Post-Stem Cell Transplant Chimerism Monitoring Programme

All Participant Report

Distribution - 222301 Sample - 295 Participant ID -

Date Issued - 19 May 2022 Closing Date - 17 June 2022

Trial Comments

This trial was issued to 109 participants, of which 98 (89.9%) returned results within the trial window. Of the 11 non returns, one laboratory gave pre-notification of their intention not to return results, six requested an extension to the results submission period and one has been excluded from scoring because of ongoing difficulties when shipping samples to Belgium. We are working with Belgian participants to resolve these issues.

Sample Comments

Four 1ml samples of peripheral blood representing Donor (293), Recipient (294) and two Post- Stem Cell Transplant samples (Post-SCT 295 and 296) were distributed to participants.

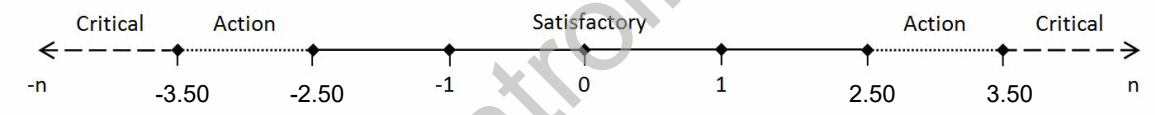
Results and Performance

Reported Percentage Donor	Your Results (%)	Robust Mean (%)	Robust SD (%)
	91	94.3	1.4

Reported Percentage Donor	z Score*	Performance Status for this Sample	Performance Status Classification Over 6 Sample Period		
			Satisfactory	Action	Critical
	-2.36	Satisfactory	5	0	1

*z Score Limits Definitions

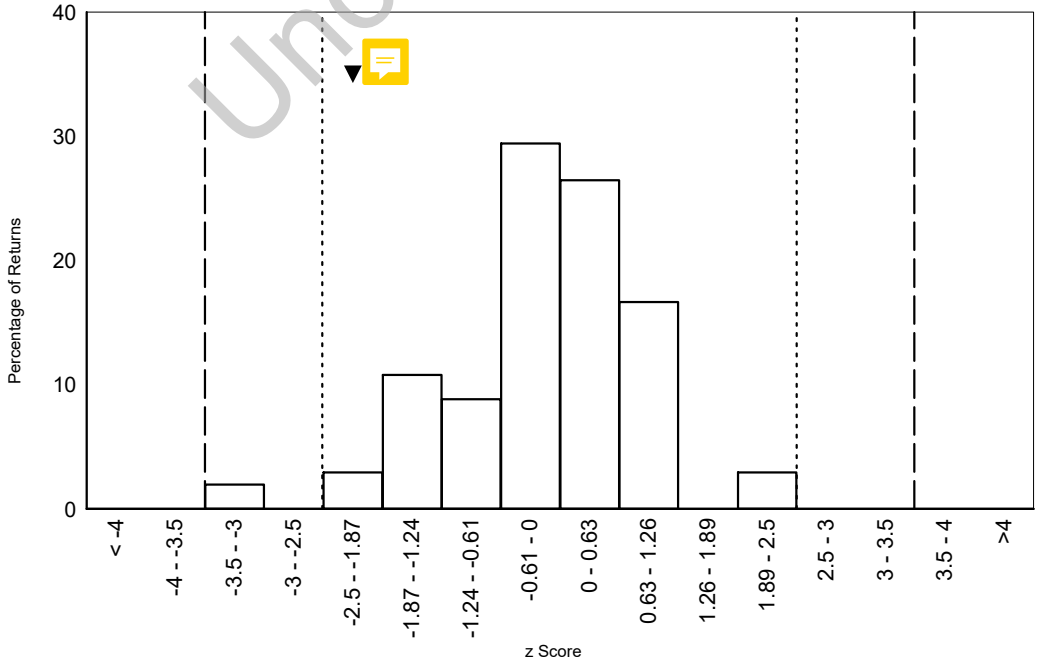
Please note the scale below is applicable to the tables above and to the z score histograms and Shewhart control charts that follow. It is not applicable to the Cusum control charts.



Histograms of Participant z Scores

Percentage donor chimerism result -

Please note ▼ denotes your result

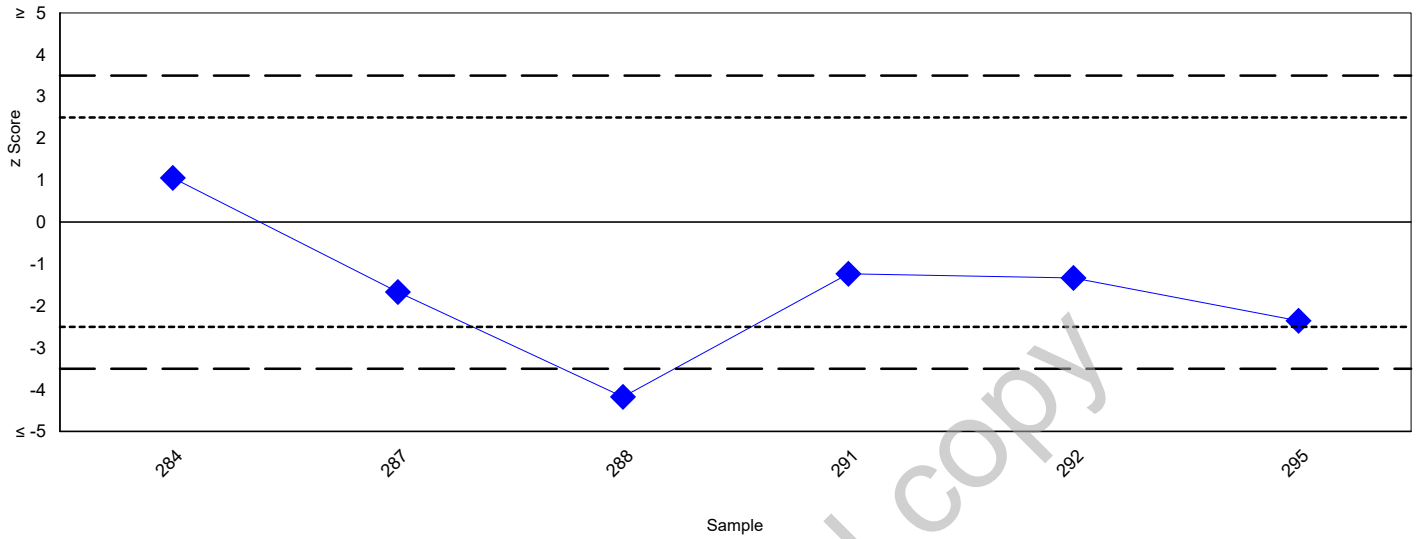


Post-Stem Cell Transplant Chimerism Monitoring Programme

Shewhart Control Charts

(Please note each data point represents a single sample)

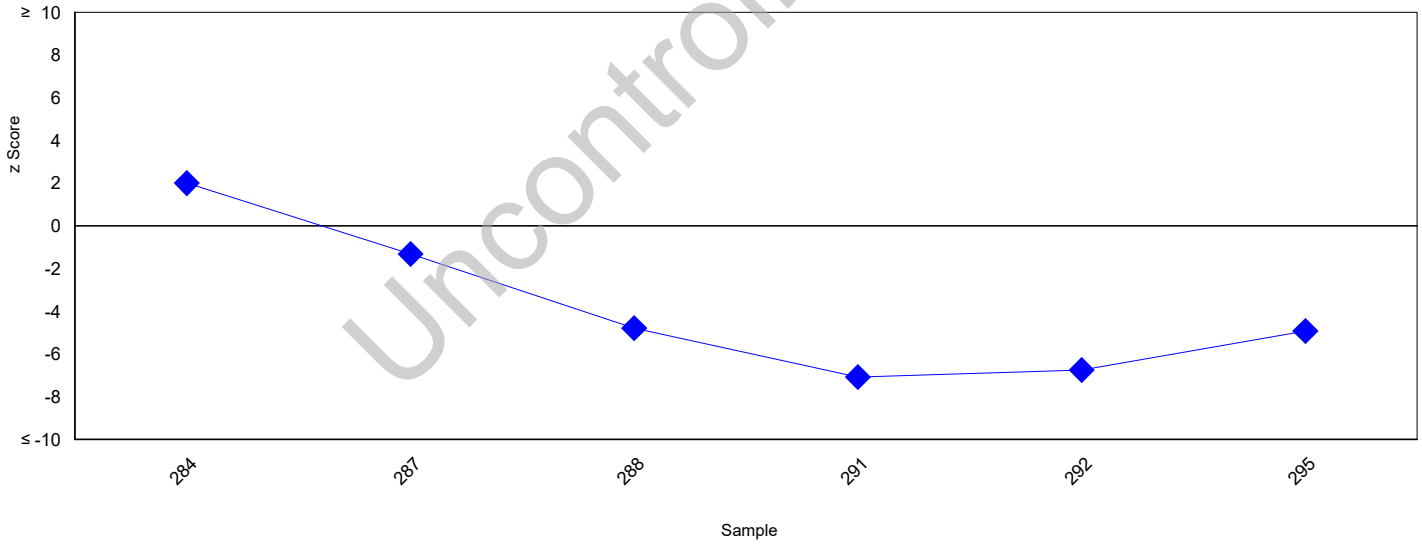
Values (Percentage (%) Donor)



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	29	94.4	1.3
ABI 3500xl	14		
ABI 3130xl	11		
Illumina MiSeq	6		
ABI 3130	6		
ABI SeqStudio	5		
ABI 3730	5		
ABI 7500 Real-Time PCR	4		
ABI 310	4		
Bio-Rad QX200	2		
ABI QuantStudio Absolute Q dPCR Sys	2		
Bio-Rad CFX96	2		
ABI 3730xl	2		

PCR Type Specific Statistics

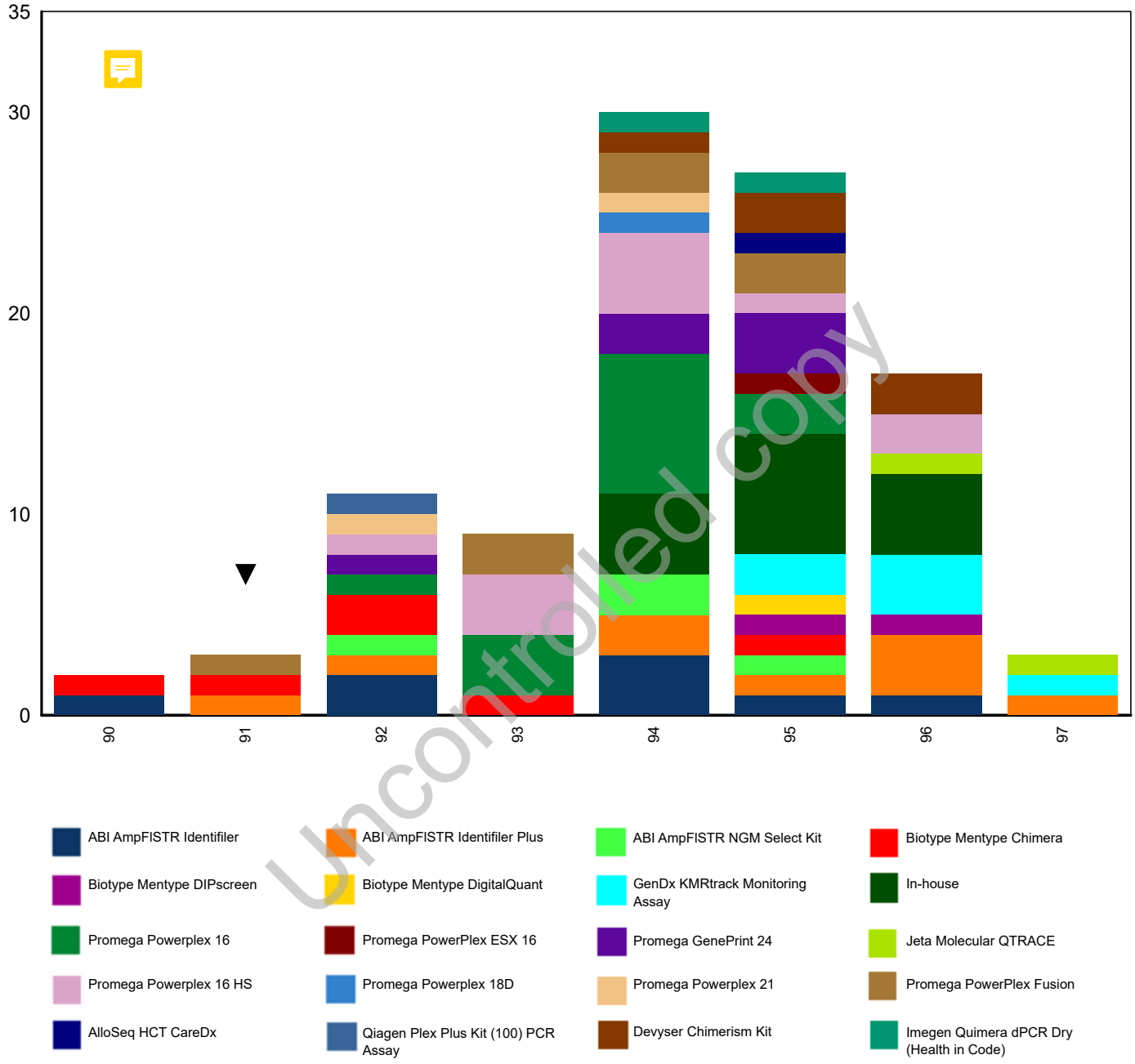
Method	Returns	Robust Mean	Robust SD
Multiplex	70	93.9	1.4
Real - Time PCR	11		
Single	7		
NGS	6		
Droplet Digital PCR	2		
Plate-based digital PCR	2		

Kit/Method Specific Statistics

Method	Returns	Robust Mean	Robust SD
In-house	13		
Promega Powerplex 16	13		
Promega Powerplex 16 HS	11		
ABI AmpFISTR Identifiler	8		
ABI AmpFISTR Identifiler Plus	7		
Promega PowerPlex Fusion	7		
Promega GenePrint 24	6		
GenDx KMRtrack Monitoring Assay	6		
Devyser Chimerism Kit	5		
Biotype Mentype Chimera	5		
ABI AmpFISTR NGM Select Kit	4		
Imegen Quimera dPCR Dry (Health in	2		
Jeta Molecular QTRACE	2		
Biotype Mentype DIPscreen	2		
Promega Powerplex 21	2		

Post-Stem Cell Transplant Chimerism Monitoring Programme

Frequency distribution histogram showing percentage donor engraftment for sample Post-SCT 295



Post-Stem Cell Transplant Chimerism Monitoring Programme

Distribution - 222301 Sample - 296 Participant ID -

Date Issued - 19 May 2022 Closing Date - 17 June 2022

Trial Comments

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Sample Comments

Four 1ml samples of peripheral blood representing Donor (293), Recipient (294) and two Post- Stem Cell Transplant samples (Post-SCT 295 and 296) were distributed to participants.

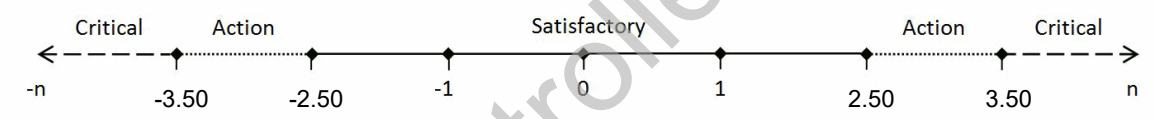
Results and Performance

Reported Percentage Donor	Your Results (%)	Robust Mean (%)	Robust SD (%)
	91	92.5	1.4

Reported Percentage Donor	z Score*	Performance Status for this Sample	Performance Status Classification Over 6 Sample Period		
			Satisfactory	Action	Critical
	-1.07	Satisfactory	5	0	1

*z Score Limits Definitions

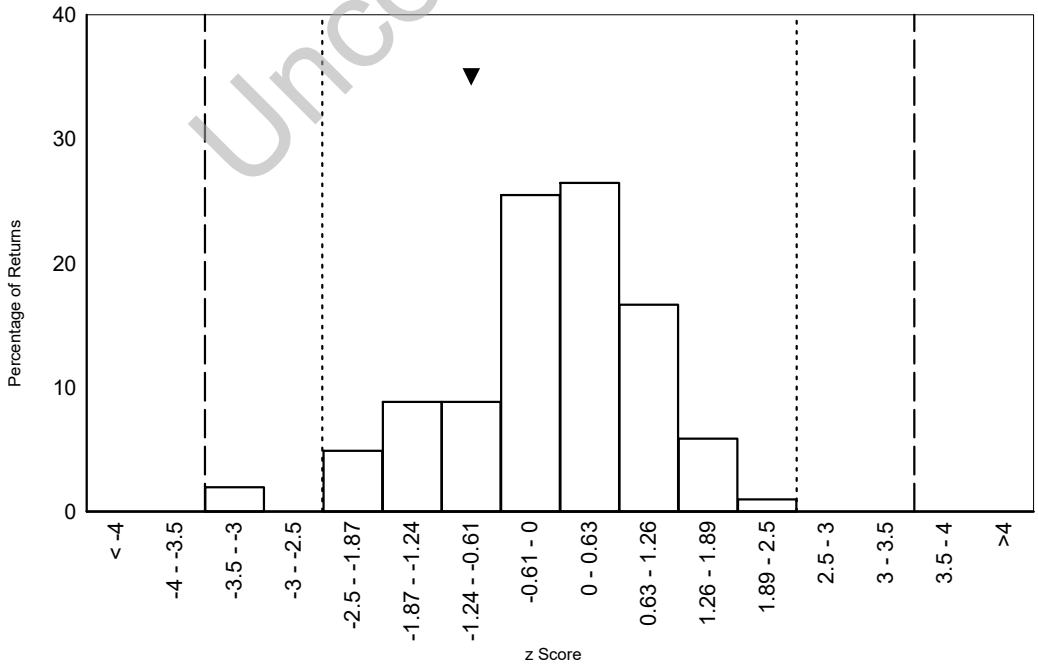
Please note the scale below is applicable to the tables above and to the z score histograms and Shewhart control charts that follow. It is not applicable to the Cusum control charts.



Histograms of Participant z Scores

Percentage donor chimerism result -

Please note ▼ denotes your result

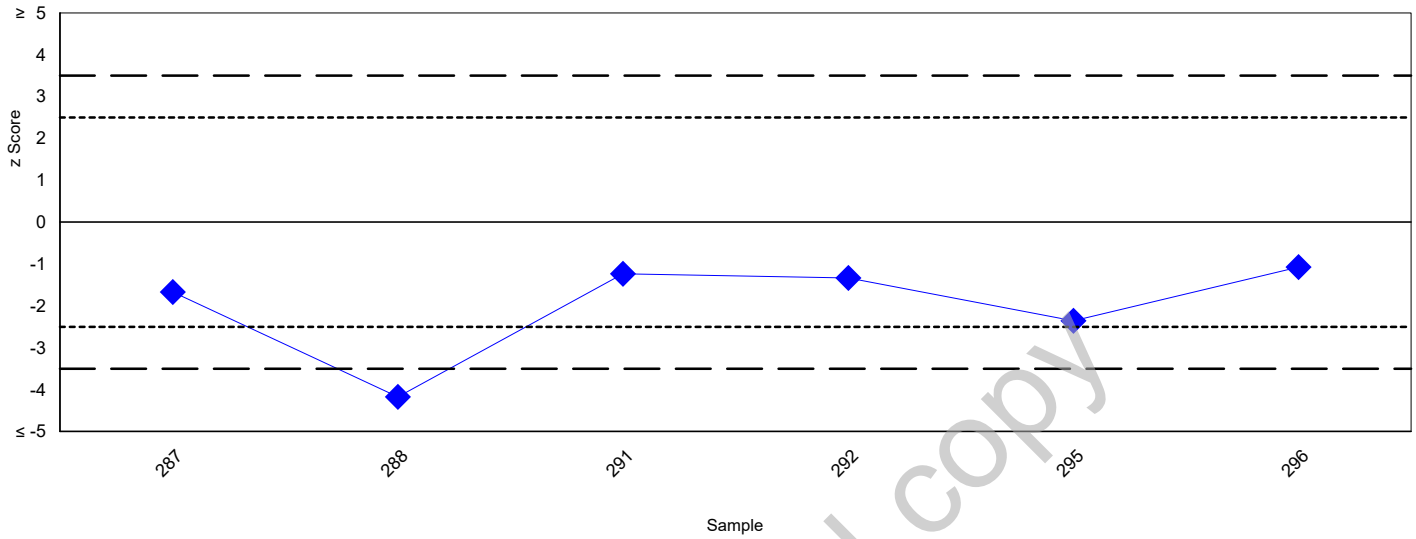


Post-Stem Cell Transplant Chimerism Monitoring Programme

Shewhart Control Charts

(Please note each data point represents a single sample)

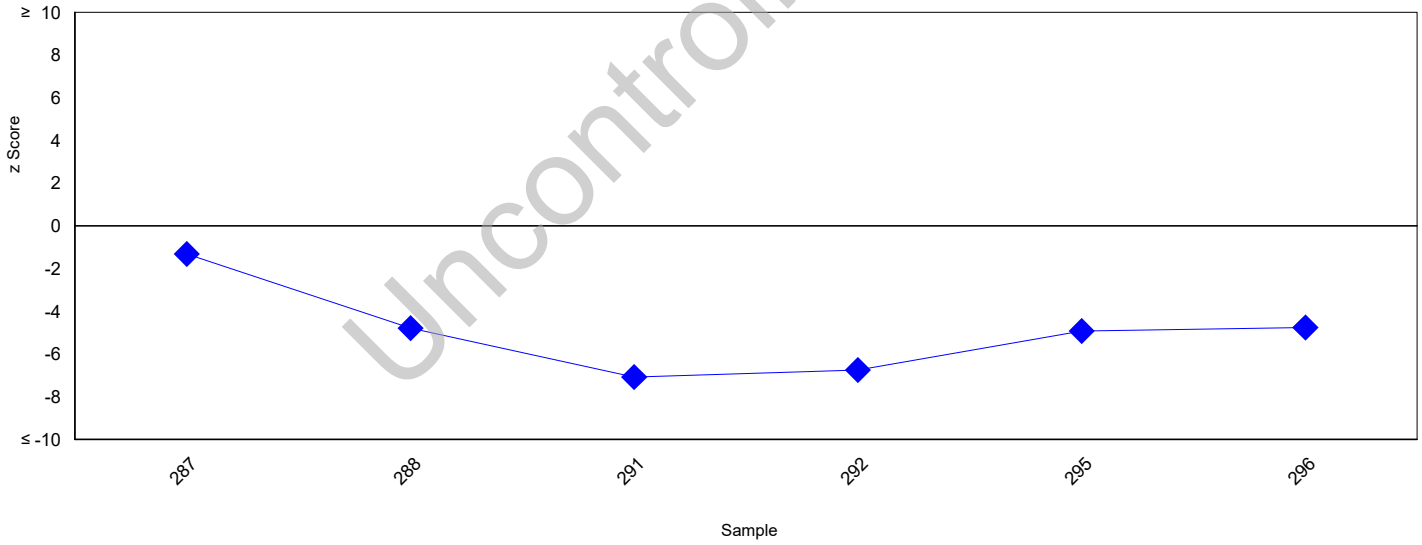
Values (Percentage (%) Donor)



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

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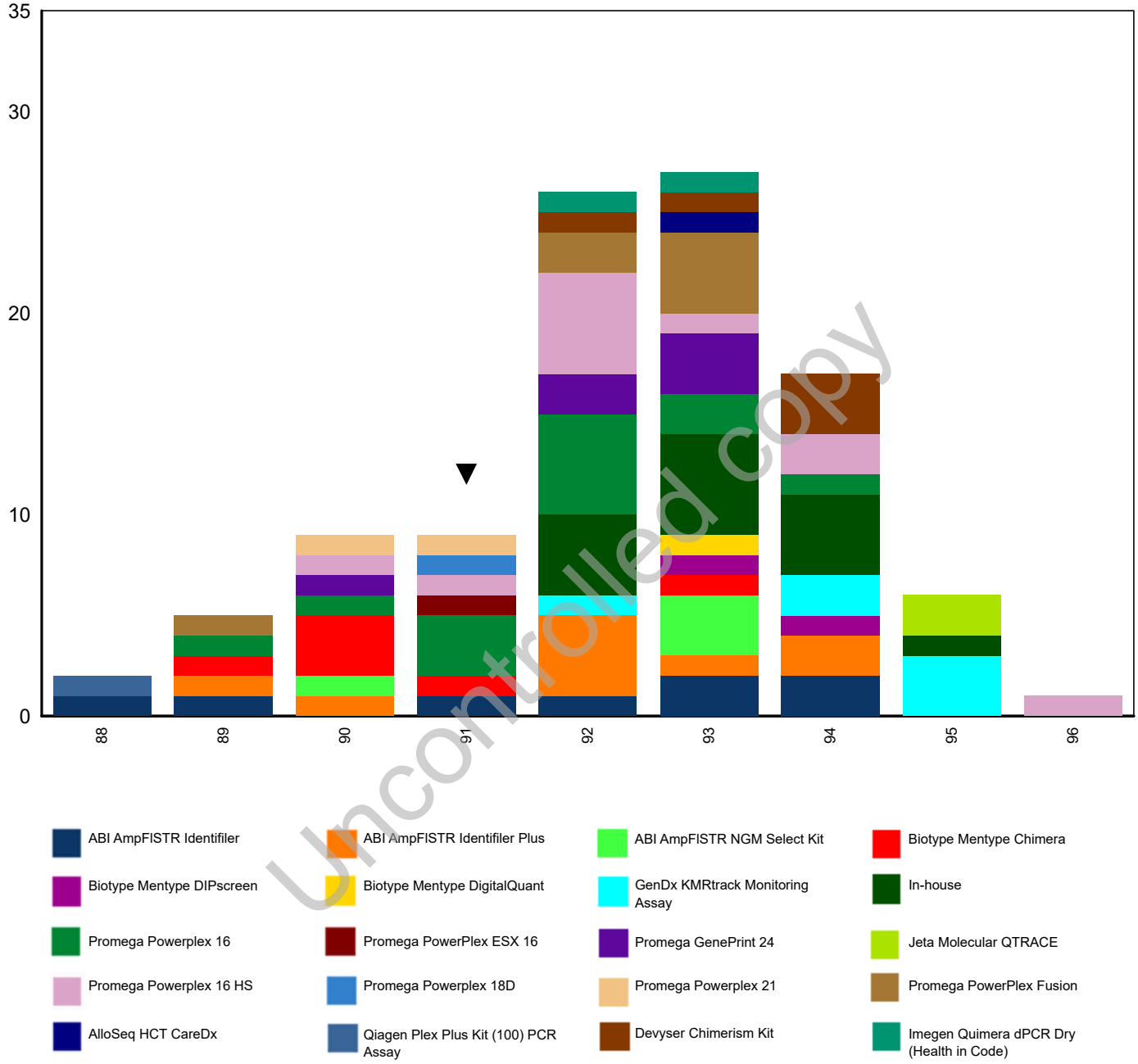
GenDx KMRtrack Monitoring Assay	6		
Devyser Chimerism Kit	5		
Biotype Mentype Chimera	5		
ABI AmpFISTR NGM Select Kit	4		
Imegen Quimera dPCR Dry (Health in	2		
Jeta Molecular QTRACE	2		
Biotype Mentype DIPscreen	2		
Promega Powerplex 21	2		

Post-Stem Cell Transplant Chimerism Monitoring Programme

Frequency distribution histogram showing percentage donor engraftment for sample Post-SCT 296



Post-Stem Cell Transplant Chimerism Monitoring Programme

Comments

Post-SCT Sample 295

- The overall robust mean for sample Post-SCT 295 was 94.3% donor chimerism with a robust SD of 1.4%.
- No participants received a critical z-score for this sample.

Post-SCT Sample 296

- The overall robust mean for sample Post-SCT 296 was 92.5% donor chimerism with a robust SD of 1.4%.
- No participants received a critical z-score for this sample.

General Trial Comments

- All 98 participants returned information on the number of markers used in their chimerism calculations. For samples Post-SCT 295 and 296 respectively, 83 and 82 participants (84.7% and 83.7%) calculated % donor chimerism using a minimum of at least three informative markers, as recommended in the 2014 UK guidelines[1], (median number of markers used was five for both samples). One participant used a single locus to calculate % donor chimerism in both samples.
- Considering the similar levels of 'donor' cells in the two post-SCT samples, it was pleasing to see that the majority of participants identified the correct trend between samples post SCT 296 and post SCT 295. In line with sample formulation, 91/98 participants (92.9%) found the % donor chimerism in Post-SCT 296 to be lower than in Post-SCT 295. Six participants found no difference between the samples and a single participant reported the % donor chimerism to be higher in Post-SCT 296 than in Post-SCT 295. Whilst potentially indicating a sample transposition event, this participant's z-scores were both considered satisfactory (-0.21 and 2.5* for samples 295 and 296 respectively).
- In line with sample formulation, the majority of participants (59, 60.2%) reported a difference of -2%, with 17 (17.3%) indicating a difference of -1%, see table below. The single participant reporting a difference of -6% used the Promega Power Plex 16 kit; again, their z-scores were both considered satisfactory (0.5 and -2.5*).

*Please note that -2.5 and 2.5 are the limits of satisfactory z-scores.

Reported percentage difference between samples 295 and 296	Number of participants (%)
2	1 (1.0)
0	6 (6.1)
-1	17 (17.3)
-2	59 (60.2)
-3	10 (10.2)
-4	4 (4.1)
-6	1 (1.0)
Total	98 (100)

Post-Stem Cell Transplant Chimerism Monitoring Programme

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
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/