UK NEQAS
Leucocyte Immunophenotyping

Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Post-Stem Cell Transplant Chimerism Monitoring Programme

All Participant Report

Distribution - 202104 Sample - 267 Participant ID -

Date Issued - 21 January 2021 Closing Date - 26 February 2021

Trial Comments

FINAL REPORT: This trial was issued to 105 participants, of which 99 (94.3%) returned results. Of the non returns, two laboratories submitted a request for an extension in results submission in light of the ongoing Covid-19 pandemic.

Sample Comments

Four 1ml samples of peripheral blood representing Donor (265), Recipient (266) and two Post-Stem Cell transplant samples (Post- SCT 267 and 268) were distributed to participants.

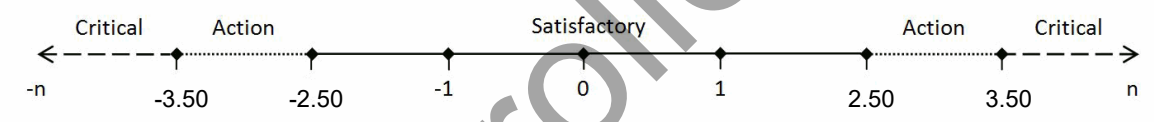
Results and Performance

Reported Percentage Donor	Your Results (%)	Robust Mean (%)	Robust SD (%)
		73.6	2.5

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

*z Score Limits Definitions

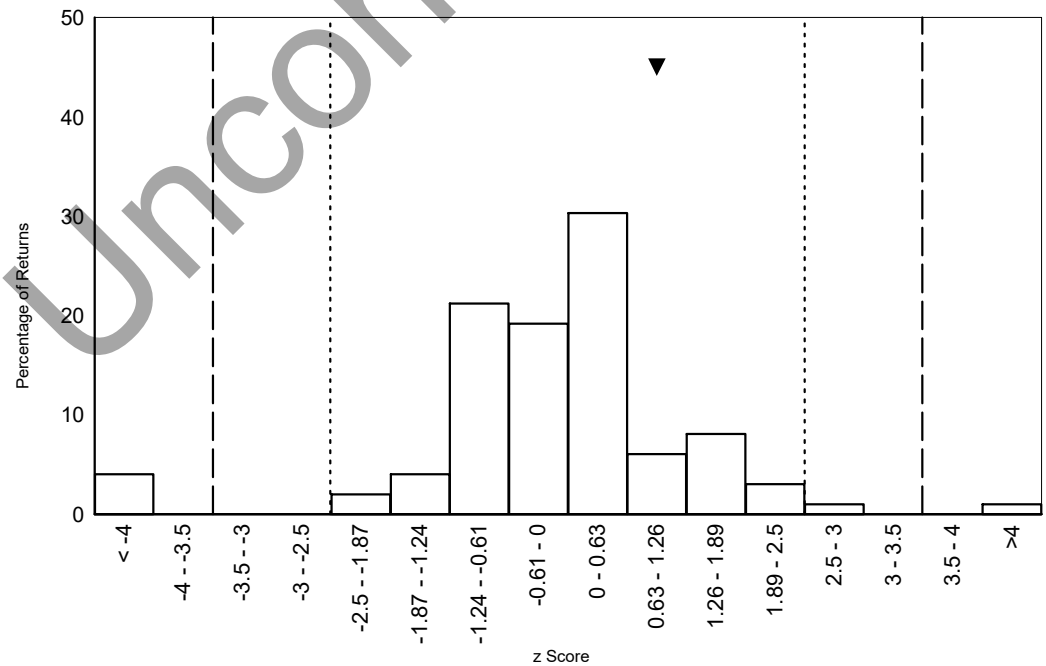
Please note the scale below is applicable to the tables above and to the z score histograms and Shewhart control charts that follow. It is not applicable to the Cusum control charts.



Histograms of Participant z Scores

Percentage donor chimerism result -

Please note ▼ denotes your result

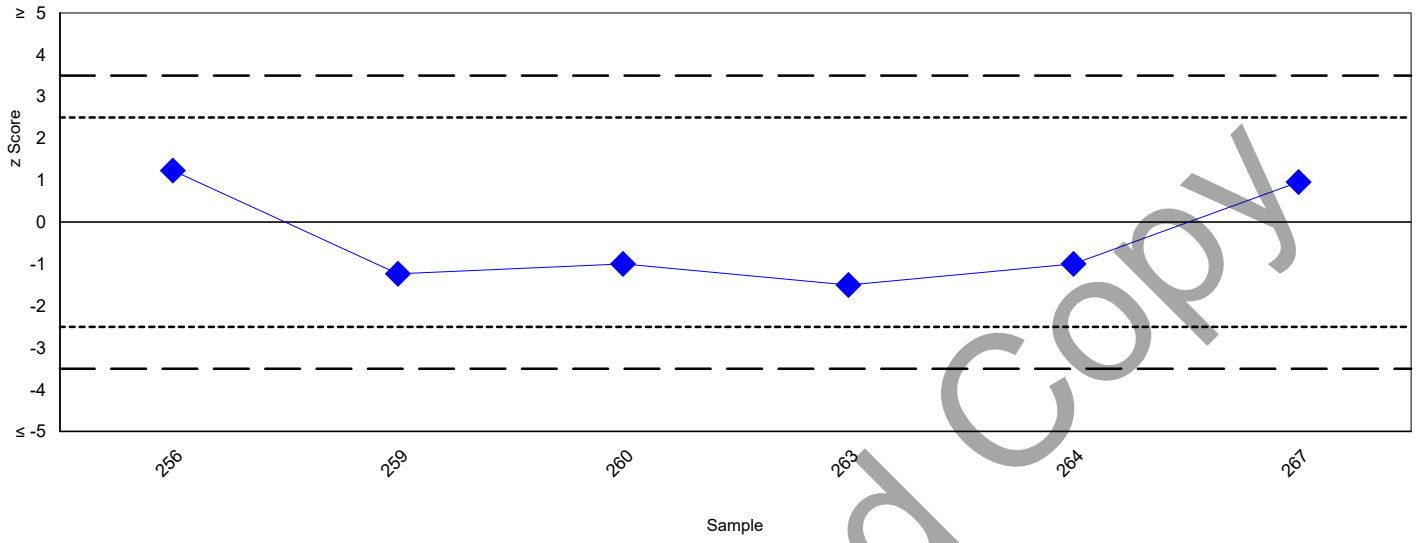


Post-Stem Cell Transplant Chimerism Monitoring Programme

Shewhart Control Charts

(Please note each data point represents a single sample)

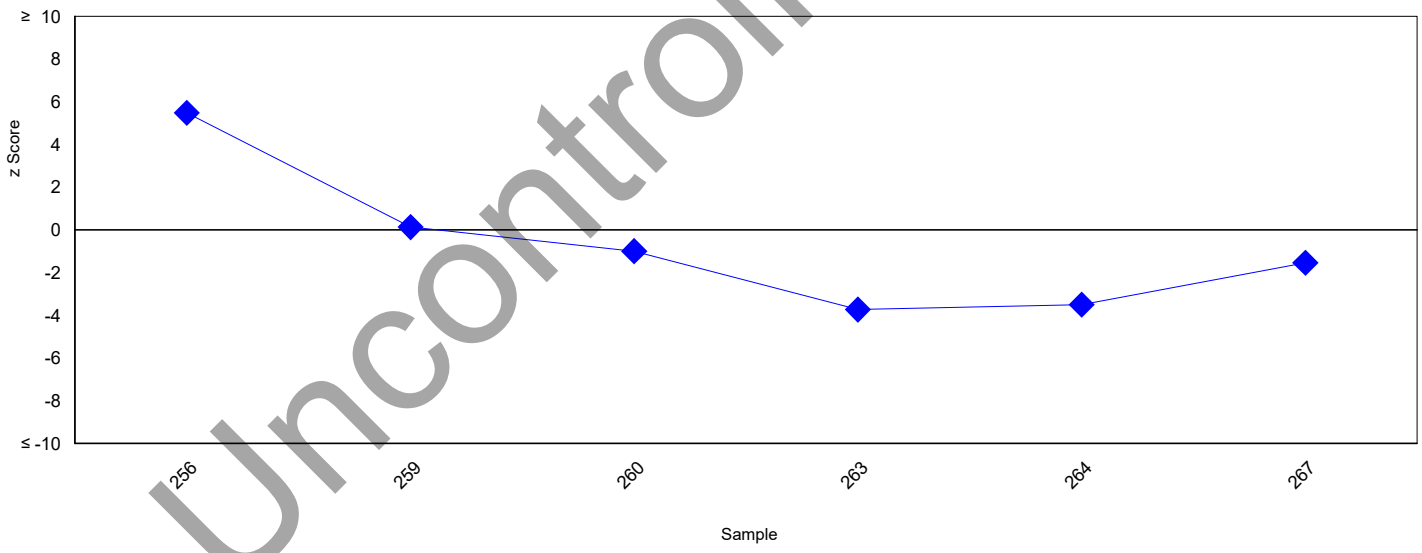
Values (Percentage (%) Donor)



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)



Post-Stem Cell Transplant Chimerism Monitoring Programme

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 3500	28	73.4	2.1
ABI 3130xl	16		
ABI 3500xl	13		
ABI 3130	7		
ABI 310	6		
ABI 7500 Real-Time PCR	5		
ABI 3730	5		
ABI SeqStudio	4		
Illumina Miseq	4		
Corbett Rotorgene	2		
Bio-Rad QX200	2		
Roche LC480	2		

PCR Type Specific Statistics

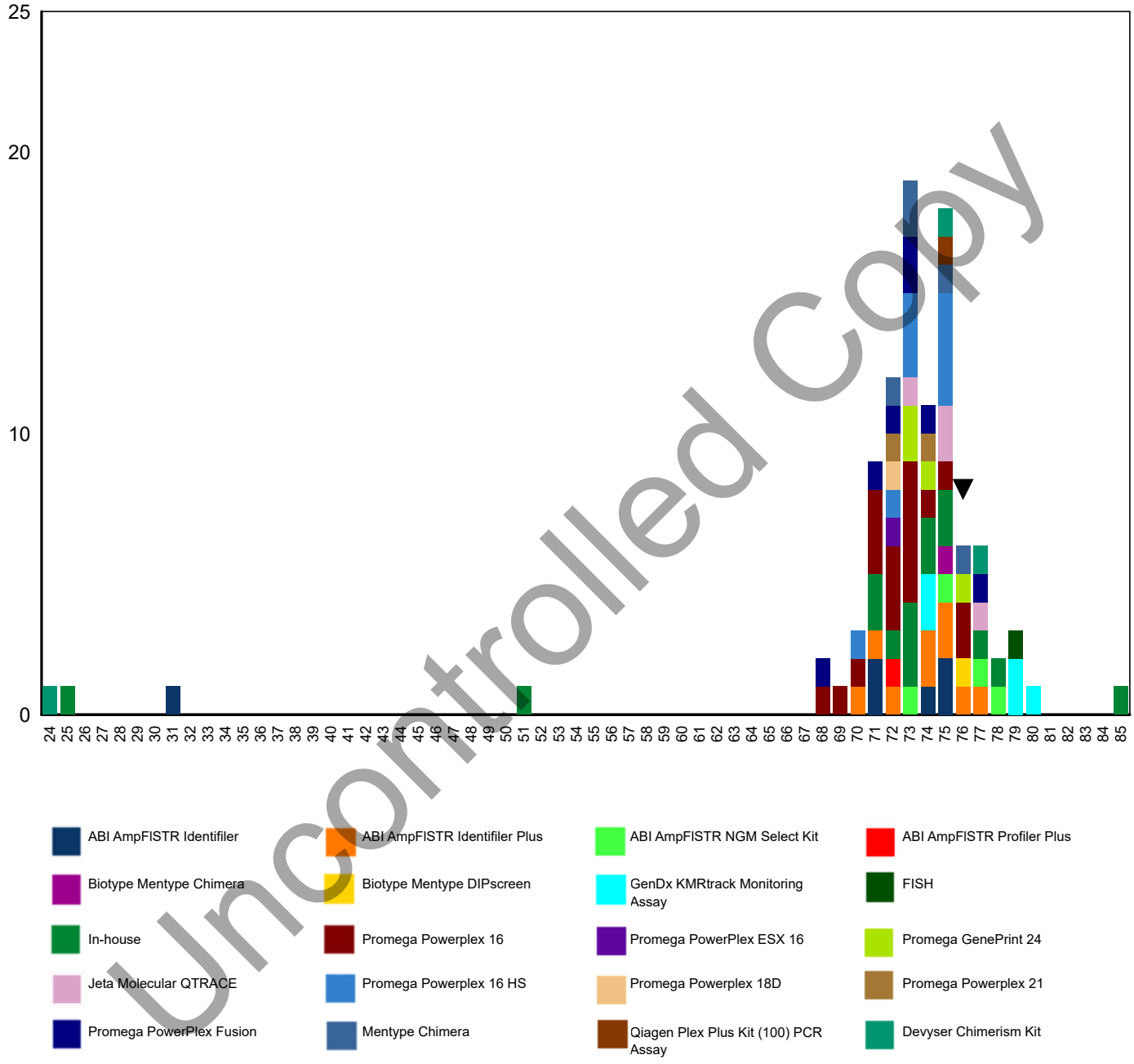
Method	Returns	Robust Mean	Robust SD
Multiplex	71	73.3	2.2
Single	12		
Real - Time PCR	10		
NGS	3		
Droplet Digital PCR	2		

Kit/Method Specific Statistics

Method	Returns	Robust Mean	Robust SD
Promega Powerplex 16	18		
In-house	15		
Promega Powerplex 16 HS	9		
ABI AmpFISTR Identifiler Plus	9		
Promega PowerPlex Fusion	7		
ABI AmpFISTR Identifiler	6		
GenDx KMRtrack Monitoring Assay	5		
Mentype Chimera	5		
ABI AmpFISTR NGM Select Kit	4		
Jeta Molecular QTRACE	4		
Promega GenePrint 24	4		
Devyser Chimerism Kit	3		
Promega Powerplex 21	2		

Post-Stem Cell Transplant Chimerism Monitoring Programme

Frequency distribution histogram showing percentage donor engraftment for sample Post-SCT 267



Post-Stem Cell Transplant Chimerism Monitoring Programme

Distribution - 202104 Sample - 268 Participant ID -

Date Issued - 21 January 2021 Closing Date - 26 February 2021

Trial Comments

FINAL REPORT: This trial was issued to 105 participants, of which 99 (94.3%) returned results. Of the non returns, two laboratories submitted a request for an extension in results submission in light of the ongoing Covid-19 pandemic.

Sample Comments

Four 1ml samples of peripheral blood representing Donor (265), Recipient (266) and two Post-Stem Cell transplant samples (Post- SCT 267 and 268) were distributed to participants.

Results and Performance

Reported Percentage Donor	Your Results (%)	Robust Mean (%)	Robust SD (%)
		86.3	2.3

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

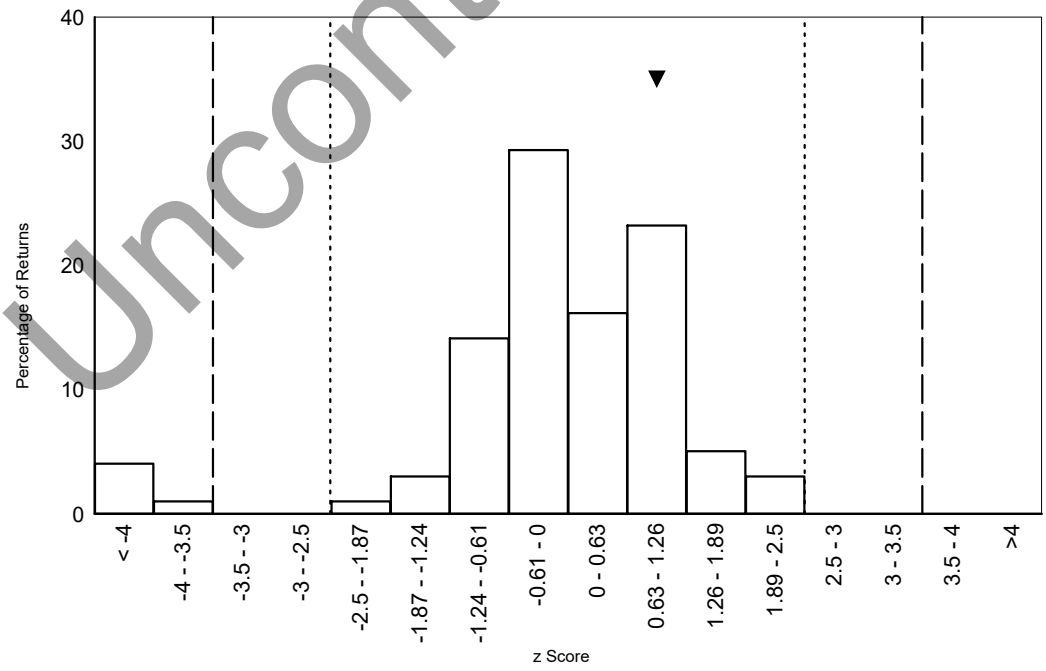
*z Score Limits Definitions

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

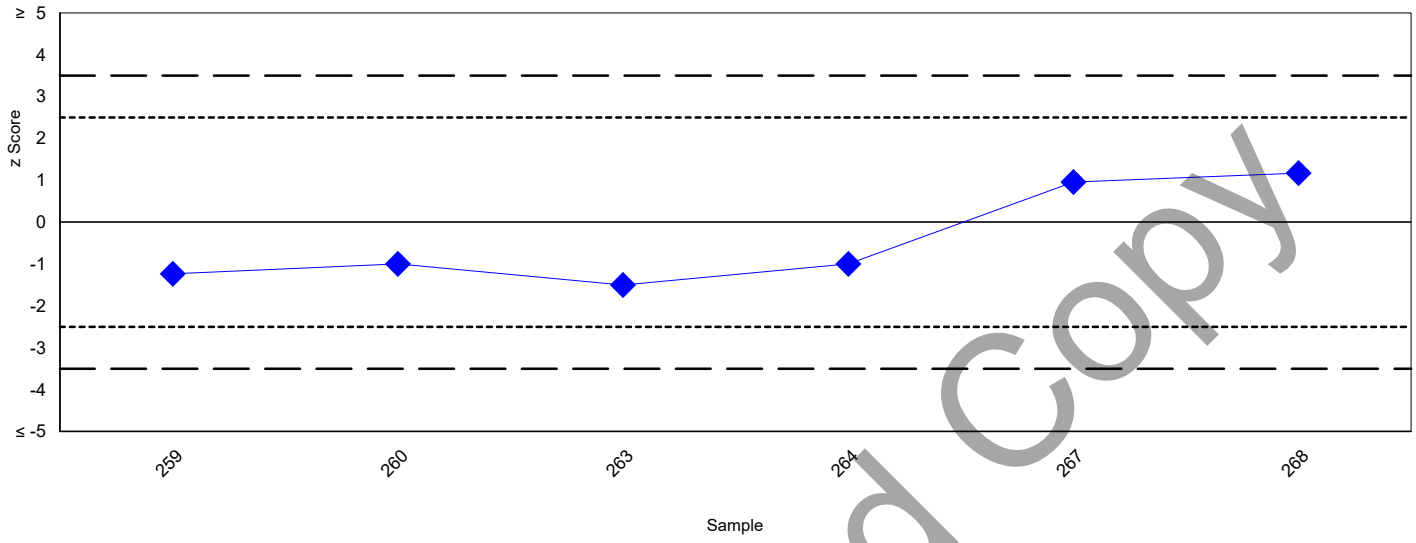


Post-Stem Cell Transplant Chimerism Monitoring Programme

Shewhart Control Charts

(Please note each data point represents a single sample)

Values (Percentage (%) Donor)



Cusum Control Charts

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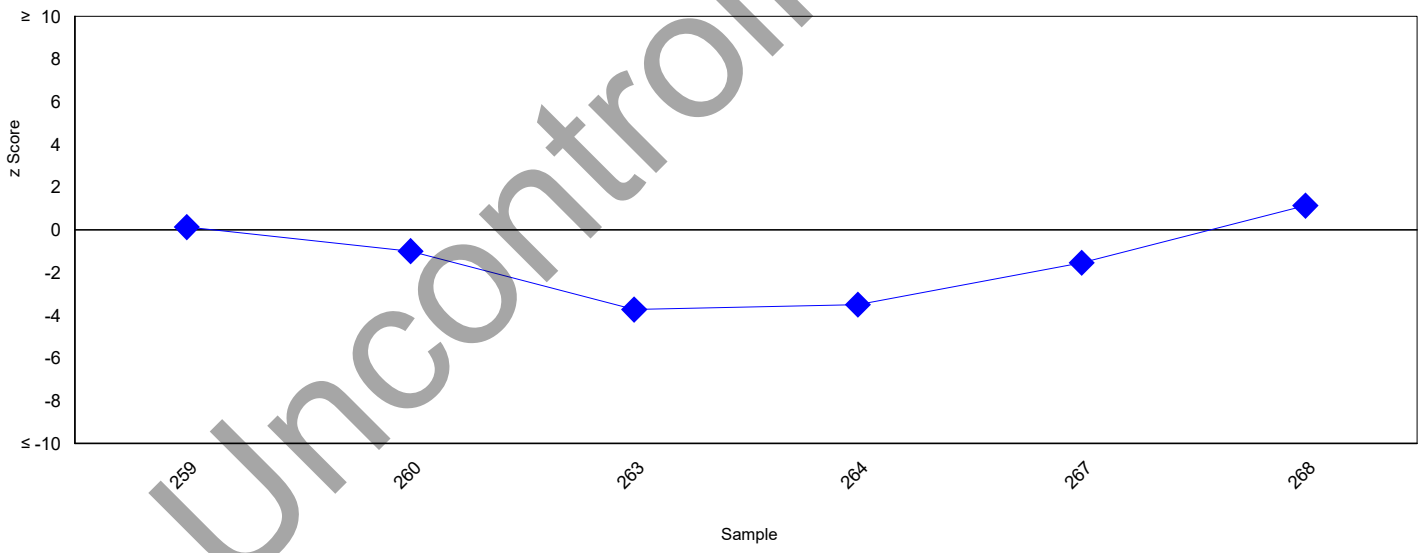
Values (Percentage (%) Donor)



Post-Stem Cell Transplant Chimerism Monitoring Programme

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 3500	28	85.9	1.8
ABI 3130xl	16		
ABI 3500xl	13		
ABI 3130	7		
ABI 310	6		
ABI 7500 Real-Time PCR	5		
ABI 3730	5		
ABI SeqStudio	4		
Illumina Miseq	4		
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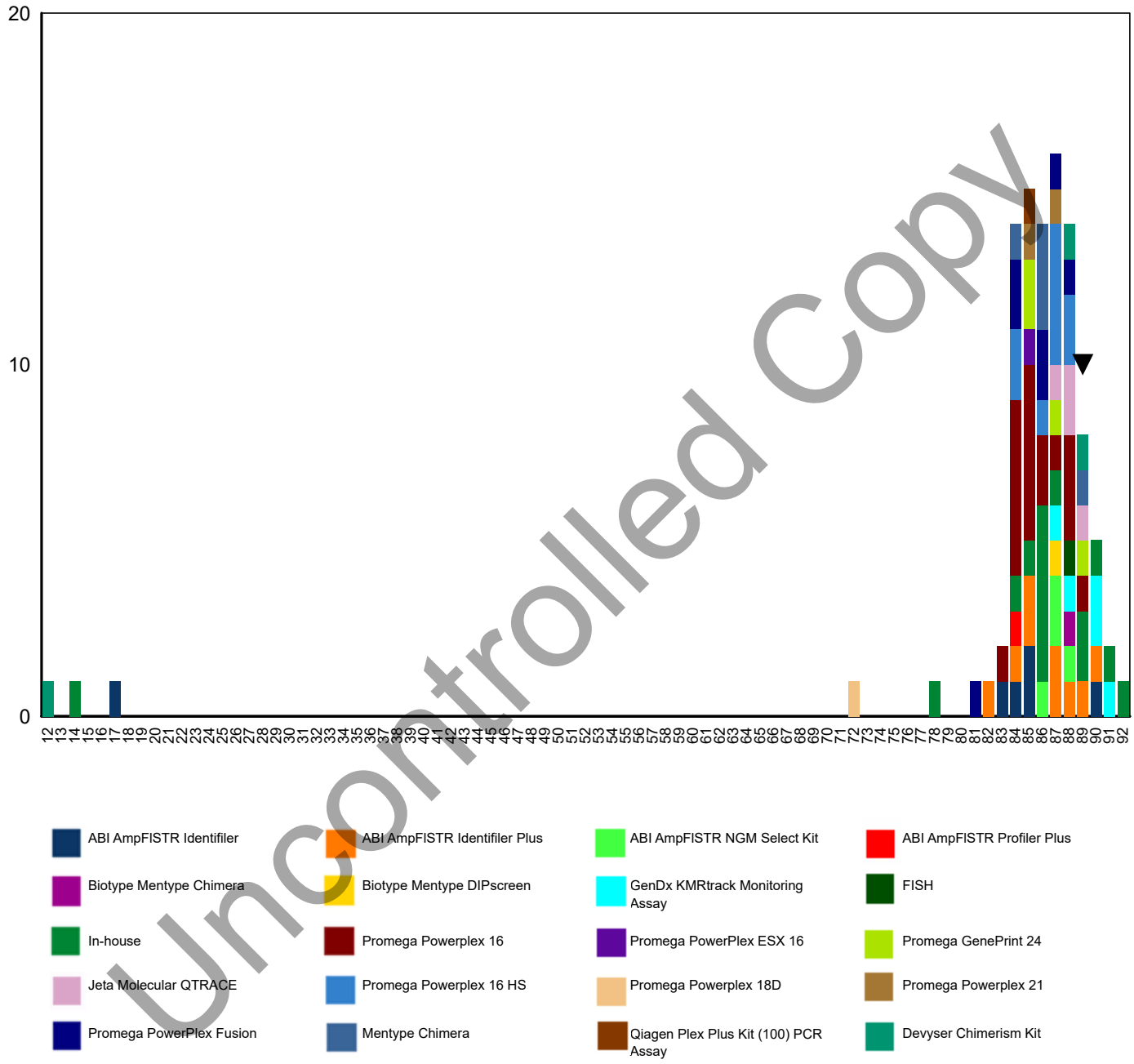
Promega Powerplex 16 HS	9		
Promega PowerPlex Fusion	7		
ABI AmpFISTR Identifiler	6		
GenDx KMRtrack Monitoring Assay	5		
Mentype Chimera	5		
ABI AmpFISTR NGM Select Kit	4		
Jeta Molecular QTRACE	4		
Promega GenePrint 24	4		
Devyser Chimerism Kit	3		
Promega Powerplex 21	2		

Post-Stem Cell Transplant Chimerism Monitoring Programme

Frequency distribution histogram showing percentage donor engraftment for sample Post-SCT 268



Post-Stem Cell Transplant Chimerism Monitoring Programme

Comments

Post-SCT Sample 267

- The overall robust mean for sample 267 was 73.6% donor chimerism with a robust SD of 2.5%.
- Five participants received a critical score for this sample. Three participants appeared to report the % recipient in sample 267. The remaining participants utilised in-house assays: one used a single marker and the other used two markers analysed by real-time PCR.

Post-SCT Sample 268

- The overall robust mean for sample 268 was 86.3% donor chimerism with a robust SD of 2.3%.
- Five participants received a critical score for this sample. The same three laboratories appeared to again report the % recipient. In addition, the laboratory analysing two markers by real-time PCR and a further laboratory using four markers from the Promega Powerplex 18D kit also received critical scores.

General Trial Comments

- Ninety-seven participants informed us how many markers they used. Eighty-three laboratories (85.6%) calculated donor chimerism in Post-SCT 267 and 268 using a minimum of at least three informative markers (median number of markers = 5), as recommended in the 2014 UK guidelines[1]. Three participants used a single locus to calculate donor chimerism in Post-SCT 267 and two used a single locus in Post-SCT 268.

Reference

1. Clark, J. R. *et al.* Monitoring of chimerism following allogeneic haematopoietic stem cell transplantation (HSCT): Technical recommendations for the use of Short Tandem Repeat (STR) based techniques, on behalf of the United Kingdom National External Quality Assessment Service. *Br. J. Haematol.* (2014). doi:10.1111/bjh.13073

Post-Stem Cell Transplant Chimerism Monitoring 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: amanda.newbould@ukneqasli.co.uk

4.8.2 b) The coordinators of UK NEQAS LI programmes are Mr Liam Whitby (Director) and Mr Stuart Scott (Centre Manager).

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) 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. 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/

4.8.4) The UK NEQAS LI Policy for the Use of Reports by Individuals and Organisations states that all EQA reports are subject to copyright, and, as such, permission must be sought from UK NEQAS LI for the use of any data and/or reports in any media prior to use. See associated policy on the UK NEQAS LI website: http://www.ukneqasli.co.uk/eqa-pt-programmes/new-participant-information/