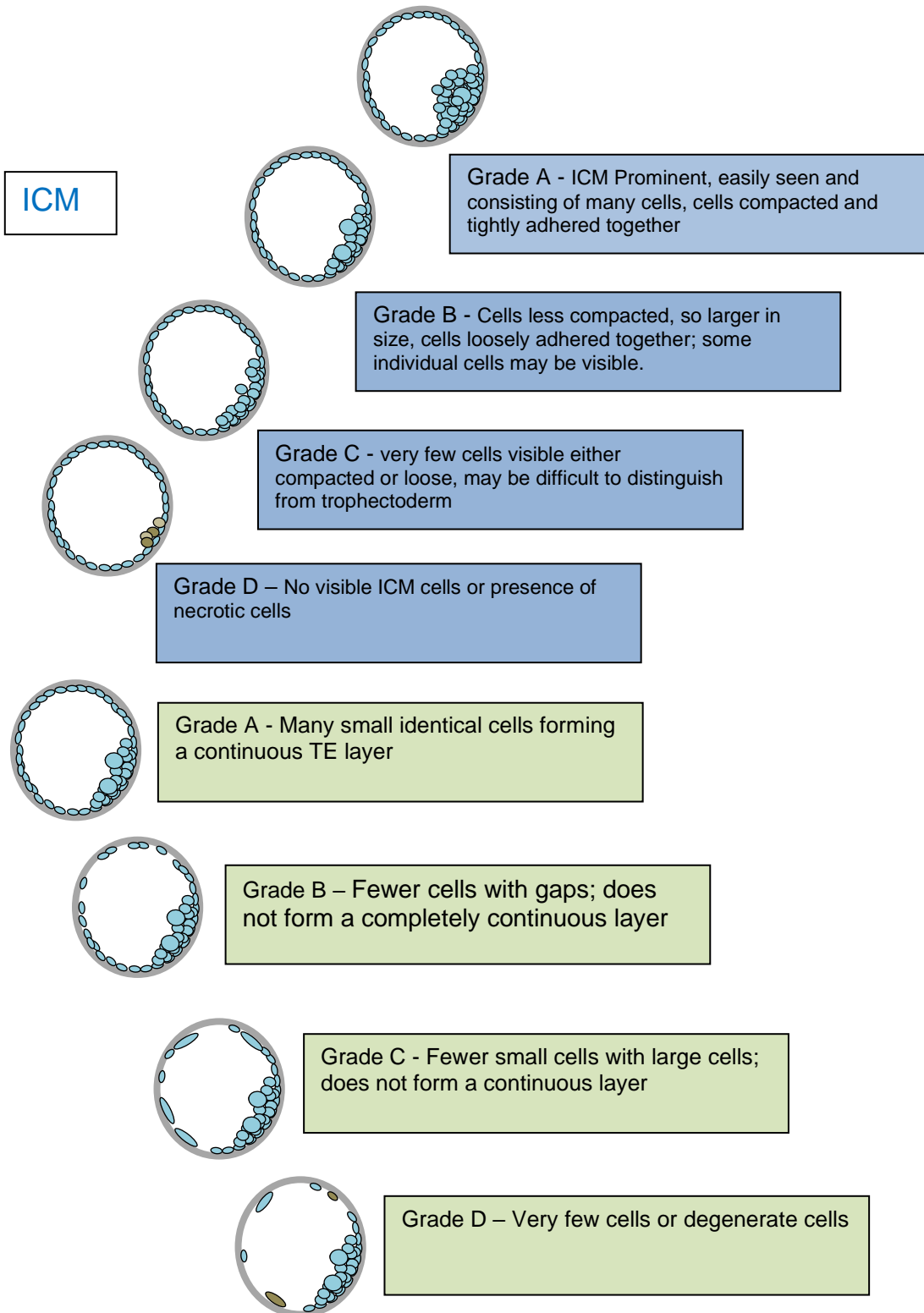
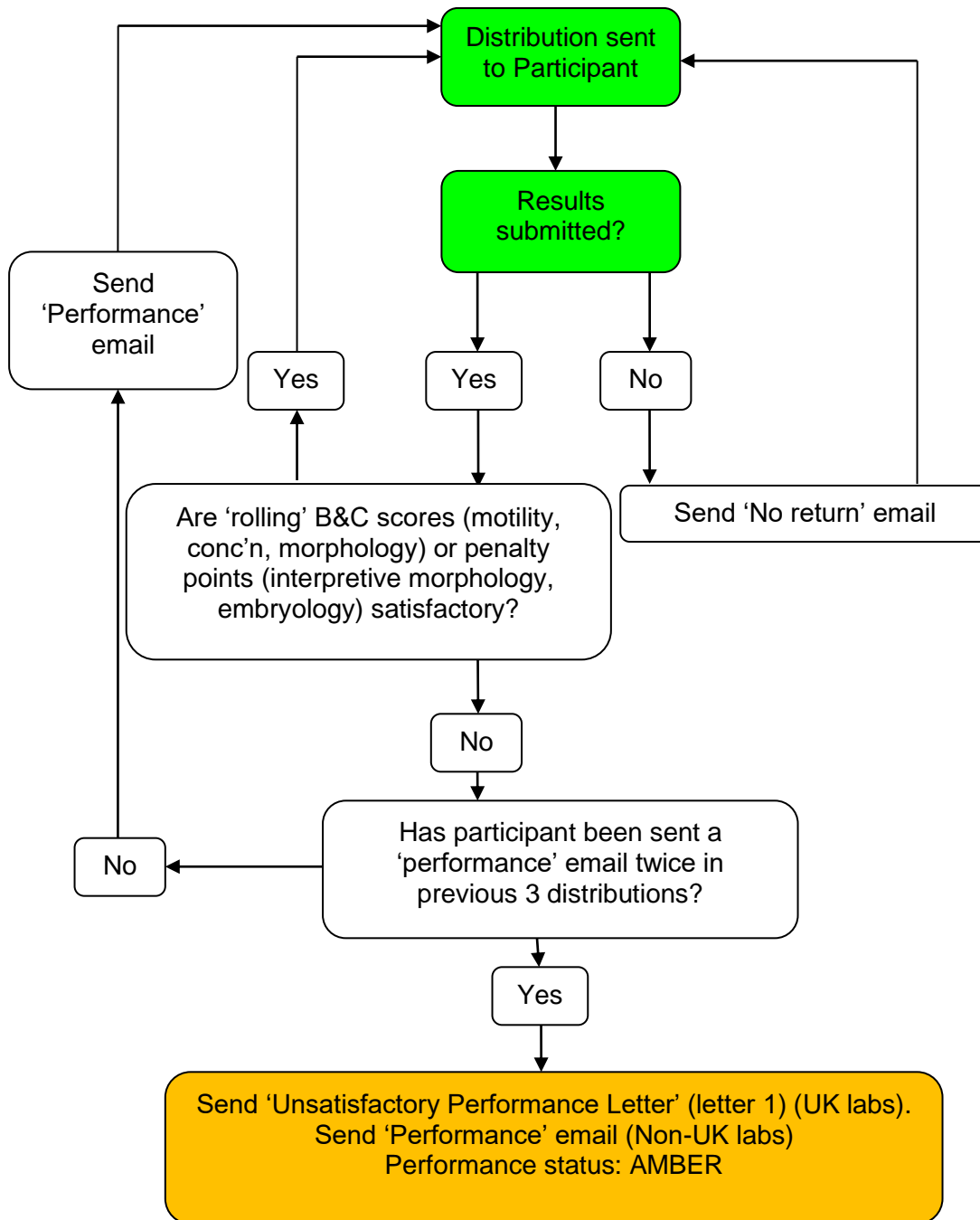
1-cell		
2-cell		
3-cell		
4-cell		
5-cell		
6-cell		
7-cell		
8-cell		

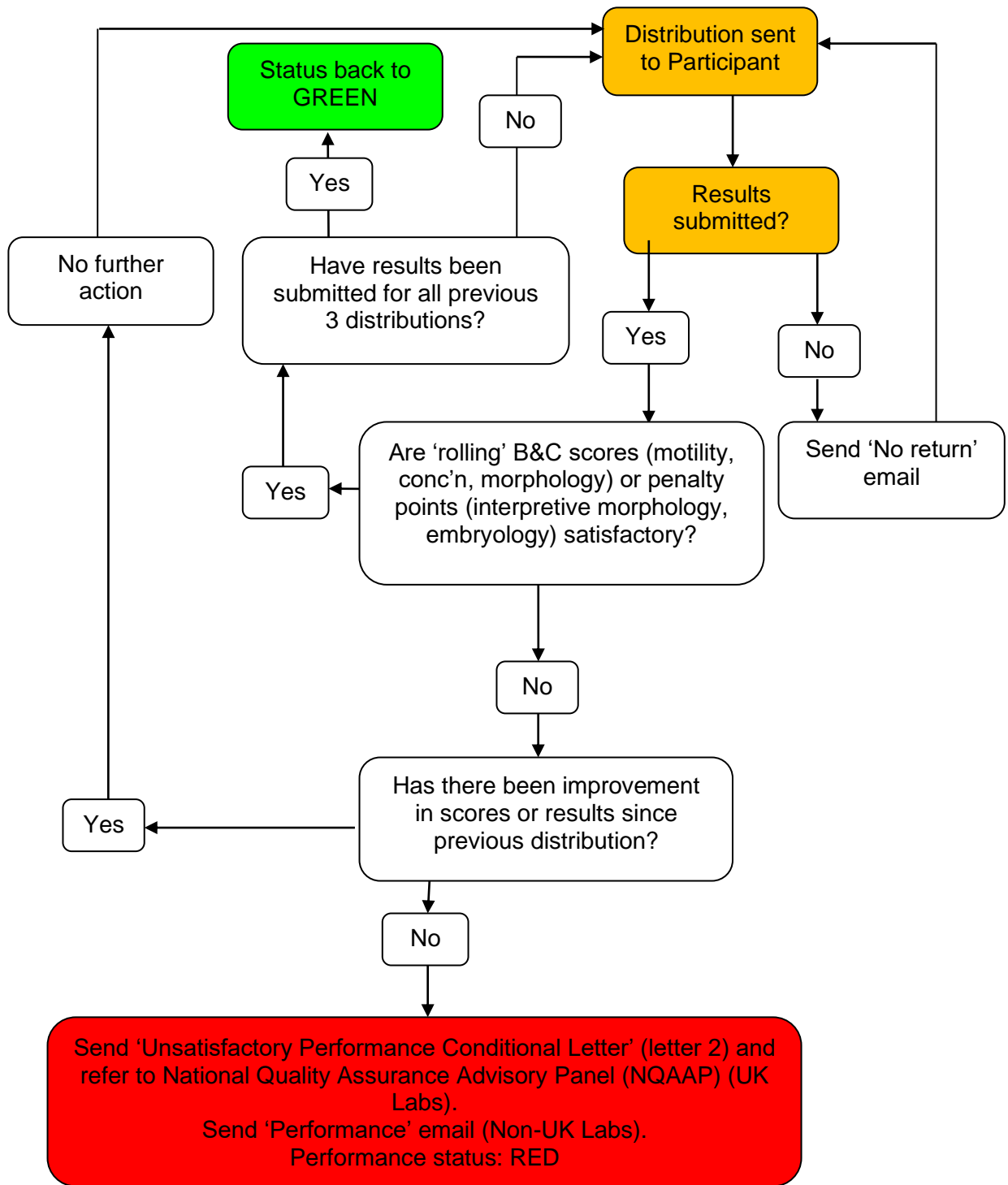
Figure 2: The blastocyst grading scheme is illustrated below



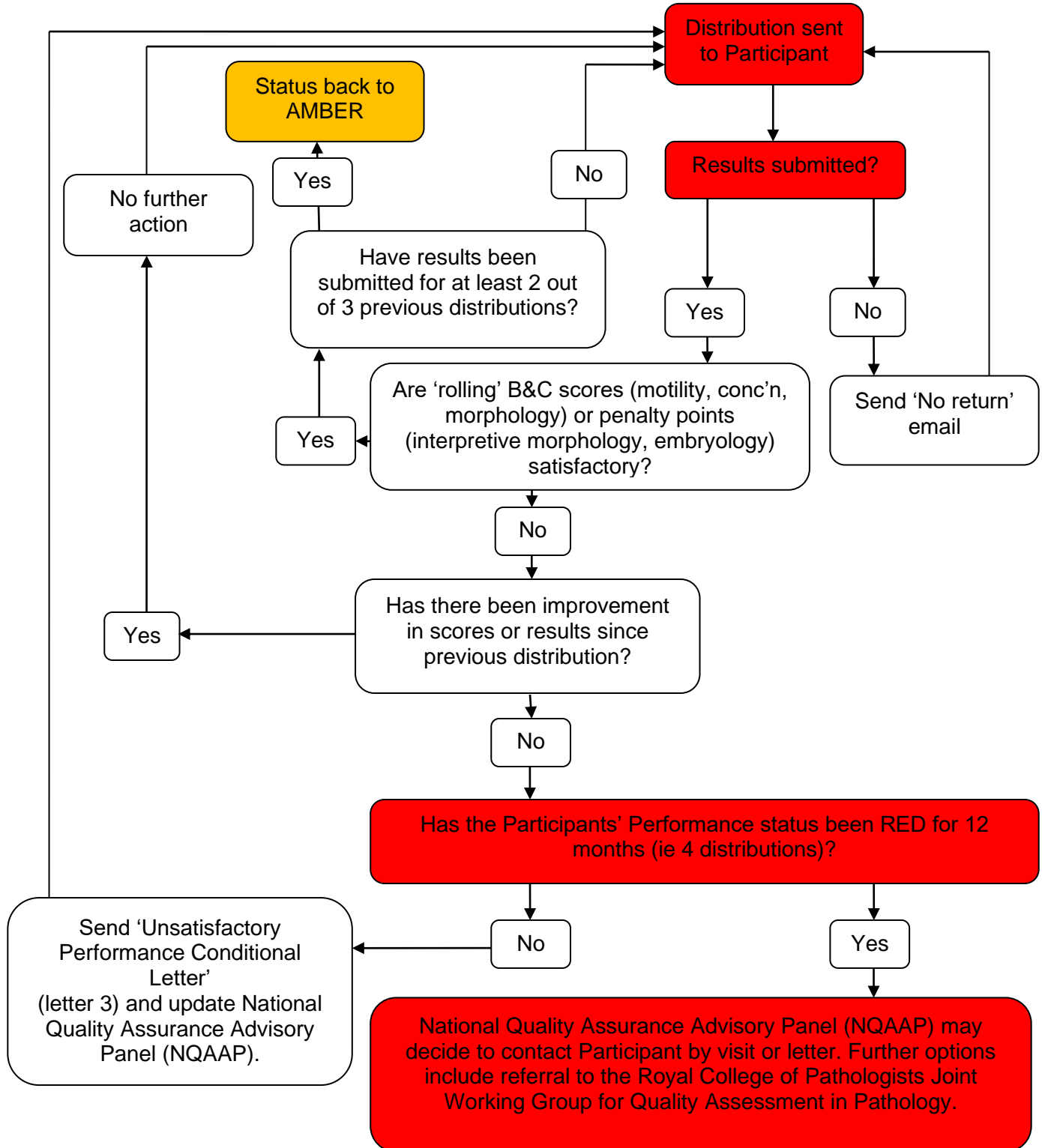
**Appendix 4: Performance in UK NEQAS Reproductive Science Schemes
GREEN to AMBER**



**Performance in UK NEQAS Reproductive Science Schemes
AMBER to RED**



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



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

V3 January 2019

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

Appendix 6: FREQUENTLY ASKED QUESTIONS (FAQ)

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

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

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 for your ID number and the reason for your request.

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

A: Email the Scheme at 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 50 years of experience in offering EQA schemes. Our Semen analysis and Embryology schemes are accredited by UKAS to ISO 17043:2010 standards.

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

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

Q: Why do we have two morphology schemes?

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

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

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

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

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

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

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

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

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

Performance troubleshooting:

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

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

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

If further assistance is required, contact repscience@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/ARCS criteria (see appendix 3)?

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

Appendix 7: Embryo time-lapse annotation analyte

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

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

Time Lapse Annotation

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

1. **tPNf**: The time when both (or the last) PN disappear. This annotation is made at the first frame whereby the embryo is still at the 1-cell stage but pronuclei can no longer be visualized.
2. **t2**: The time of the first cell cleavage, or mitosis. t2 is the first frame at which the two blastomeres are completely separated by individual cell membranes.
3. **t3**: The first observation of three discrete cells. The three cells stage marks initiation of the second round of cleavage.
4. **T4**: The first observation of four discrete cells.
5. **T5**: The first observation of five discrete cells.
6. **T8**: The first observation of eight discrete cells.
7. **tSC** (From distribution 97): The first frame in which evidence of compaction is present; the initial frame that any (two) cells start to compact is observed. (The precise timing of initiation of compaction may be difficult to observe due to the increased number of cells and the type of compaction (partial or complete).

N.B Previously tM (April 2017- March 2018): This marks the end of the compaction process; when observable compaction is complete. The morula may be fully or partially compacted, where f is full and p is partial; the morula has excluded material.

8. **tSB** ¼ initiation/start of blastulation. The first frame when initiation of a cavity formation is observed.
9. **tB** full blastocyst. The last frame before the zona pellucida starts to thin.