Paroxysmal Nocturnal Haemoglobinuria

Sample - 087

Distribution - 161702

Participant ID -

Date Issued - 26 July 2016

Closing Date - 15 August 2016

Trial Comments

This trial was issued to 163 participants.

Sample Comments

This sample was manufactured from stabilised whole blood spiked with stabilised PNH material from a consented patient.

Results and Performance

Your Results

Cell Population	Your Results	Consensus Result
Red Blood Cells PNH Clone	Present	Clone Absent
Monocytes PNH Clone	Present	Clone Present
Granulocytes PNH Clone	Present	Clone Present

Your Performance

Cell Population	Performance Status for this Trial	Performance Status Classification Over 12 Sample Period	
		Satisfactory	Critical
Red Blood Cells PNH Clone	Critical	2	1
Monocytes PNH Clone	Satisfactory	2	1
Granulocytes PNH Clone	Satisfactory	3	0

N/A = Not Applicable

Percentage Value Results

Cell Population	Your Results (%)	Median Result (%)	Lower Quartile (%)	Upper Quartile (%)
Red Blood Cells PNH Clone	0.81	0.01	0.00	0.05
Monocytes PNH Clone	5.30	55.00	45.70	58.77
Granulocytes PNH Clone	7.00	8.50	7.77	9.80

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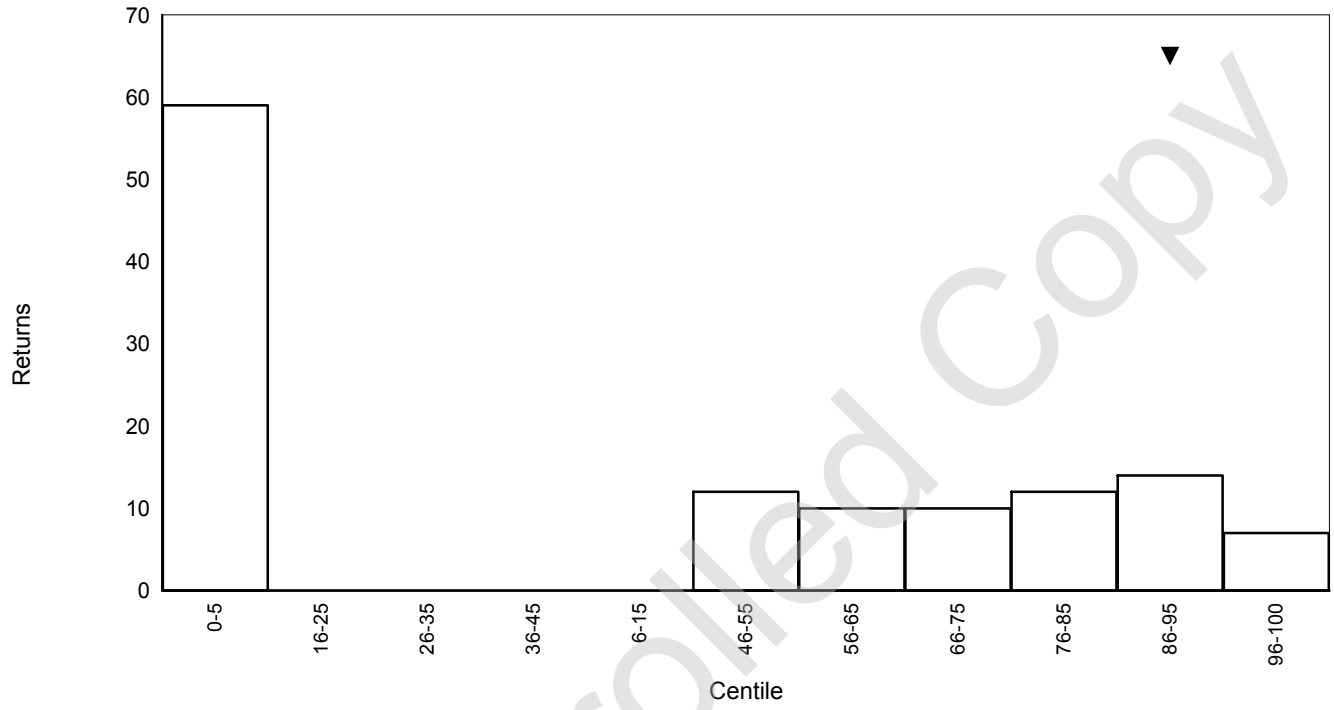
Histograms of Percentage Results

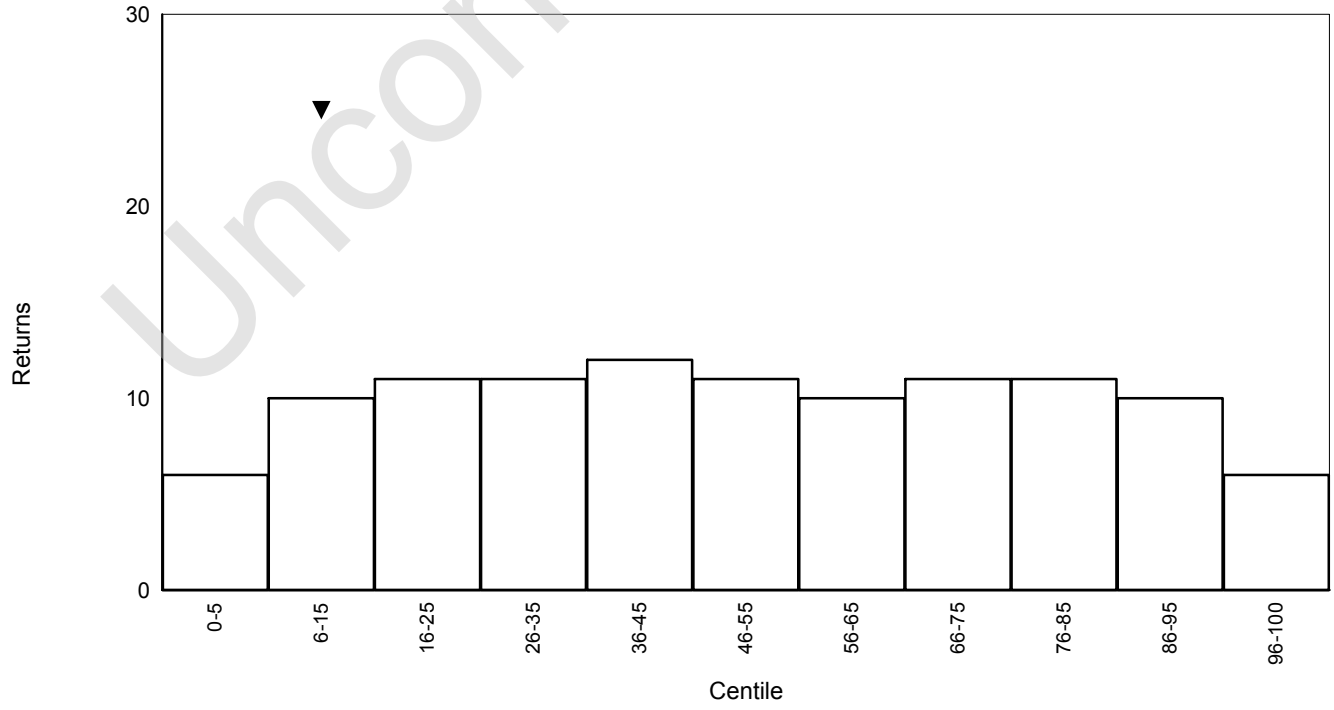
Red Blood Cells PNH Clone Percentage Population

Please note ▼ denotes your result



Monocytes PNH Clone Percentage Population

Please note ▼ denotes your result



Paroxysmal Nocturnal Haemoglobinuria

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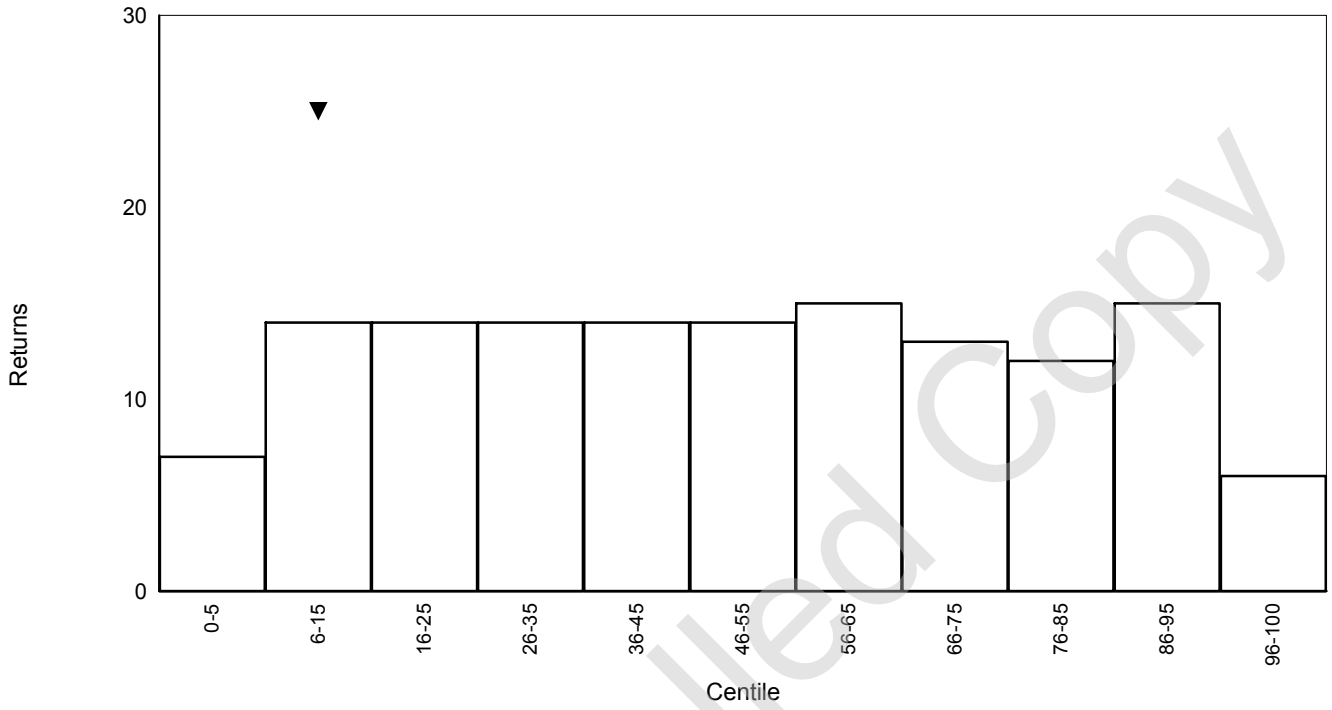
Granulocytes PNH Clone Percentage Population

Please note ▼ denotes your result



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Flow Cytometer Specific Statistics

(Please note only groups of >20 returns are displayed)

Red Blood Cell PNH Clone

Flow Cytometer	Returns	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Median Clone Size (%)	Lower Quartile (%)	Upper Quartile (%)
Facs Canto II	67	30	37	0.01	0.00	0.10
Navios	25	13	12	0.01	0.00	0.05

Monocytes PNH Clone

Flow Cytometer	Returns	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Median Clone Size (%)	Lower Quartile (%)	Upper Quartile (%)
Facs Canto II	61	59	2	55.60	48.30	59.00
Navios	23	22	1	52.20	38.02	56.85

Granulocytes PNH Clone

Flow Cytometer	Returns	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Median Clone Size (%)	Lower Quartile (%)	Upper Quartile (%)
Facs Canto II	77	75	2	8.54	7.90	9.50
Navios	26	26	0	8.22	7.46	9.69

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Gating Antibodies Used Statistics

(Please note only groups of >20 returns are displayed)

Red Blood Cell PNH Clone

Gating Strategy Used	Returns	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Median Clone Size (%)	Lower Quartile (%)	Upper Quartile (%)
CD235a	99	44	55	0.01	0.00	0.04

Monocytes PNH Clone

Gating Strategy Used	Returns	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Median Clone Size (%)	Lower Quartile (%)	Upper Quartile (%)
CD33	23	23	0	57.00	54.90	59.60
CD33/CD45	35	35	0	57.30	54.28	60.22

Granulocytes PNH Clone

Gating Strategy Used	Returns	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Median Clone Size (%)	Lower Quartile (%)	Upper Quartile (%)
CD15	34	34	0	8.16	7.43	8.75
CD15/CD45	35	34	1	8.10	7.50	8.85

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GPI Linked Antibodies Used Statistics

(Please note only groups of >20 returns are displayed)

Red Blood Cell PNH Clone

GPI Linked Antibodies Combination Used	Returns	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Median Clone Size (%)	Lower Quartile (%)	Upper Quartile (%)
CD59	101	42	59	0.00	0.00	0.04

Monocytes PNH Clone

GPI Linked Antibodies Combination Used	Returns	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Median Clone Size (%)	Lower Quartile (%)	Upper Quartile (%)
CD14/FLAER	66	64	2	55.75	49.38	59.78

Granulocyte PNH Clone

GPI Linked Antibodies Combination Used	Returns	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Median Clone Size (%)	Lower Quartile (%)	Upper Quartile (%)
CD24/FLAER	74	73	1	8.40	7.81	9.00

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GPI Linked Antibodies Specific Statistics

Red Blood Cell PNH Clone

GPI Linked Antibody	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Laboratories using as part of their panel*
CD55	10	7	17
CD59	52	69	121

*** Please note the numbers in the above tables will not match the number of laboratories enrolled in the programme as each centre uses a panel with multiple antibodies**

Monocytes PNH Clone

GPI Linked Antibody	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Laboratories using as part of their panel*
CD14	79	2	81
CD157	15	0	15
CD24	3	0	3
^CD55	10	0	10
^CD59	10	0	10
FLAER	96	2	98

*** Please note the numbers in the above tables will not match the number of laboratories enrolled in the programme as each centre uses a panel with multiple antibodies**

Granulocyte PNH Clone

GPI Linked Antibody	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Laboratories using as part of their panel*
CD157	14	0	14
CD24	97	2	99
^CD55	12	0	12
^CD59	14	0	14
CD66b	20	0	20
FLAER	115	2	117

*** Please note the numbers in the above tables will not match the number of laboratories enrolled in the programme as each centre uses a panel with multiple antibodies**

^ Antigens marked above are not considered best practice and laboratories should avoid using these for leucocytes. Please see **Borowitz, M. J. *et al.* Guidelines for the diagnosis and monitoring of paroxysmal nocturnal hemoglobinuria and related disorders by flow cytometry. *Cytometry B. Clin. Cytom.* 78, 211-30 (2010)** or **Sutherland, D. R., Keeney, M. & Illingworth, A. Practical guidelines for the high-sensitivity detection and monitoring of paroxysmal nocturnal hemoglobinuria clones by flow cytometry. *Cytom. Part B - Clin. Cytom.* 82 B, 195-208 (2012)** for further explanation.

Paroxysmal Nocturnal Haemoglobinuria

Sample - 088

Distribution - 161702

Participant ID - 40003

Date Issued - 26 July 2016

Closing Date - 15 August 2016

Trial Comments

This trial was issued to 163 participants.

Sample Comments

This sample was manufactured from stabilised whole blood

Results and Performance

Your Results

Cell Population	Your Results	Consensus Result
Red Blood Cells PNH Clone	Absent	Clone Absent
Monocytes PNH Clone	Absent	Clone Absent
Granulocytes PNH Clone	Absent	Clone Absent

Your Performance

Cell Population	Performance Status for this Trial	Performance Status Classification Over 12 Sample Period	
		Satisfactory	Critical
Red Blood Cells PNH Clone	Satisfactory	3	1
Monocytes PNH Clone	Satisfactory	3	1
Granulocytes PNH Clone	Satisfactory	4	0

N/A = Not Applicable

Percentage Value Results

Cell Population	Your Results (%)	Median Result (%)	Lower Quartile (%)	Upper Quartile (%)
Red Blood Cells PNH Clone	0.00	0.00	0.00	0.00
Monocytes PNH Clone	0.00	0.00	0.00	0.00
Granulocytes PNH Clone	0.00	0.00	0.00	0.00

Paroxysmal Nocturnal Haemoglobinuria

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Histograms of Percentage Results

Red Blood Cells PNH Clone Percentage Population

Due to the Median, Lower Quartile and Upper Quartile values for this sample being 0, Histograms are not displayed.

Monocytes PNH Clone Percentage Population

Due to the Median, Lower Quartile and Upper Quartile values for this sample being 0, Histograms are not displayed.

Granulocytes PNH Clone Percentage Population

Due to the Median, Lower Quartile and Upper Quartile values for this sample being 0, Histograms are not displayed.

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Sample - 088

Flow Cytometer Specific Statistics

(Please note only groups of >20 returns are displayed)

Red Blood Cell PNH Clone

Flow Cytometer	Returns	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Median Clone Size (%)	Lower Quartile (%)	Upper Quartile (%)
Facs Canto II	67	2	65	0.00	0.00	0.00
Navios	24	1	23	0.00	0.00	0.00

Monocytes PNH Clone

Flow Cytometer	Returns	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Median Clone Size (%)	Lower Quartile (%)	Upper Quartile (%)
Facs Canto II	60	3	57	0.00	0.00	0.00
Navios	23	0	23	0.00	0.00	0.00

Granulocytes PNH Clone

Flow Cytometer	Returns	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Median Clone Size (%)	Lower Quartile (%)	Upper Quartile (%)
Facs Canto II	75	4	71	0.00	0.00	0.00
Navios	26	0	26	0.00	0.00	0.00

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Gating Antibodies Used Statistics

(Please note only groups of >20 returns are displayed)

Red Blood Cell PNH Clone

Gating Strategy Used	Returns	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Median Clone Size (%)	Lower Quartile (%)	Upper Quartile (%)
CD235a	97	4	93	0.00	0.00	0.00

Monocytes PNH Clone

Gating Strategy Used	Returns	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Median Clone Size (%)	Lower Quartile (%)	Upper Quartile (%)
CD33	22	1	21	0.00	0.00	0.00
CD33/CD45	35	0	35	0.00	0.00	0.00

Granulocytes PNH Clone

Gating Strategy Used	Returns	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Median Clone Size (%)	Lower Quartile (%)	Upper Quartile (%)
CD15	34	1	33	0.00	0.00	0.00
CD15/CD45	35	0	35	0.00	0.00	0.00

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GPI Linked Antibodies Used Statistics

(Please note only groups of >20 returns are displayed)

Red Blood Cell PNH Clone

GPI Linked Antibodies Combination Used	Returns	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Median Clone Size (%)	Lower Quartile (%)	Upper Quartile (%)
CD59	100	4	96	0.00	0.00	0.00

Monocytes PNH Clone

GPI Linked Antibodies Combination Used	Returns	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Median Clone Size (%)	Lower Quartile (%)	Upper Quartile (%)
CD14/FLAER	65	1	64	0.00	0.00	0.00

Granulocyte PNH Clone

GPI Linked Antibodies Combination Used	Returns	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Median Clone Size (%)	Lower Quartile (%)	Upper Quartile (%)
CD24/FLAER	73	0	73	0.00	0.00	0.00

Paroxysmal Nocturnal Haemoglobinuria

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GPI Linked Antibodies Specific Statistics

Red Blood Cell PNH Clone

GPI Linked Antibody	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Laboratories using as part of their panel*
CD55	0	17	17
CD59	4	117	121

*** Please note the numbers in the above tables will not match the number of laboratories enrolled in the programme as each centre uses a panel with multiple antibodies**

Monocytes PNH Clone

GPI Linked Antibody	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Laboratories using as part of their panel*
CD14	1	80	81
CD157	0	15	15
CD24	0	3	3
^CD55	0	10	10
^CD59	0	10	10
FLAER	2	96	98

*** Please note the numbers in the above tables will not match the number of laboratories enrolled in the programme as each centre uses a panel with multiple antibodies**

Granulocyte PNH Clone

GPI Linked Antibody	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Laboratories using as part of their panel*
CD157	0	14	14
CD24	1	98	99
^CD55	0	12	12
^CD59	0	14	14
CD66b	0	20	20
FLAER	2	115	117

*** Please note the numbers in the above tables will not match the number of laboratories enrolled in the programme as each centre uses a panel with multiple antibodies**

^ Antigens marked above are not considered best practice and laboratories should avoid using these for leucocytes. Please see **Borowitz, M. J. *et al.* Guidelines for the diagnosis and monitoring of paroxysmal nocturnal hemoglobinuria and related disorders by flow cytometry. *Cytometry B. Clin. Cytom.* 78, 211-30 (2010)** or **Sutherland, D. R., Keeney, M. & Illingworth, A. Practical guidelines for the high-sensitivity detection and monitoring of paroxysmal nocturnal hemoglobinuria clones by flow cytometry. *Cytom. Part B - Clin. Cytom.* 82 B, 195-208 (2012)** for further explanation.

Paroxysmal Nocturnal Haemoglobinuria

Information with respect to compliance with standards BS EN ISO/IEC 17043:2010

4.8.2 a) The proficiency testing provider for this programme is:
UK NEQAS for Leucocyte Immunophenotyping
Pegasus House, 4th Floor Suite 463A Glossop Road
Sheffield, S10 2QD
United Kingdom
Tel: +44 (0) 114 267 3600, Fax: +44 (0) 114 267 3601
e-mail: nicola.rose@ukneqasli.co.uk

4.8.2 b) The coordinators of UK NEQAS LI programmes are Prof David Barnett and Mr Liam Whitby.

4.8.2 c) Person(s) authorizing this report:
Prof David Barnett, Director or Mr Liam Whitby, Operations Manager of UK NEQAS LI

4.8.2 d) No activities in relation to this EQA exercise were subcontracted.

4.8.2 g) The UK NEQAS LI Confidentiality Policy can be found in the Quality Manual which is available by contacting the UK NEQAS LI office. Participant details, their results and their performance data remain confidential unless revealed to the relevant NQAAP when a UK participant is identified as having performance issues.

4.8.2 i) All EQA samples are prepared in accordance with strict Standard Operational Procedures by trained personnel proven to ensure homogeneity and stability. Where appropriate/ possible EQA samples are tested prior to issue. Where the sample(s) issued is stabilised blood or platelets, pre and post stability testing will have proved sample suitability prior to issue.

4.8.2 l), n), o), r) & s) Please refer to the UK NEQAS LI website at www.ukneqasli.co.ukfor detailed information on each programme including the scoring systems applied to assess performance (for BS EN ISO/IEC 17043:2010 accredited programmes only). Where a scoring system refers to the 'consensus result' this means the result reported by the majority of participants for that trial issue. Advice on the interpretation of statistical analyses and the criteria on which performance is measured is also given. Please note that where different methods/procedures are used by different groups of participants these may be displayed within your report, but the same scoring system is applied to all participants irrespective of method/procedure used.

4.8.2 m) We do not assign values against reference materials or calibrants.

4.8.2 q) Details of the programme designs as authorized by The Steering Committee and Specialist Advisory Group can be found on our website at www.ukneqasli.co.uk . The proposed trial issue schedule for each programme is also available.

4.8.2 t) If you would like to discuss the outcomes of this trial issue, please contact UK NEQAS LI using the contact details provided. Alternatively, if you are unhappy with your performance classification for this trial, please find the appeals procedure at www.ukneqasli.co.uk/contact-us/appeals-and-complaints/