

BCR-ABL1 Major Quantification Programme
All Participant Report

Distribution - 202103

Participant ID -

Date Issued - 27 January 2021

Closing Date - 05 March 2021

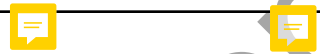
Trial Comments

Two vials of lyophilised material (BCRQ 171 and BCRQ 172) were issued for quantitative BCR-ABL1 analysis.

Sample Comments

FINAL VERSION: The trial was issued to 296 participants; 285 (96.2%) participants returned results. Of the 11 laboratories that did not return results, three prenotified us of their non-return and one participant requested an extension in light of the ongoing COVID-19 pandemic. Seven participants returned non-International Scale (IS) data only, 90 participants returned IS data only and 188 participants returned both non-IS and IS.

Results and Performance



BCR-ABL1/Control Gene (%)	Your Unconverted Results (%)	Your IS Results (%)	Your Log Transformed IS Result	Log Transformed Robust Mean
Sample BCRQ 171	5.0278	4.4295	0.65	0.65
Sample BCRQ 172	0.0315	0.0278	-1.56	-1.76

Result Type	Log Reduction Between Samples	Robust Mean Log Reduction	Robust SD Log Reduction
Unconverted	2.20	2.35	0.19
IS	2.20	2.40	0.21
The Result on which you chose to be scored		Both % and IS	

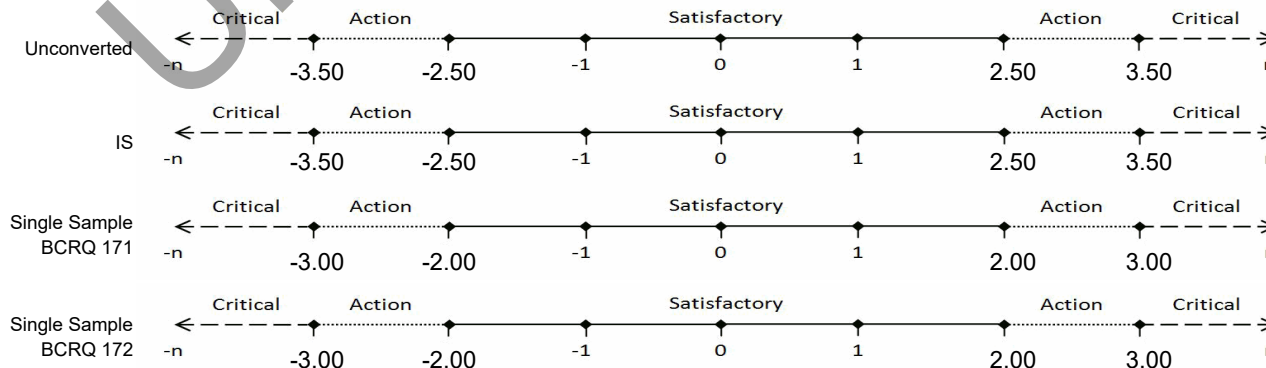
Sample	Single Sample z-score**	Performance Status for this Trial *	Performance Status Classification Over 6 Sample Period		
			Satisfactory	Action	Critical
171	0.00	Satisfactory	1	0	0
172	0.84	Satisfactory	2	0	0

* Please note, the information in this table is for information only. Performance monitoring is based on log reduction data only

Reported Log Reduction	Log Reduction z-score**	Performance Status for this Trial	Performance Status Classification Over 3 Trial Period		
			Satisfactory	Action	Critical
Unconverted	-0.79	Satisfactory	3	0	0
IS	-0.95	Satisfactory	3	0	0

****z-score Limits Definitions**

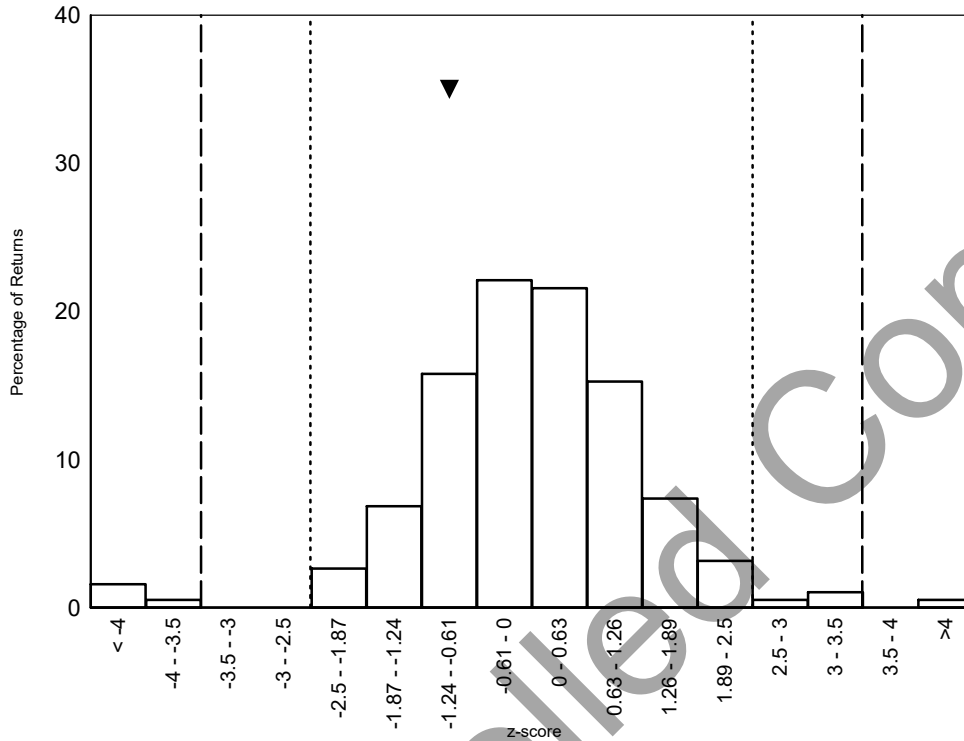
Please note the scale below is applicable to the tables above and to the z-score histograms and Shewhart control charts that follow. It is not applicable to the Cusum control charts.



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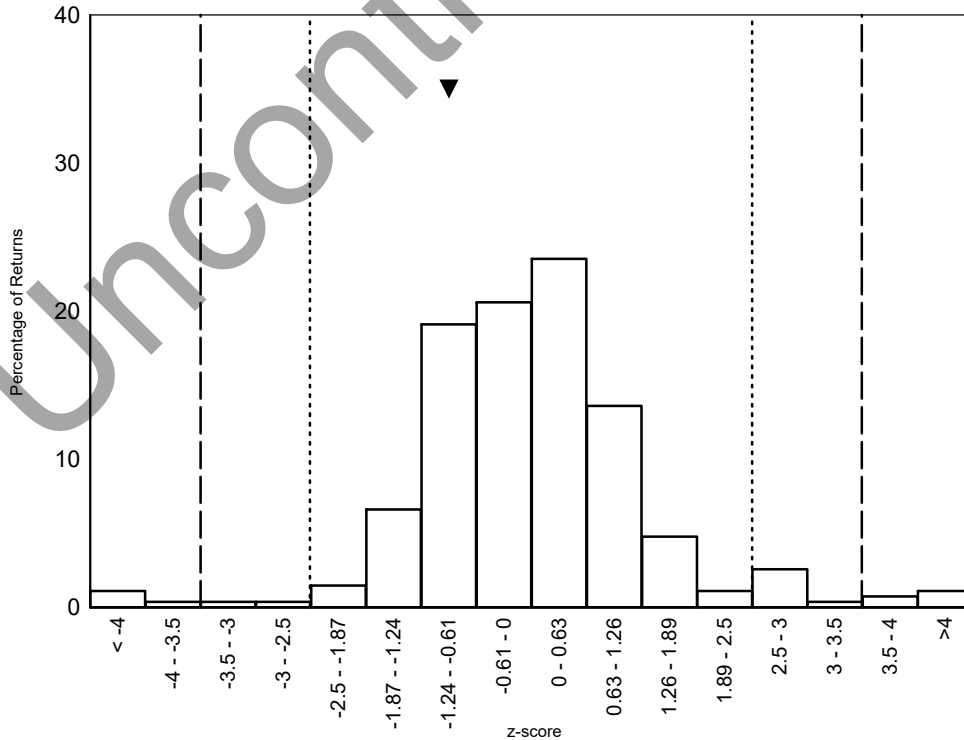
Histograms of Participant z-scores

Log Reduction between samples - Unconverted BCR-ABL1/Control Gene %
Please note ▼ denotes your result



Histograms of Participant z-scores

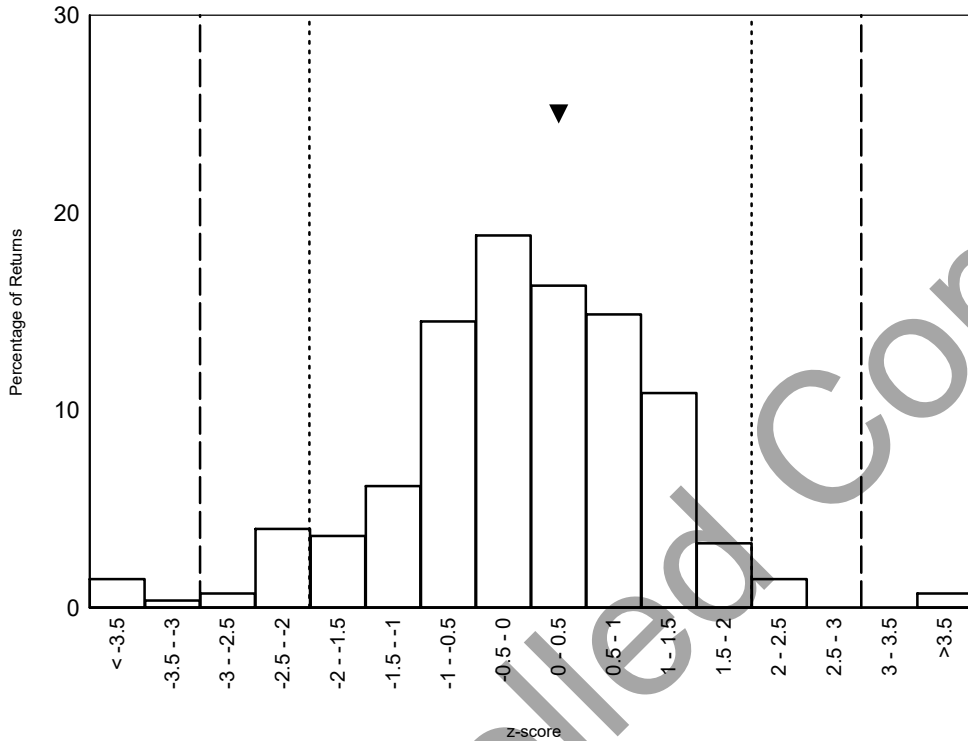
Log Reduction between samples - IS BCR-ABL1/Control Gene %
Please note ▼ denotes your result



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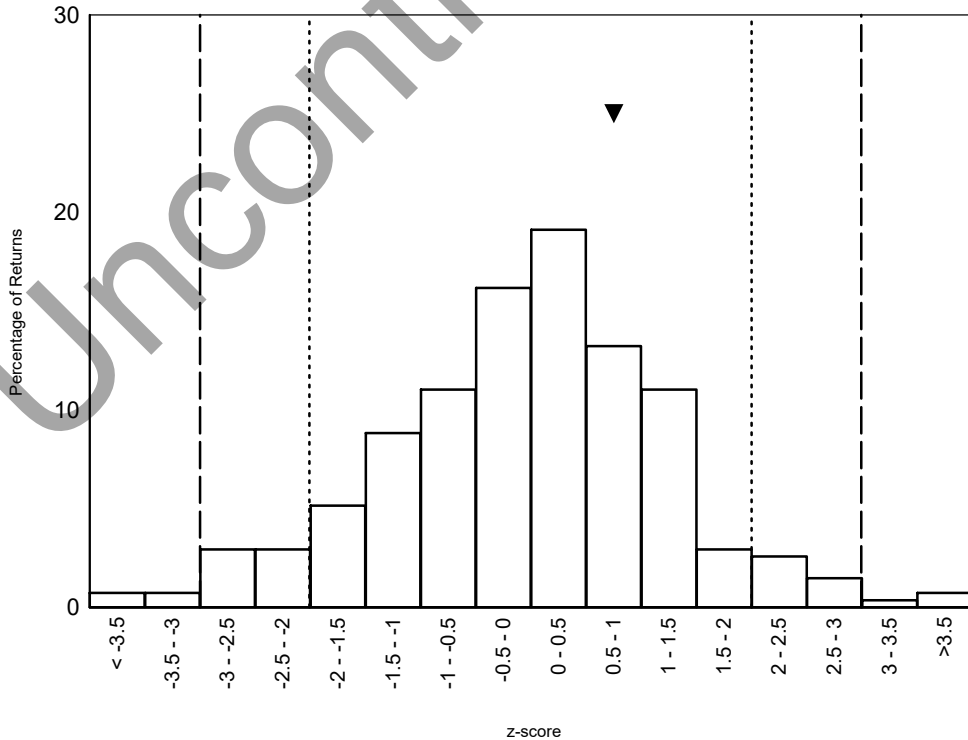
Histograms of Participant z-scores

BCRQ 171 Single Sample % BCR-ABL1 z-score
Please note ▼ denotes your result



Histograms of Participant z-scores

BCRQ 172 Single Sample % BCR-ABL1 z-score
Please note ▼ denotes your result

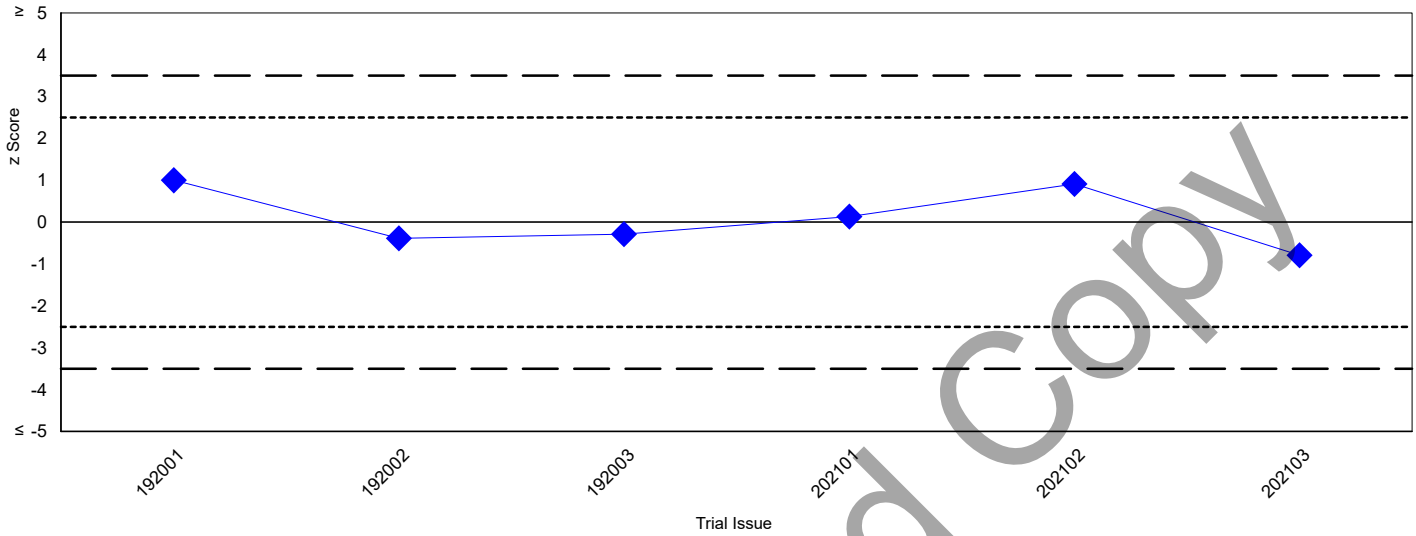


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Shewhart Control Charts

(Please note each data point represents a single trial)

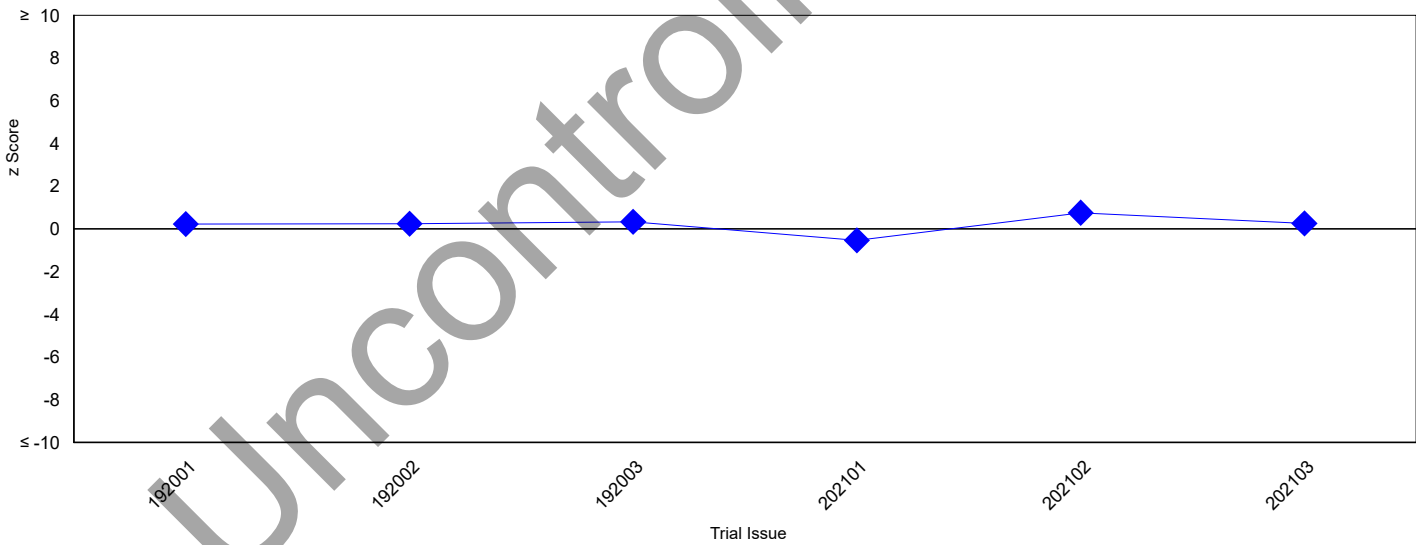
Log Reduction between samples Unconverted *BCR-ABL1*/Control Gene %



Cusum Control Charts

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

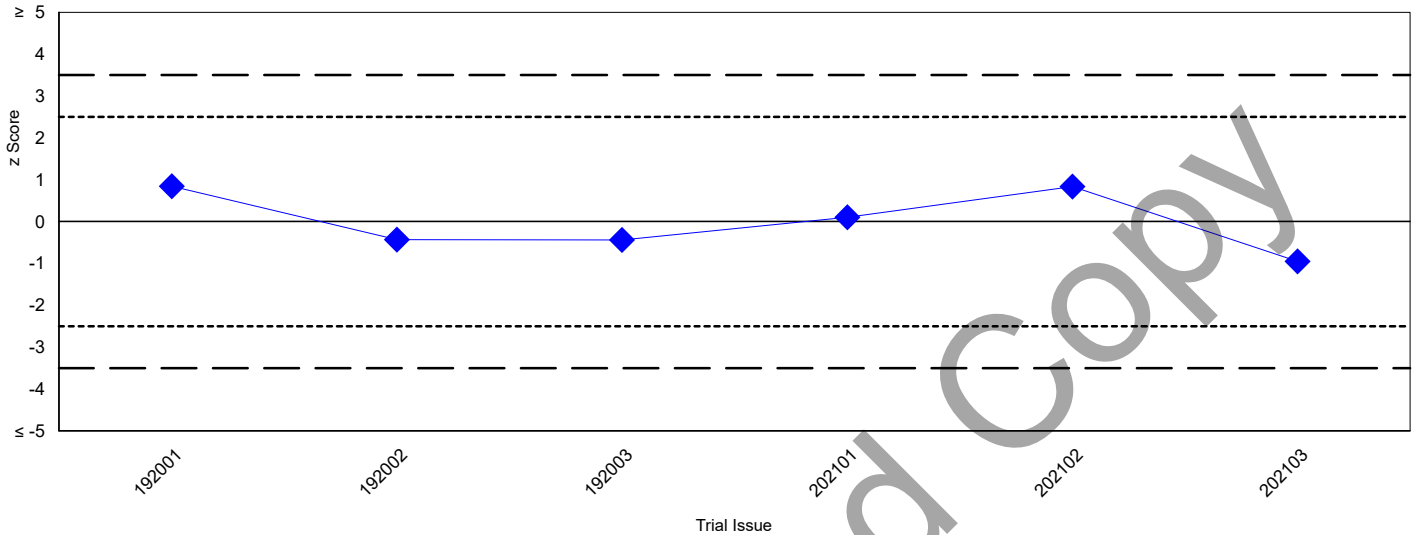
Log Reduction between samples Unconverted *BCR-ABL1*/Control Gene %



BCR-ABL1 Major Quantification Programme

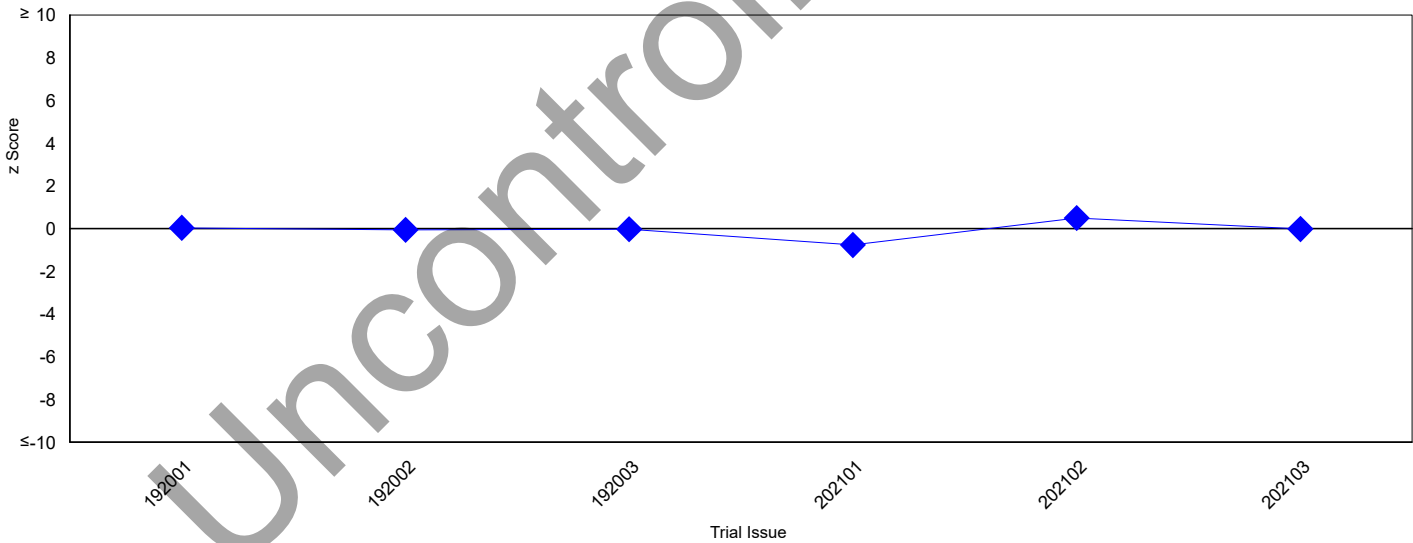
Shewhart Control Charts

(Please note each data point represents a single trial)
Log Reduction between samples IS *BCR-ABL1*/Control Gene %



Cusum Control Charts

(Please note each data point represents the sum of the z scores of the current trial and the two previous trials)
Log Reduction between samples IS *BCR-ABL1*/Control Gene %

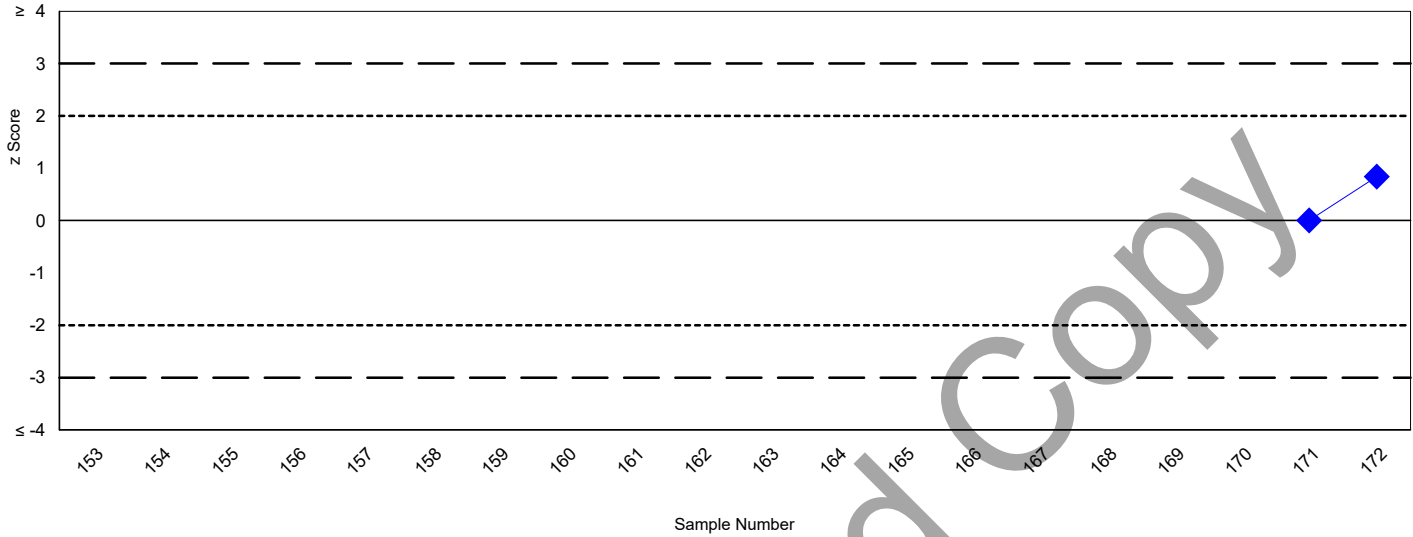


BCR-ABL1 Major Quantification Programme

Shewhart Control Charts

(Please note each data point represents a single trial)

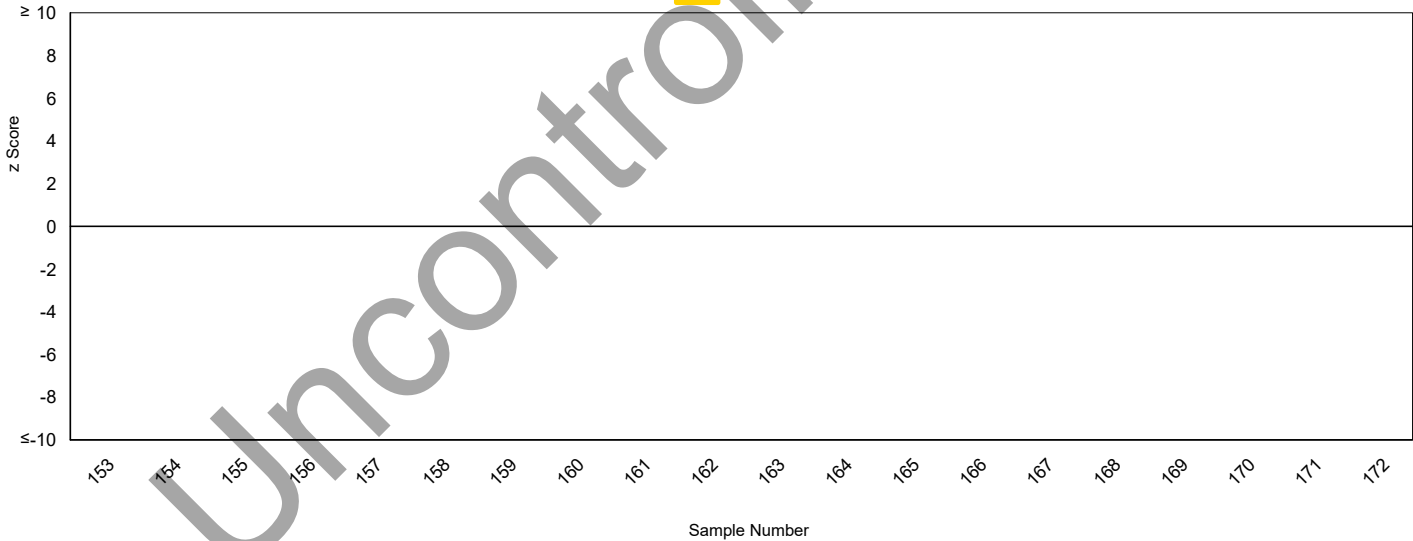
Single Sample % BCR-ABL1^{IS}



Cusum Control Charts

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

Single Sample % BCR-ABL1^{IS}



BCR-ABL1 Major Quantification Programme

Please note, only methods/instruments used by ≥ 2 participants are included in the tables.

Instrument Data Summary

Method	Returns
Cepheid GeneXpert	83
ABI 7500	44
Qiagen Rotorgene	39
Roche LC 480	35
ABI QuantStudio 5	13
ABI 7900HT	8
ABI QuantStudio 7	8
Biorad CFX96	7
ABI 7300	6
ABI Step One Plus	6
ABI 7500 FastDx	6
Roche LC 2.0	5
ABI Vii A7	4
Biorad QX200 Droplet Digital PCR	4
ABI 7900	2
Corbett Rotorgene	2
ABI 7500HT	2
Agilent AriaMX Real Time PCR System	2

Standard Dilution Data Summary

Method	Returns
Not Applicable	80
ERM-AD623 Certified Reference Material	39
Ipsogen Fusion Quant standards	32
Ipsogen IS MMR standards	23
Ipsogen BCR-ABL1 MbcR IS-MMR Kits single plasmid	22
Ipsogen plasmids	17
Yuanqi	17
In-house plasmids	8
Ipsogen BCRA BL1 MbcR RGQ RTPCR Single Plasmid	8
BCR-ABL P210 ELITE Standard	6
In-house standards	5
Bioclarma SensiQuant P210 Standards	3
Asuragen QuantideX BCRA BL IS Kit calibrators	3
Mannheim standards	2
TIB MOLBIOL LightMix t(9;22) bcr-abl	2
BlackBio TRUPCR Standards	2

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Kit/Method Data Summary

Method	Returns
Cepheid GeneXpert Ultra BCR-ABL assay	82
In-house protocol (EAC)	52
Qiagen (formerly Ipsogen) IS MMR Kit	38
In-house protocol	28
Other	16
In-house (EAC-modified)	13
Qiagen (formerly Ipsogen) Fusion Quant Kit	13
QIAGEN Ipsogen BCR-ABL1 MbcR RGQ RT-PCR	13
BCR-ABL P210 ELITe MGB Kit (Elitech Group)	6
Ipsogen kit	4
Bioclarma SensiQuant P210 Kit	3
Biorad CE-IVD QXDx BCR-ABL IS Kit	3
Asuragen QuantideX qPCR BCRABL IS Kit	3
Roche kit	2
TIB MOLBIOL LightMix t(9;22) bcr-abl	2
BlackBio TRUPCR BCR-ABL1 Kit	2

Control Gene Data Summary

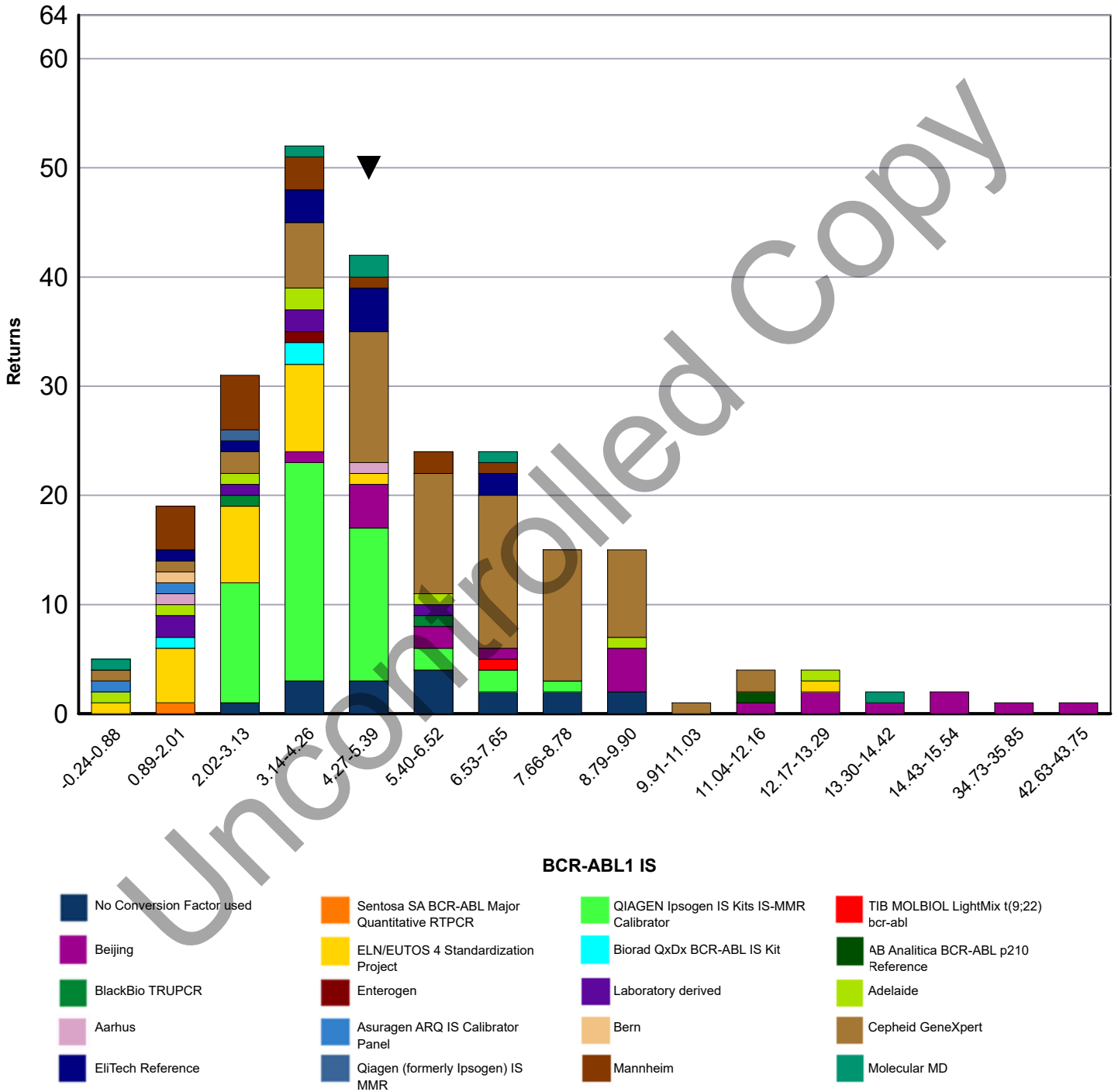
Method	Returns
ABL1	261
GUSB	15
BCR	4

Source of Conversion to the IS Data Summary

Method	Returns
Cepheid GeneXpert	70
QIAGEN Ipsogen IS Kits IS-MMR Calibrator	50
ELN/EUTOS 4 Standardization Project	24
Beijing	20
Wessex	20
Mannheim	16
Napoli	11
EliTech Reference	11
Adelaide	8
Laboratory derived	6
Molecular MD	6
Biorad QxDx BCR-ABL IS Kit	3
BlackBio TRUPCR	2
Asuragen ARQ IS Calibrator Panel	2
Aarhus	2
TIB MOLBIOL LightMix t(9;22) bcr-abl	2

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Frequency distribution histogram showing participant BCR-ABL1/control gene results, classified by IS conversion method for sample 171



BCR-ABL1 Major Quantification Programme

Frequency distribution histogram showing participant BCR-ABL1/control gene results, classified by IS conversion method for sample 172

