

Chimerism Programme
All Participant Report

Sample - 169

Distribution - 151603

Participant ID -

Date Issued - 16 March 2016

Closing Date - 15 April 2016

Trial Comments

The trial was issued to 102 participants for Post-SCT Chimerism analysis with 96 (94.1%) participants returning results.

Sample Comments

Four 1ml samples of peripheral blood representing Donor (167), Recipient (168) and 2 Post-Stem Cell Transplant samples (169 and 170) were distributed to participants.

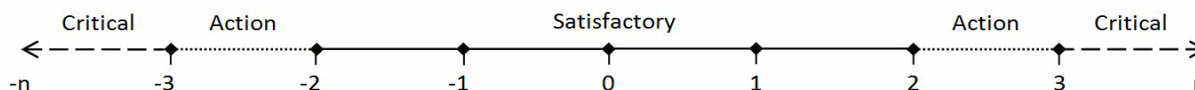
Results and Performance

Reported Percentage Donor	Your Results (%)	Robust Mean (%)	Robust SD (%)
		89.0	1.4

Reported Percentage Donor	z Score*	Performance Status for this Sample	Performance Status Classification Over 6 Sample Period		
			Satisfactory	Action	Critical
	0.71	Satisfactory	6	0	0

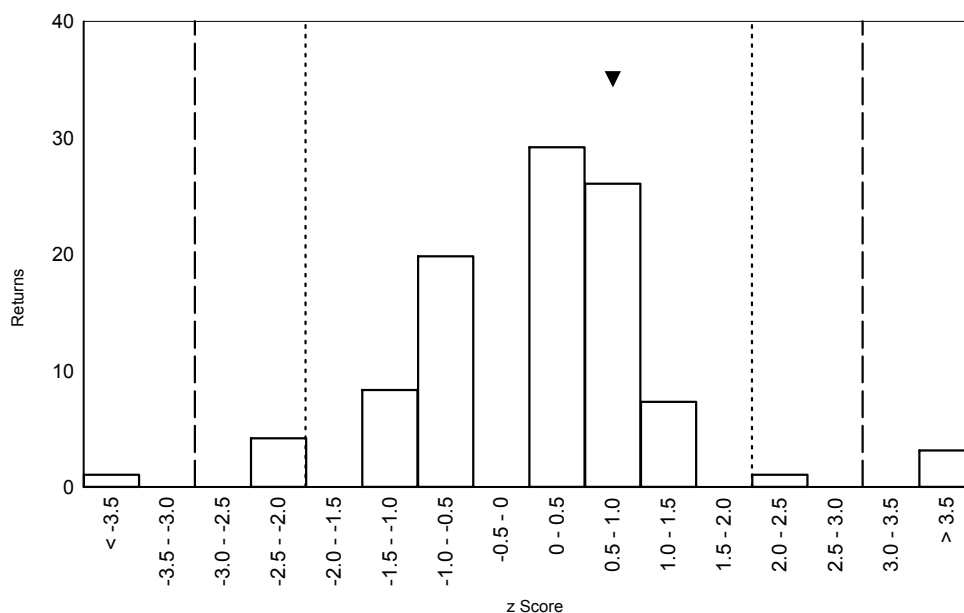
***z Score Limits Definitions**

Please note the scale below is applicable to the tables above and to the z score histograms and Shewhart control charts that follow. It is not applicable to the Cusum control charts.



Histograms of Participant z Scores

Percentage donor chimerism result -
Please note ▼ denotes your result



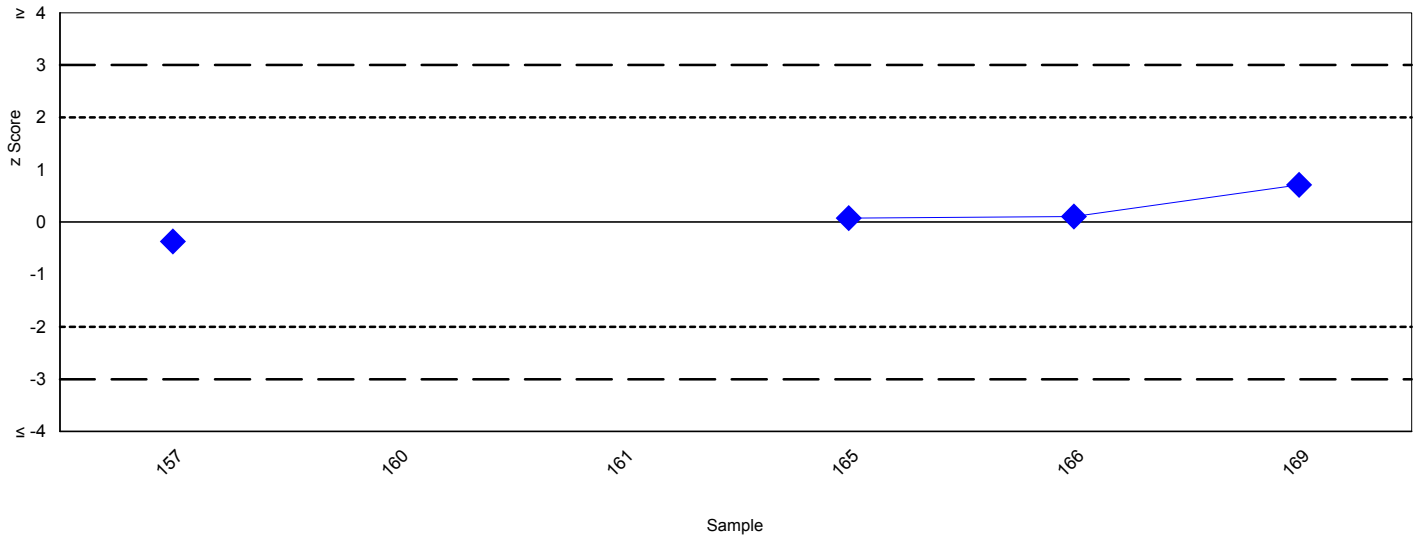
Chimerism Programme

Sample - 169

Shewhart Control Charts

(Please note each data point represents a single sample)

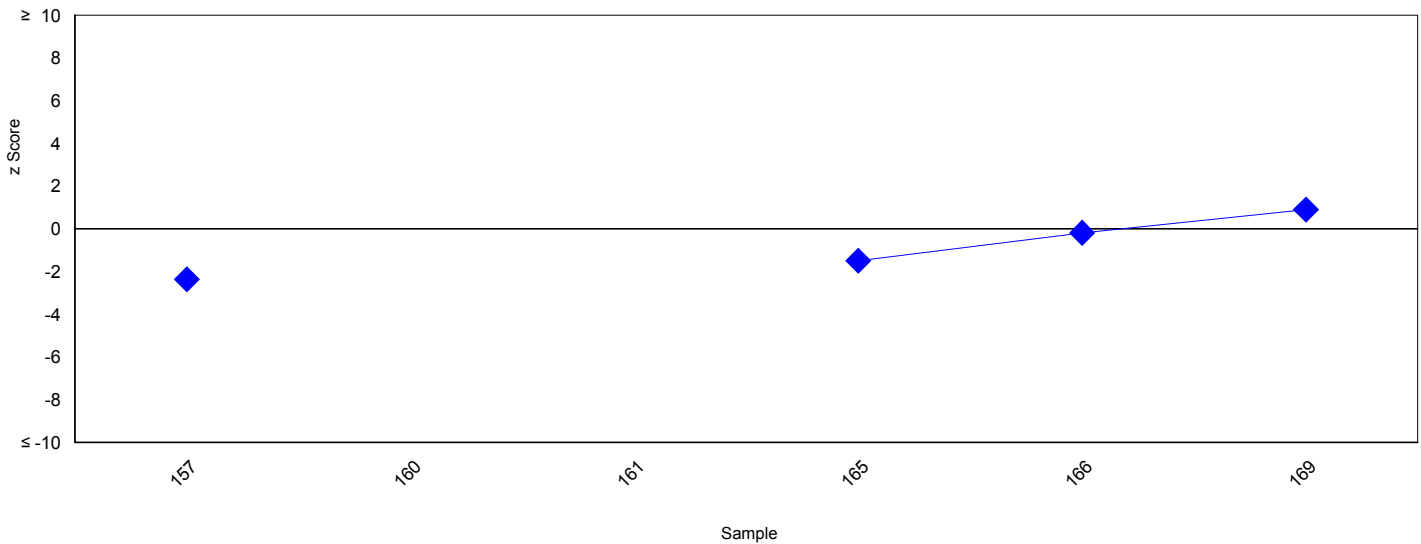
Values (Percentage (%) Donor)



Cusum Control Charts

(Please note each data point represents the sum of the z scores of the current sample and the two previous samples)

Values (Percentage (%) Donor)



Chimerism Programme

Sample - 169

Please note, only methods/instruments used by ≥ 2 participants are included in the tables. Robust statistics can only be calculated where we have ≥ 20 returns.

Instrument Specific Statistics

Method	Returns	Robust Mean	Robust SD
ABI 3130xl	23	89.2	1.1
ABI 3130	19		
ABI 3500	17		
ABI 310	12		
ABI 3500xl	9		
ABI 3730	3		
ABI 3730xl	2		
ABI 3100	2		
ABI 7900 HT	2		

PCR Type Specific Statistics

Method	Returns	Robust Mean	Robust SD
Multiplex	74	89.0	1.3
Single	16		
Real - Time PCR	4		

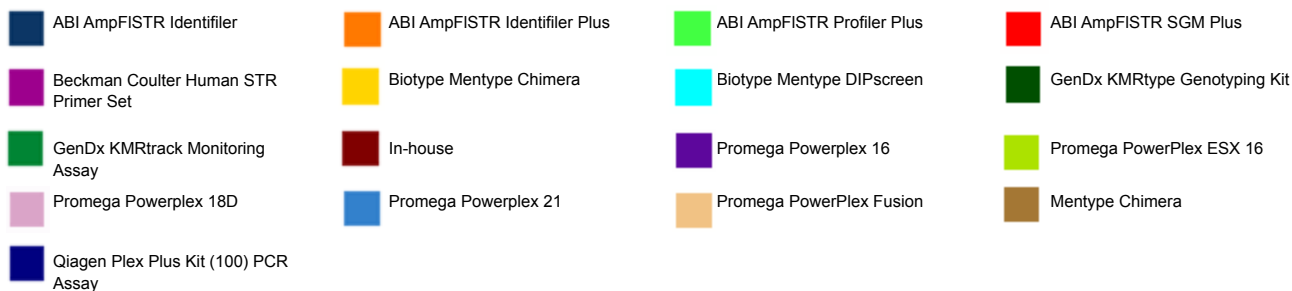
Kit/Method Specific Statistics

Method	Returns	Robust Mean	Robust SD
Promega Powerplex 16	34	88.7	1.0
In-house	21	89.6	1.5
ABI AmpFISTR Profiler Plus	8		
ABI AmpFISTR Identifier	7		
ABI AmpFISTR Identifier Plus	5		
Biotype Mentype Chimera	3		
Promega PowerPlex Fusion	3		
ABI AmpFISTR SGM Plus	2		
Mentype Chimera	2		
Promega PowerPlex ESX 16	2		

Chimerism Programme

Sample - 169

Frequency distribution histogram showing percentage donor engraftment for sample Post-SCT 169



Chimerism Programme

Sample - 170

Distribution - 151603

Participant ID -

Date Issued - 16 March 2016

Closing Date - 15 April 2016

Trial Comments

The trial was issued to 102 participants for Post-SCT Chimerism analysis with 96 (94.1%) participants returning results.

Sample Comments

Four 1ml samples of peripheral blood representing Donor (167), Recipient (168) and 2 Post- Stem Cell Transplant samples (169 and 170) were distributed to participants.

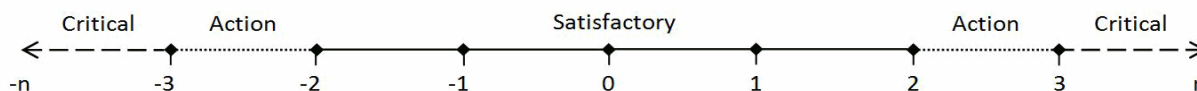
Results and Performance

Reported Percentage Donor	Your Results (%)	Robust Mean (%)	Robust SD (%)
		90.8	1.4

Reported Percentage Donor	z Score*	Performance Status for this Sample	Performance Status Classification Over 6 Sample Period		
			Satisfactory	Action	Critical
	0.14	Satisfactory	6	0	0

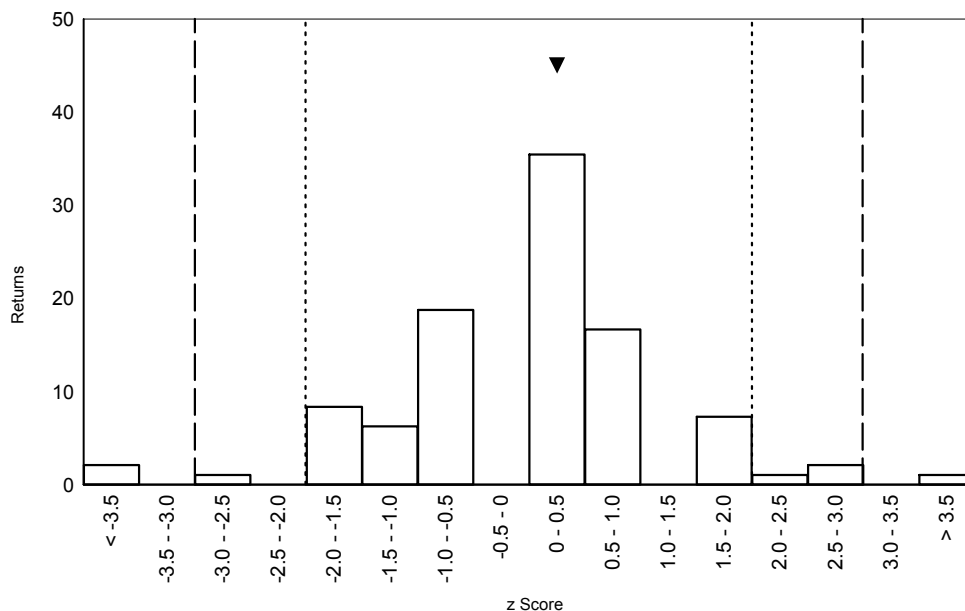
*z Score Limits Definitions

Please note the scale below is applicable to the tables above and to the z score histograms and Shewhart control charts that follow. It is not applicable to the Cusum control charts.



Histograms of Participant z Scores

Percentage donor chimerism result -
Please note ▼ denotes your result



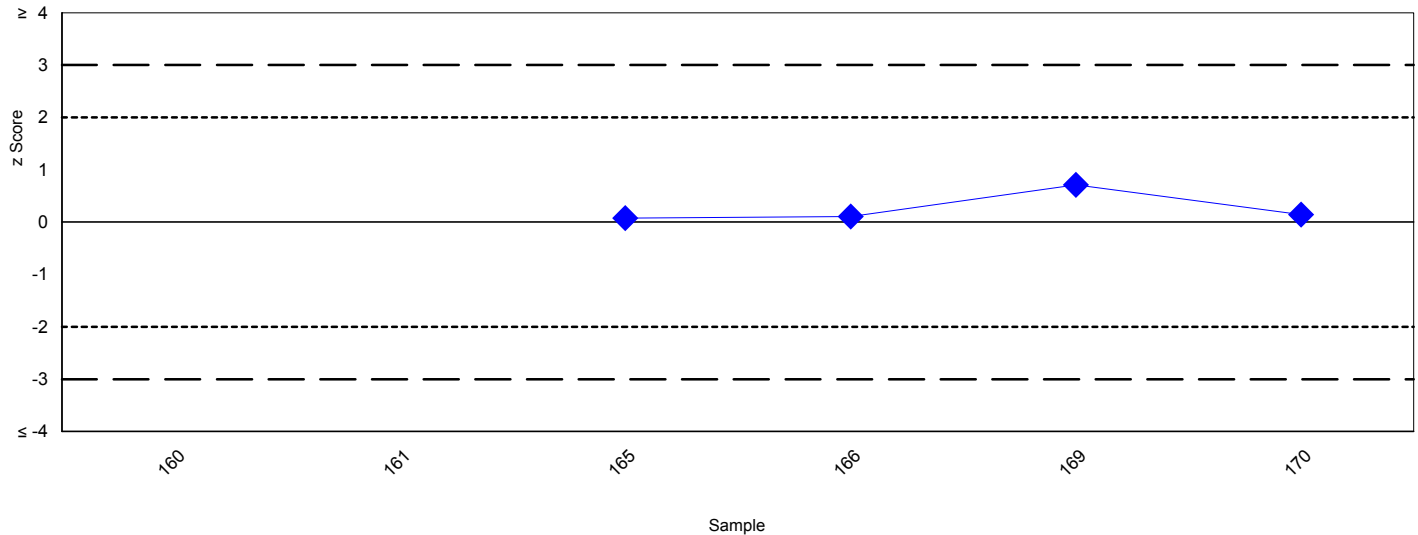
Chimerism Programme

Sample - 170

Shewhart Control Charts

(Please note each data point represents a single sample)

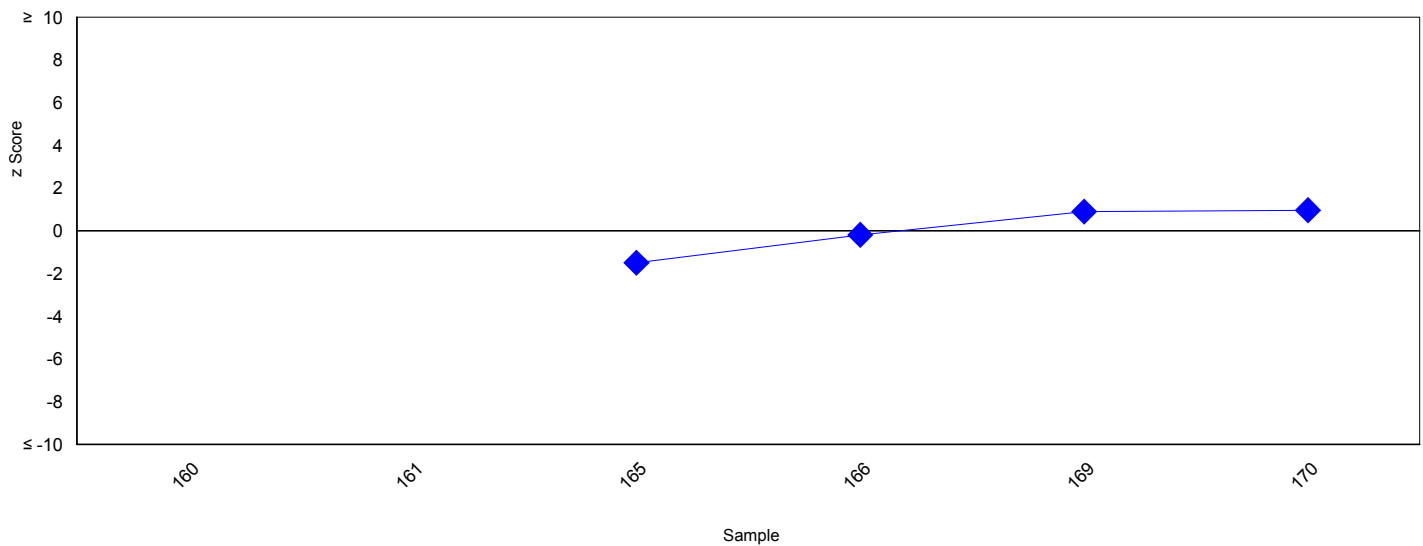
Values (Percentage (%) Donor)



Cusum Control Charts

(Please note each data point represents the sum of the z scores of the current sample and the two previous samples)

Values (Percentage (%) Donor)



Chimerism Programme

Sample - 170

Please note, only methods/instruments used by ≥ 2 participants are included in the tables. Robust statistics can only be calculated where we have ≥ 20 returns.

Instrument Specific Statistics

Method	Returns	Robust Mean	Robust SD
ABI 3130xl	23	90.5	1.3
ABI 3130	19		
ABI 3500	17		
ABI 310	12		
ABI 3500xl	9		
ABI 3730	3		
ABI 3730xl	2		
ABI 3100	2		
ABI 7900 HT	2		

PCR Type Specific Statistics

Method	Returns	Robust Mean	Robust SD
Multiplex	74	90.8	1.4
Single	16		
Real - Time PCR	4		

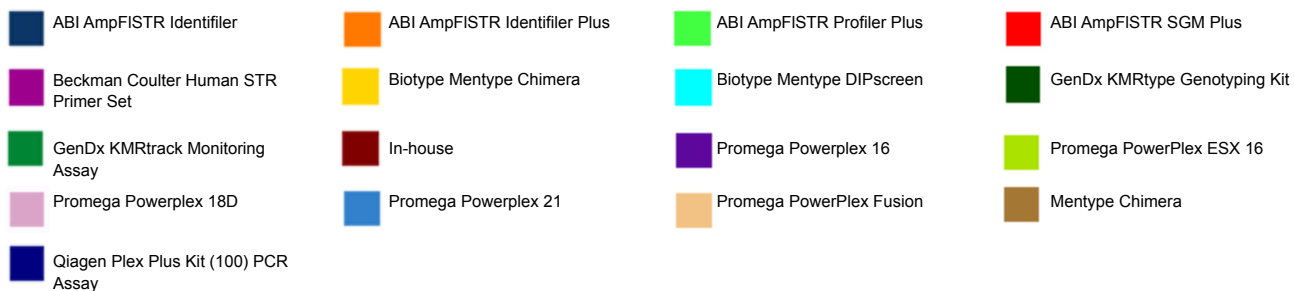
Kit/Method Specific Statistics

Method	Returns	Robust Mean	Robust SD
Promega Powerplex 16	34	90.7	1.0
In-house	21	91.4	1.3
ABI AmpFISTR Profiler Plus	8		
ABI AmpFISTR Identifier	7		
ABI AmpFISTR Identifier Plus	5		
Promega PowerPlex Fusion	3		
Biotype Mentype Chimera	3		
Mentype Chimera	2		
Promega PowerPlex ESX 16	2		
ABI AmpFISTR SGM Plus	2		

Chimerism Programme

Sample - 170

Frequency distribution histogram showing percentage donor engraftment for sample Post-SCT 170



Chimerism Programme

Trial Summary

- Post SCT samples 169 and 170 were manufactured to carry a majority of donor cells, with sample Post SCT 170 designed to carry marginally more.
- The overall robust mean for sample 169 was 89.0% donor chimerism with a robust SD of 1.4%.
- The overall robust mean for sample 170 was 90.8% donor chimerism with a robust SD of 1.4%.
- 86/96 (89.6%) participants identified the correct trend between the samples. The modal difference identified by participants between the samples was 2%.
- Five participants incurred a critical score in one or both samples. One entered a result of 7% for sample 169 and 5% for sample 170, indicative of returning the % recipient results rather than the % donor result.
- Of the remaining critical results, two participants used an in-house PCR methodology, one used the ABI AmpFISTR Identifier kit and one used the Mentype Chimera kit.
- As of 1st April 2016 there will be an increase in trial issues in our Post SCT Chimerism Programme (5 trial issues of 4 samples: 1x donor, 1x recipient and 2x post SCT/trial issue, per annum). This change is as a result of amendments to the European Federation of Immunogenetics (EFI) Standards for Histocompatibility & Immunogenetics Testing Version 6.3 that were published on the 1st Oct 2015. This mandates in Standard C6.4.7: '10 EQA tests of different donor/recipient mixtures in the range 0% - 100%, excluding the reference donor and recipient samples to be tested [per annum].' These changes will ensure that our programme is fully compliant with these standards and ensure that all laboratories can meet their accreditation requirements when being inspected to EFI standards and furthermore will help us maintain our ISO 17043 accreditation.
- As a result of this there will be no increase in cost (other than the planned 1% inflationary increase) for this forthcoming financial year (April 2016-March 2017) as UKNEQAS LI will absorb the increased sample manufacture and associated analysis and reporting costs. However, please note where a participant has samples shipped by courier then this will incur the additional courier services which are of course outside of our control. Please note, the costs of all UKNEQAS LI's EQA programmes are reviewed on an annual basis.
- If you require any further information do not hesitate to contact us:
admin@ukneqasli.co.uk

Chimerism 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, 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.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. 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.