

## Paroxysmal Nocturnal Haemoglobinuria Programme

Distribution - 202105

Sample - 141

Participant ID - 4XXXX

Date Issued - 03 March 2021

Closing Date - 23 March 2021

### Trial Comments

This exercise was issued to 179 participants. This is the final version of the report.

### Sample Comments

This sample was manufactured from stabilised whole blood only.

## 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
Neutrophils 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	12	0
Monocytes PNH Clone	Satisfactory	12	0
Neutrophils PNH Clone	Satisfactory	12	0

N/A = Not Applicable

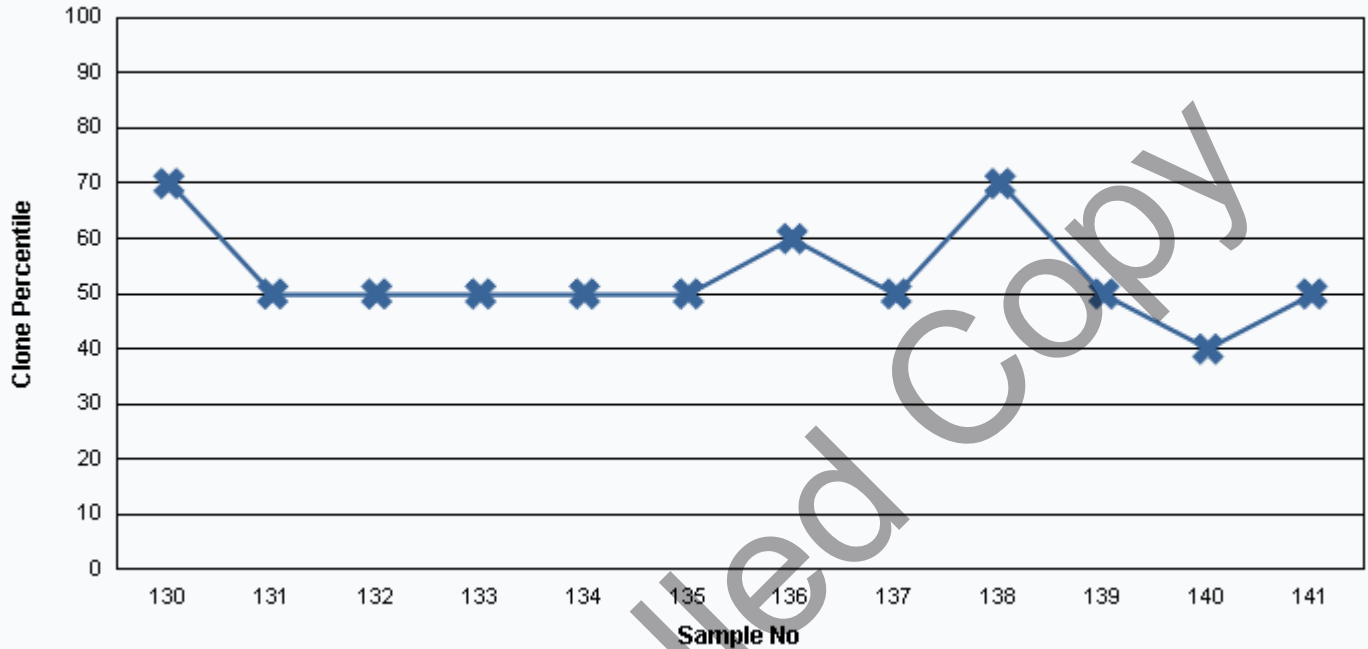
### Percentage Value Results

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
Neutrophils PNH Clone	0.00	0.00	0.00	0.00

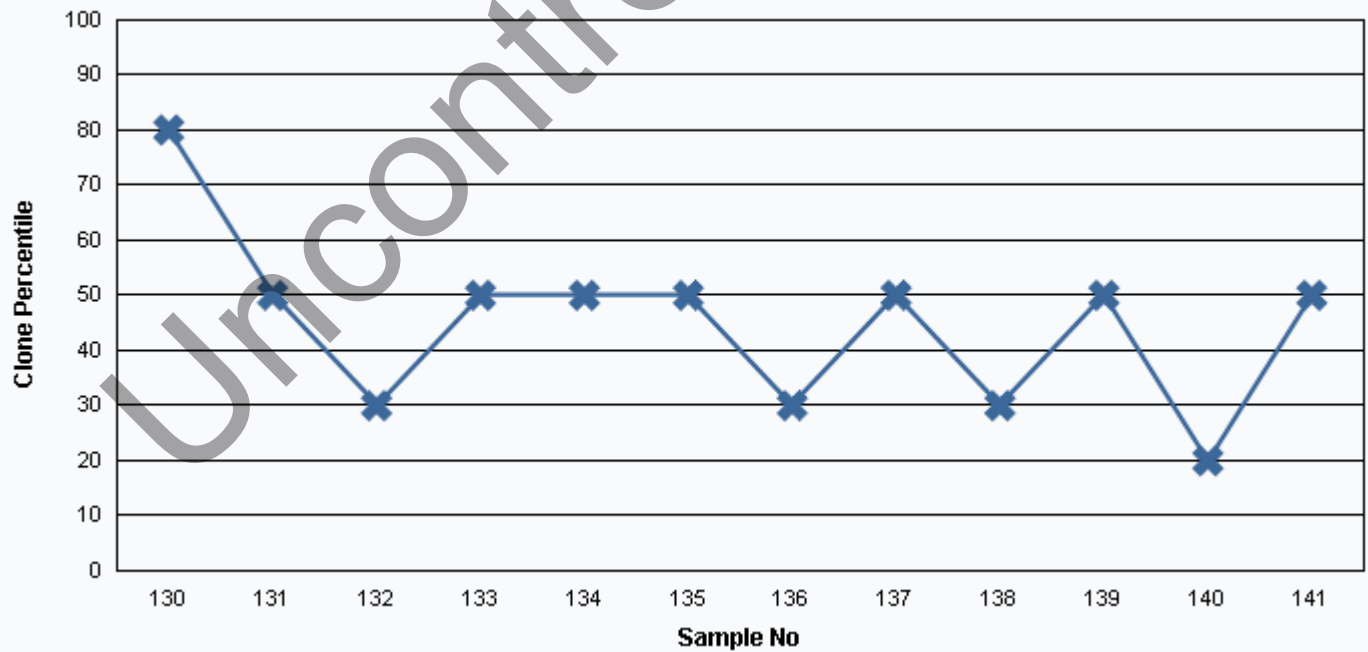
## Paroxysmal Nocturnal Haemoglobinuria Programme

### Centile graph of Percentage Results

Red Blood Cells PNH Clone Percentage Population over last 12 months

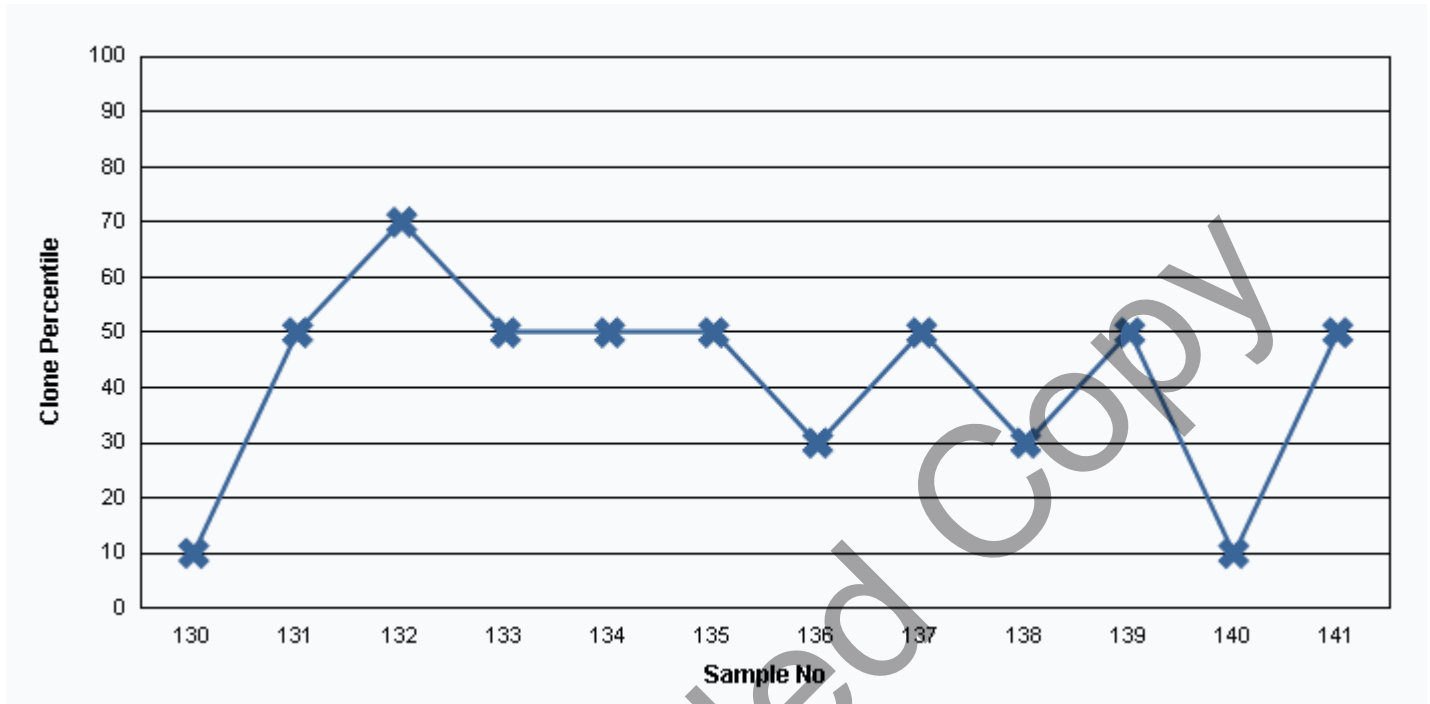


Monocytes PNH Clone Percentage Population over last 12 months



### Paroxysmal Nocturnal Haemoglobinuria Programme

Neutrophils PNH Clone Percentage Population over last 12 months



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## Paroxysmal Nocturnal Haemoglobinuria Programme

### 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 (%)
Navios	38	0	38	0.00	0.00	0.00
FACSCanto II	59	0	59	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 (%)
Navios	43	1	42	0.00	0.00	0.00
FACSCanto II	59	0	59	0.00	0.00	0.00

#### Neutrophils PNH Clone

Flow Cytometer	Returns	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Median Clone Size (%)	Lower Quartile (%)	Upper Quartile (%)
Navios	43	1	42	0.00	0.00	0.00
FACSCanto II	64	0	64	0.00	0.00	0.00

## Paroxysmal Nocturnal Haemoglobinuria Programme

### 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	108	0	108	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/CD45	34	0	34	0.00	0.00	0.00
CD45/CD64	64	0	64	0.00	0.00	0.00

#### Neutrophils PNH Clone

Gating Strategy Used	Returns	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Median Clone Size (%)	Lower Quartile (%)	Upper Quartile (%)
CD15	26	1	25	0.00	0.00	0.00
CD15/CD45	81	0	81	0.00	0.00	0.00

## Paroxysmal Nocturnal Haemoglobinuria Programme

### 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	120	0	120	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 (%)
CD157/FLAER	30	0	30	0.00	0.00	0.00
CD14/FLAER	71	1	70	0.00	0.00	0.00

#### Neutrophils PNH Clone

GPI Linked Antibodies Combination Used	Returns	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Median Clone Size (%)	Lower Quartile (%)	Upper Quartile (%)
CD157/FLAER	30	0	30	0.00	0.00	0.00
CD24/FLAER	77	1	76	0.00	0.00	0.00

## Paroxysmal Nocturnal Haemoglobinuria Programme

### 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	12	12
CD59	0	144	144

\*se 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	101	102
CD157	0	47	47
CD24	0	4	4
^CD55	0	6	6
^CD59	0	4	4
CD66b	0	1	1
FLAER	1	147	148

\*se 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

#### Neutrophils PNH Clone

GPI Linked Antibody	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Laboratories using as part of their panel*
CD157	0	46	46
CD24	1	112	113
^CD55	0	6	6
^CD59	0	6	6
^CD66b	0	9	9
FLAER	1	158	159

\*se 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, in the GPI linked antibodies specific statistics table, are not considered best practice and laboratories should avoid using these.

Please see Sutherland DR, Illingworth A, Marinov I, Ortiz F, Andreasen J, Payne D, Wallace PK and Keeney M. ICCS/ESCCA Consensus Guidelines to detect GPI-deficient cells in Paroxysmal Nocturnal Hemoglobinuria (PNH) and related Disorders Part 2 - Reagent Selection and Assay Optimization for High-Sensitivity Testing. Cytometry Part B 2018; 94B: 23-48 for further explanation.

## Paroxysmal Nocturnal Haemoglobinuria Programme

### Methodology

#### Red Blood Cells

Reagents	Antibody	Clone	Manufacturer	Fluorochrome	Best Practice
Testing	CD59	MEM-43	Life Technologies	PE	No
Gating	CD235a	KC16	Beckman Coulter	FITC	Yes

#### Monocytes

Reagents	Antibody	Clone	Manufacturer	Fluorochrome	Best Practice
Testing	FLAER		Cedarlane/Pinewood Scientific	AlexaFluor 488	Yes
Testing	CD14	MoP9	BD Biosciences	APC-H7	No
Gating	CD64	10.1	BD Biosciences	BV421	No
Gating	CD45	2D1	BD Biosciences	V500-C	No

#### Neutrophils

Reagents	Antibody	Clone	Manufacturer	Fluorochrome	Best Practice
Testing	FLAER		Cedarlane/Pinewood Scientific	AlexaFluor 488	Yes
Testing	CD24	ML5	BD Biosciences	PE	Yes
Gating	CD15	HI98	BD Biosciences	APC	No
Gating	CD45	2D1	BD Biosciences	V500-C	No

#### Recommended Reading

Sutherland DR, Illingworth A, Marinov I, Ortiz F, Andreasen J, Payne D, Wallace PK and Keeney M. ICCS/ESCCA Consensus Guidelines to detect GPI-deficient cells in Paroxysmal Nocturnal Hemoglobinuria (PNH) and related Disorders Part 2 - Reagent Selection and Assay Optimization for High-Sensitivity Testing. Cytometry Part B 2018; 94B: 23-48.



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### Your Performance

Cell Population	Performance Status for this Trial	Performance Status Classification Over 12 Sample Period	
		Satisfactory	Critical
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Neutrophils PNH Clone	Satisfactory	12	0

N/A = Not Applicable

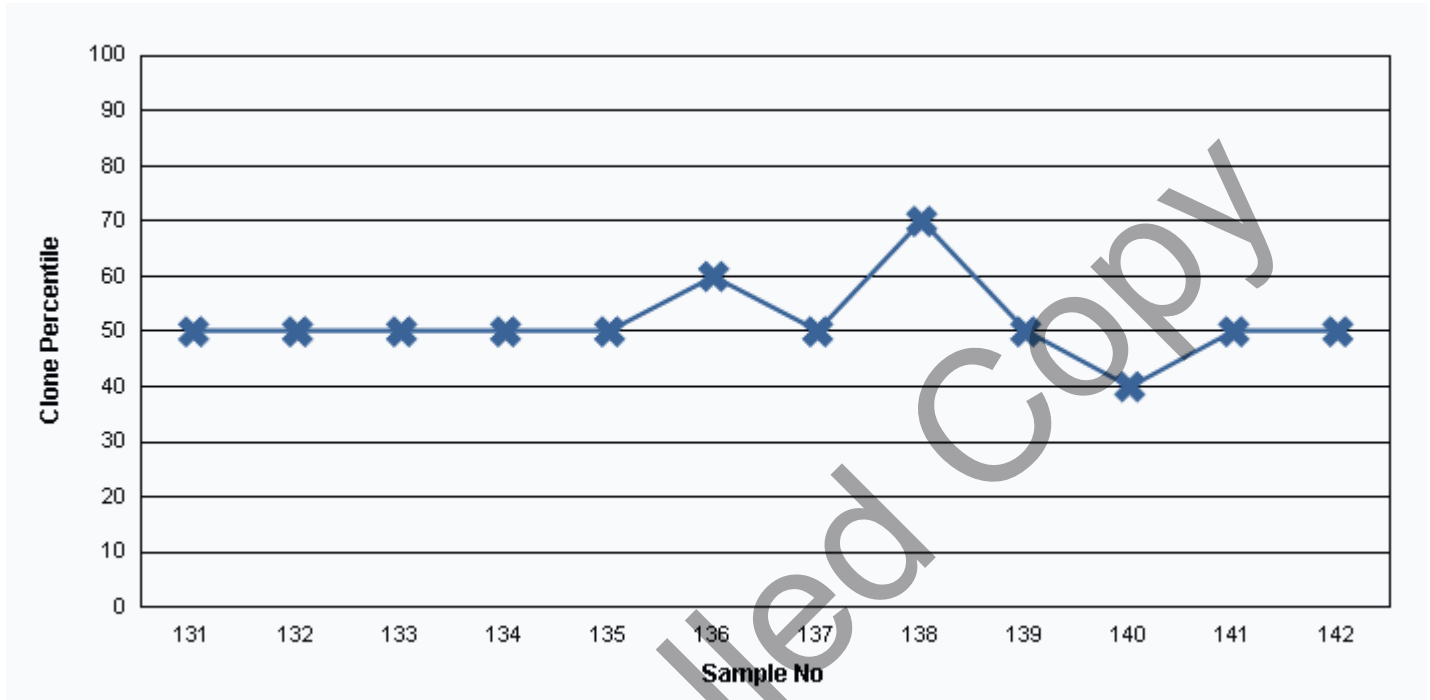
### Percentage Value Results

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
Neutrophils PNH Clone	0.00	0.00	0.00	0.00

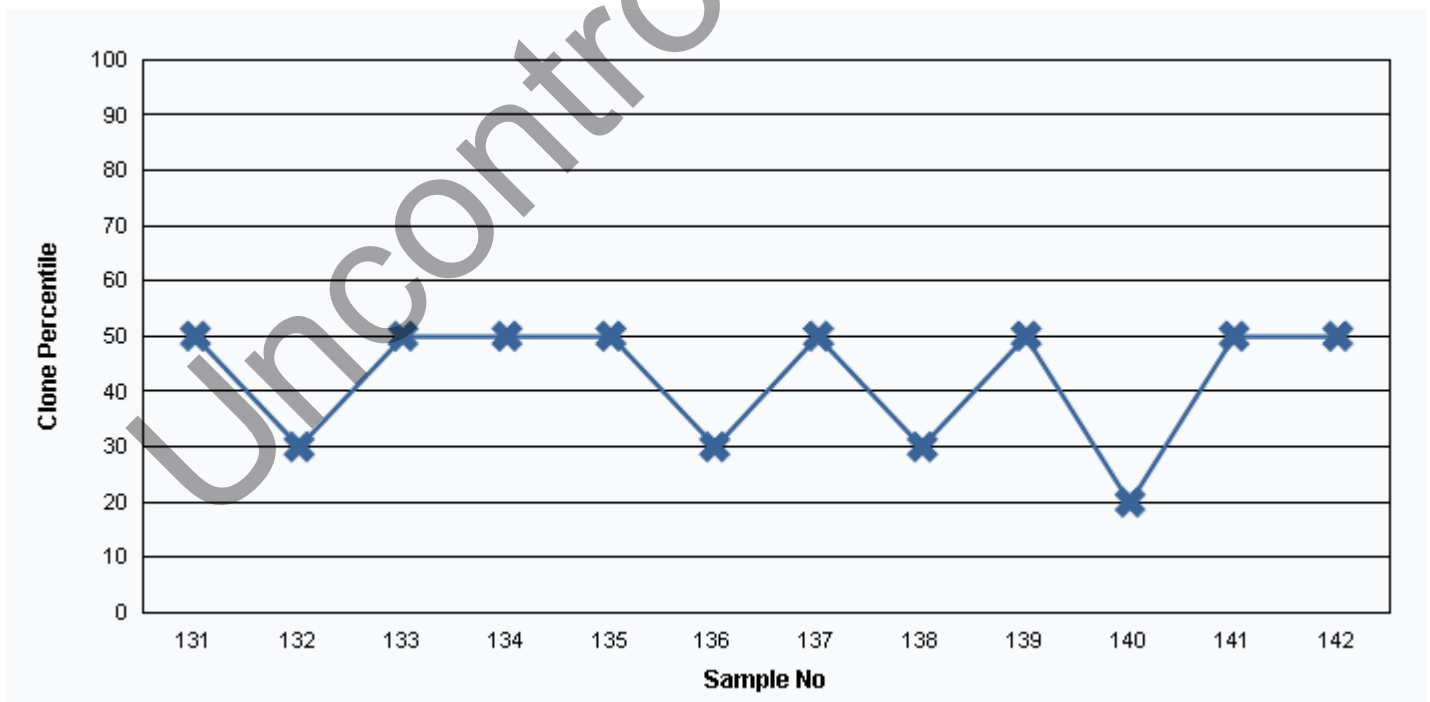
## Paroxysmal Nocturnal Haemoglobinuria Programme

### Centile graph of Percentage Results

Red Blood Cells PNH Clone Percentage Population over last 12 months

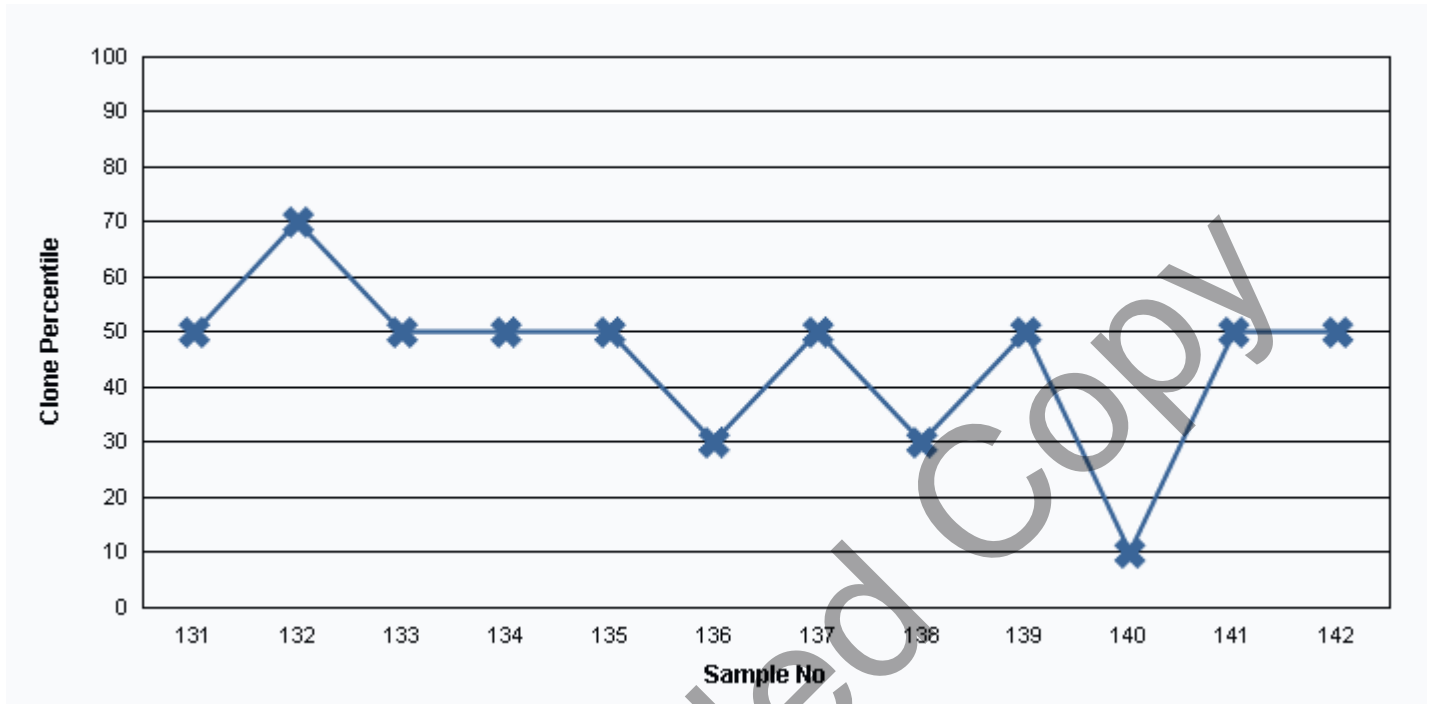


Monocytes PNH Clone Percentage Population over last 12 months



### Paroxysmal Nocturnal Haemoglobinuria Programme

Neutrophils PNH Clone Percentage Population over last 12 months



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## Paroxysmal Nocturnal Haemoglobinuria Programme

### 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 (%)
Navios	38	0	38	0.00	0.00	0.00
FACSCanto II	59	0	59	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 (%)
Navios	43	0	43	0.00	0.00	0.00
FACSCanto II	59	0	59	0.00	0.00	0.00

#### Neutrophils PNH Clone

Flow Cytometer	Returns	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Median Clone Size (%)	Lower Quartile (%)	Upper Quartile (%)
Navios	43	0	43	0.00	0.00	0.00
FACSCanto II	64	1	63	0.00	0.00	0.00

## Paroxysmal Nocturnal Haemoglobinuria Programme

### 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	108	0	108	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/CD45	33	0	33	0.00	0.00	0.00
CD45/CD64	64	0	64	0.00	0.00	0.00

#### Neutrophils PNH Clone

Gating Strategy Used	Returns	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Median Clone Size (%)	Lower Quartile (%)	Upper Quartile (%)
CD15	26	1	25	0.00	0.00	0.00
CD15/CD45	81	0	81	0.00	0.00	0.00

## Paroxysmal Nocturnal Haemoglobinuria Programme

### GPI Linked Antibodies Used Statistics

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#### 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	120	0	120	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 (%)
CD157/FLAER	30	0	30	0.00	0.00	0.00
CD14/FLAER	70	0	70	0.00	0.00	0.00

#### Neutrophils PNH Clone

GPI Linked Antibodies Combination Used	Returns	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Median Clone Size (%)	Lower Quartile (%)	Upper Quartile (%)
CD157/FLAER	30	1	29	0.00	0.00	0.00
CD24/FLAER	77	0	77	0.00	0.00	0.00

## Paroxysmal Nocturnal Haemoglobinuria Programme 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	1	11	12
CD59	1	143	144

\*se 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	0	102	102
CD157	0	47	47
CD24	0	4	4
^CD55	0	6	6
^CD59	0	4	4
CD66b	0	1	1
FLAER	0	148	148

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### Neutrophils PNH Clone

GPI Linked Antibody	Laboratories Reporting Clone Present	Laboratories Reporting Clone Absent	Laboratories using as part of their panel*
CD157	1	45	46
CD24	0	113	113
^CD55	1	5	6
^CD59	1	5	6
^CD66b	0	9	9
FLAER	1	158	159

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## Paroxysmal Nocturnal Haemoglobinuria Programme

### Methodology

#### Red Blood Cells

Reagents	Antibody	Clone	Manufacturer	Fluorochrome	Best Practice
Testing	CD59	MEM-43	Life Technologies	PE	No
Gating	CD235a	KC16	Beckman Coulter	FITC	Yes

#### Monocytes

Reagents	Antibody	Clone	Manufacturer	Fluorochrome	Best Practice
Testing	FLAER		Cedarlane/Pinewood Scientific	AlexaFluor 488	Yes
Testing	CD14	MoP9	BD Biosciences	APC-H7	No
Gating	CD64	10.1	BD Biosciences	BV421	No
Gating	CD45	2D1	BD Biosciences	V500-C	No

#### Neutrophils

Reagents	Antibody	Clone	Manufacturer	Fluorochrome	Best Practice
Testing	FLAER		Cedarlane/Pinewood Scientific	AlexaFluor 488	Yes
Testing	CD24	ML5	BD Biosciences	PE	Yes
Gating	CD15	HI98	BD Biosciences	APC	No
Gating	CD45	2D1	BD Biosciences	V500-C	No

#### Recommended Reading

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## Paroxysmal Nocturnal Haemoglobinuria Programme

### 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, 4<sup>th</sup> 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 Mr Liam Whitby and Mr Stuart Scott.

4.8.2 c) Person(s) authorizing this report:

Mr Liam Whitby, Director or Mr Stuart Scott, Centre Manager of UK NEQAS LI

4.8.2 d) Pre issue testing of samples for this programme is subcontracted, although the final decision about sample suitability lies with the EQA provider; no other 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.uk](http://www.ukneqasli.co.uk) for 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](http://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/](http://www.ukneqasli.co.uk/contact-us/appeals-and-complaints/)