

BCR-ABL1 Quantification Programme
All Participant Report

Distribution - 161701

Participant ID -

Date Issued - 17 May 2016

Closing Date - 17 June 2016

Trial Comments

The trial was issued to 196 participants; 183 (93.4%) participants returned results. 28 participants returned non International Scale (IS) data only, 24 participants returned IS data only and 131 participants returned both non IS and IS data.

Sample Comments

Two vials of lyophilised cell line material (BCRQ 142 and BCRQ 143) were issued for quantitative BCR-ABL1 analysis.

Results and Performance

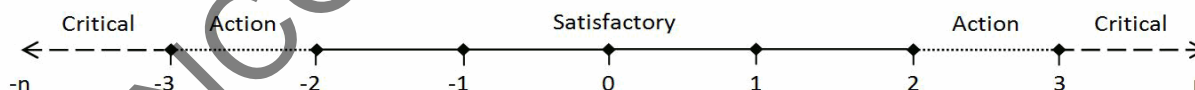
BCR-ABL1/Control Gene (%)	Your Unconverted Results (%)	Your IS Results (%)
Sample BCRQ 142		
Sample BCRQ 143		

Result Type	Log Reduction Between Samples	Robust Mean Log Reduction	Robust SD Log Reduction
Unconverted		0.30	0.08
IS		0.30	0.09
The Result on which you chose to be scored		Both % and IS	

Reported Log Reduction	z Score*	Performance Status for this Trial	Performance Status Classification Over 3 Trial Period		
			Satisfactory	Action	Critical
Unconverted					
IS					

***z Score Limits Definitions**

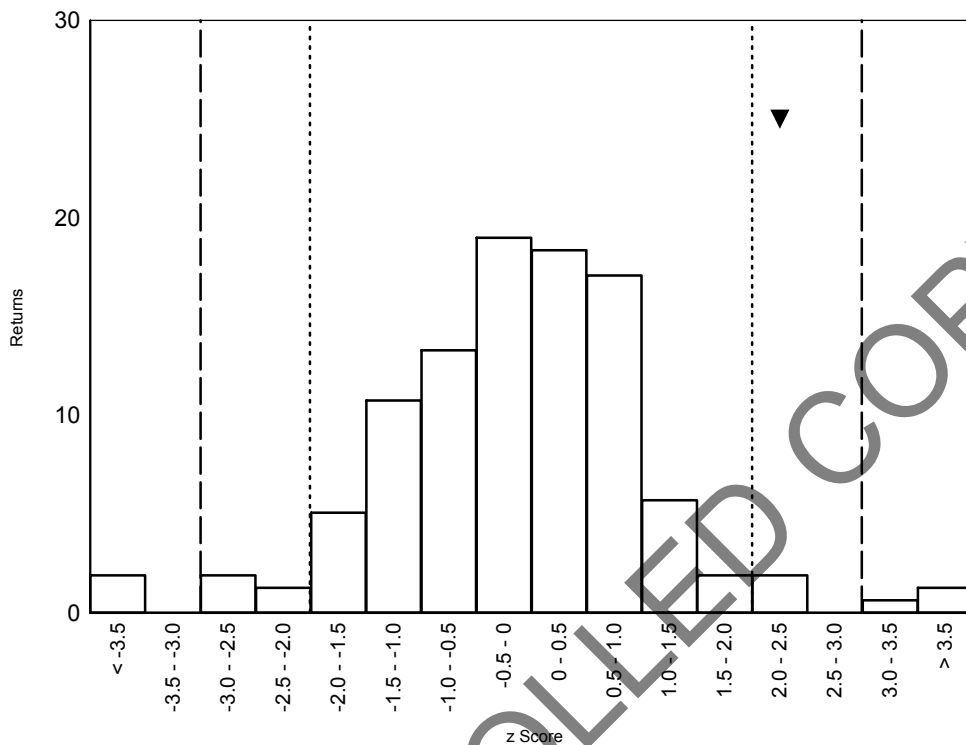
Please note the scale below is applicable to the tables above and to the z score histograms and Shewhart control charts that follow. It is not applicable to the Cusum control charts.



BCR-ABL1 Quantification Programme

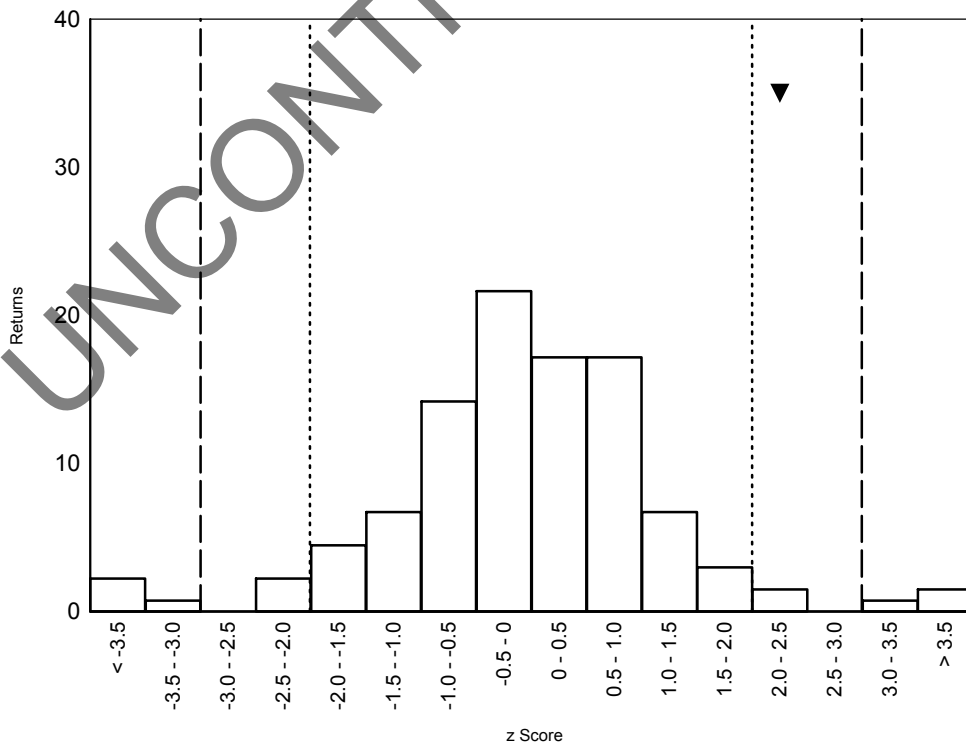
Histograms of Participant z Scores

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

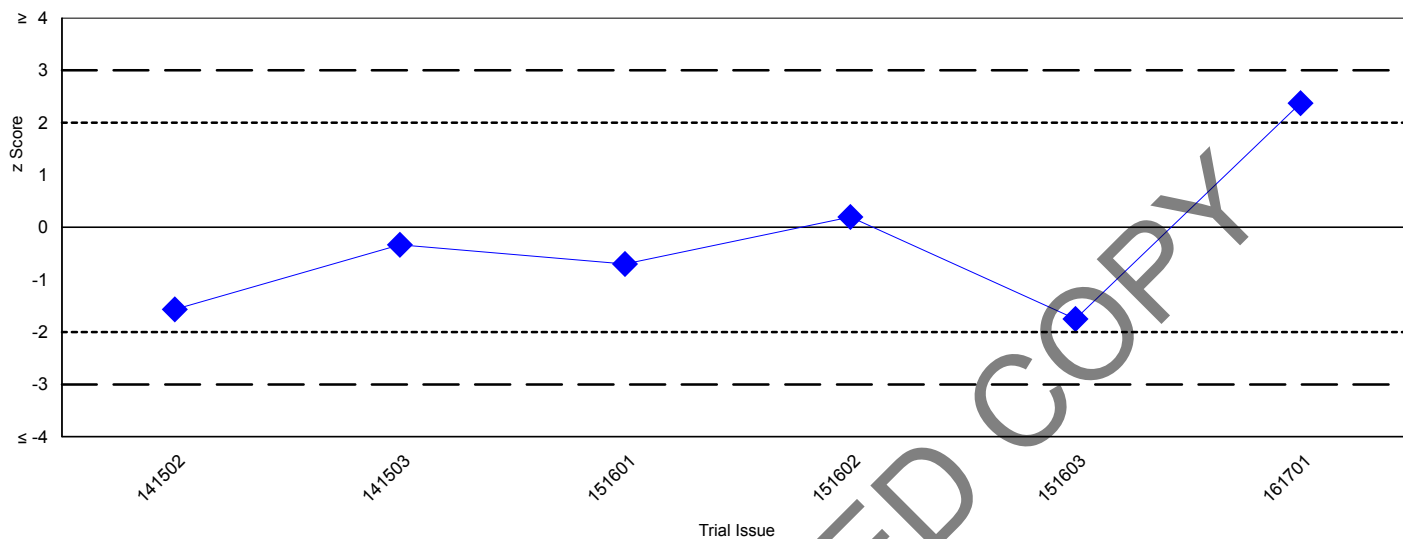


BCR-ABL1 Quantification Programme

Shewhart Control Charts

(Please note each data point represents a single trial)

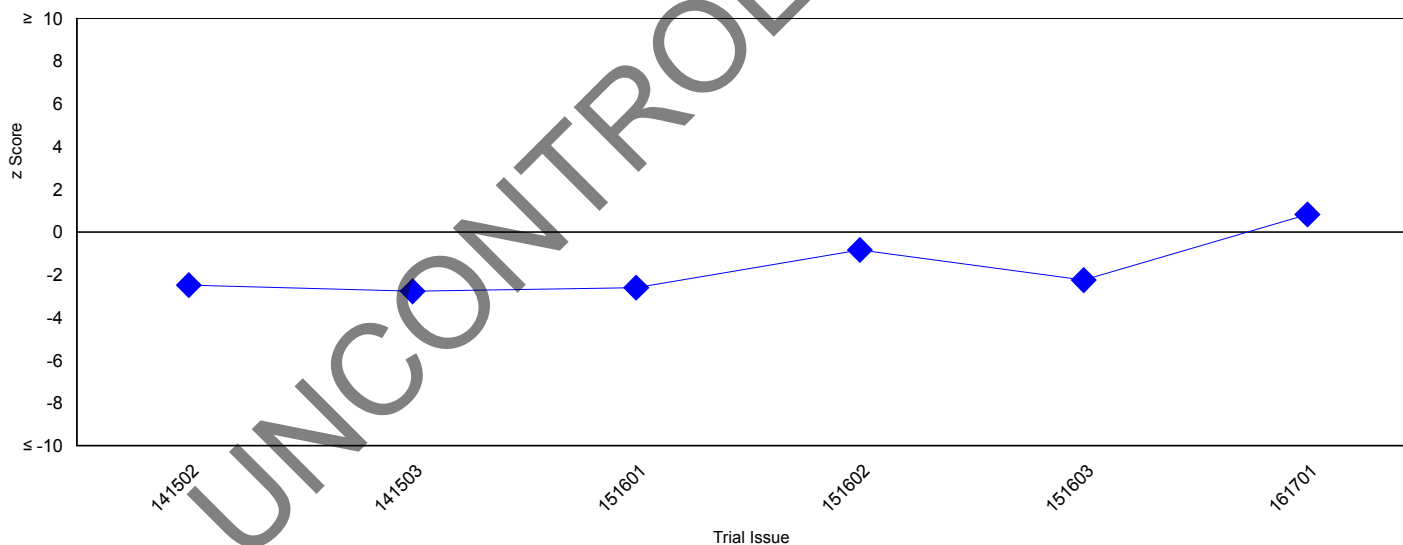
Log Reduction between samples Unconverted BCR-ABL1/Control Gene %



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 %

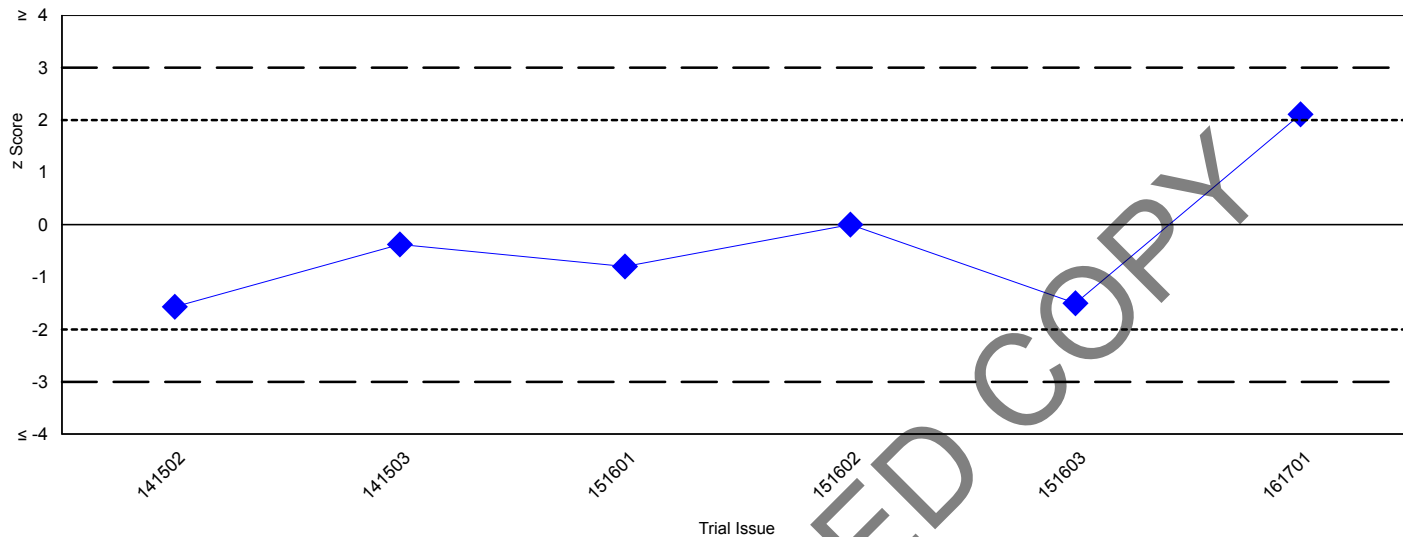


BCR-ABL1 Quantification Programme

Shewhart Control Charts

(Please note each data point represents a single trial)

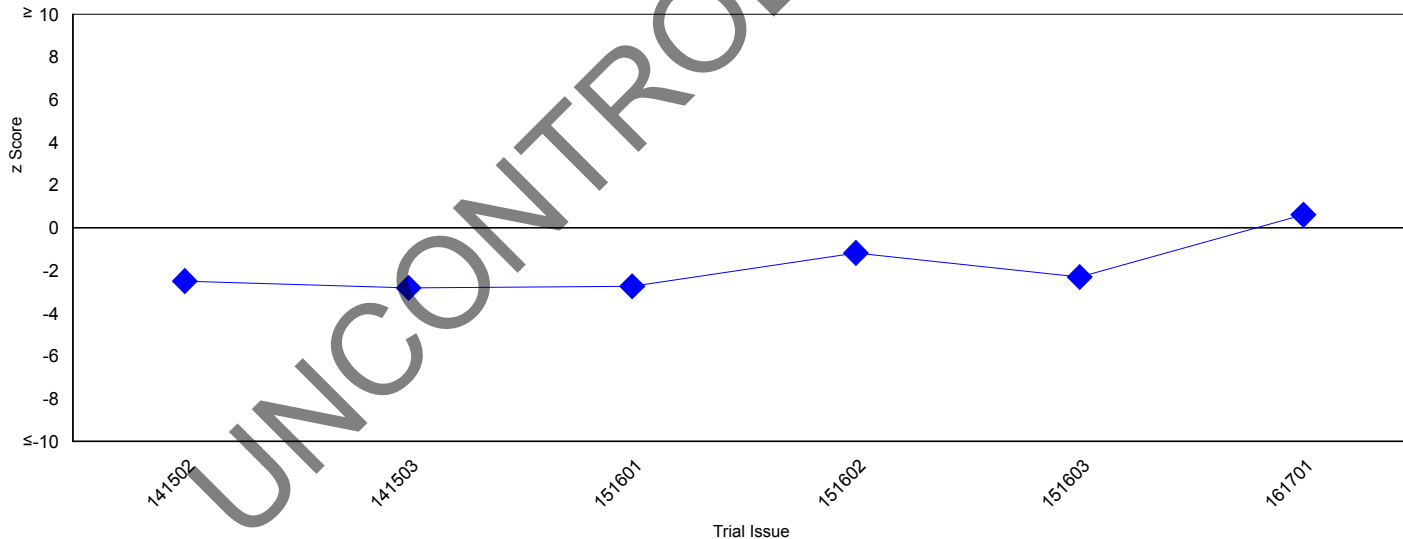
Log Reduction between samples IS *BCR-ABL1*/Control Gene %



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 Quantification Programme

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

Instrument Data Summary

Method	Returns
ABI 7500	41
Roche LC 480	28
Cepheid GeneXpert	21
Qiagen Rotorgene	17
ABI 7900HT	15
Corbett Rotorgene	9
Biorad CFX96	8
Roche LC 2.0	8
ABI 7300	5
ABI Step One Plus	5
ABI Vii A7	4
ABI 7000	3
Roche LC 1.5	3
ABI QuantStudio 12K	3
Raindance Raindrop Digital PCR System	3
Roche Lightcycler	2
ABI 7500HT	2
Roche LC96	2

Standard Dilution Data Summary

Method	Returns
Ipsogen IS MMR standards	41
Ipsogen Fusion Quant standards	33
ERM-AD623 Certified Reference Material	29
Ipsogen plasmids	20
Cepheid GeneXpert Kit therefore n/a	20
In-house plasmids	7
Roche standards	5
BCR-ABL P210 ELITE Standard	4
K562 cDNA	3
In-house standards	3
Nanogen Alert standards	3
Mannheim standards	3
Molecular MD standards	2

BCR-ABL1 Quantification Programme

Kit/Method Data Summary

Method	Returns
In-house protocol (EAC)	52
Qiagen (formerly Ipsogen) IS MMR Kit	35
Cepheid GeneXpert BCR-ABL assay	21
Qiagen (formerly Ipsogen) Fusion Quant Kit	17
In-house (EAC-modified)	14
In-house protocol	12
Roche kit	6
QIAGEN Ipsogen BCR-ABL1 MbcR RGQ RT-PCR	6
Ipsogen kit	5
Other	3
BCR-ABL P210 ELITe MGB Kit (Elitech Group)	3
RainDance BCABL e14a2	3
Molecular MD IS Kit	2
Elitech Philadelphia QPCR Alert	2

Control Gene Data Summary

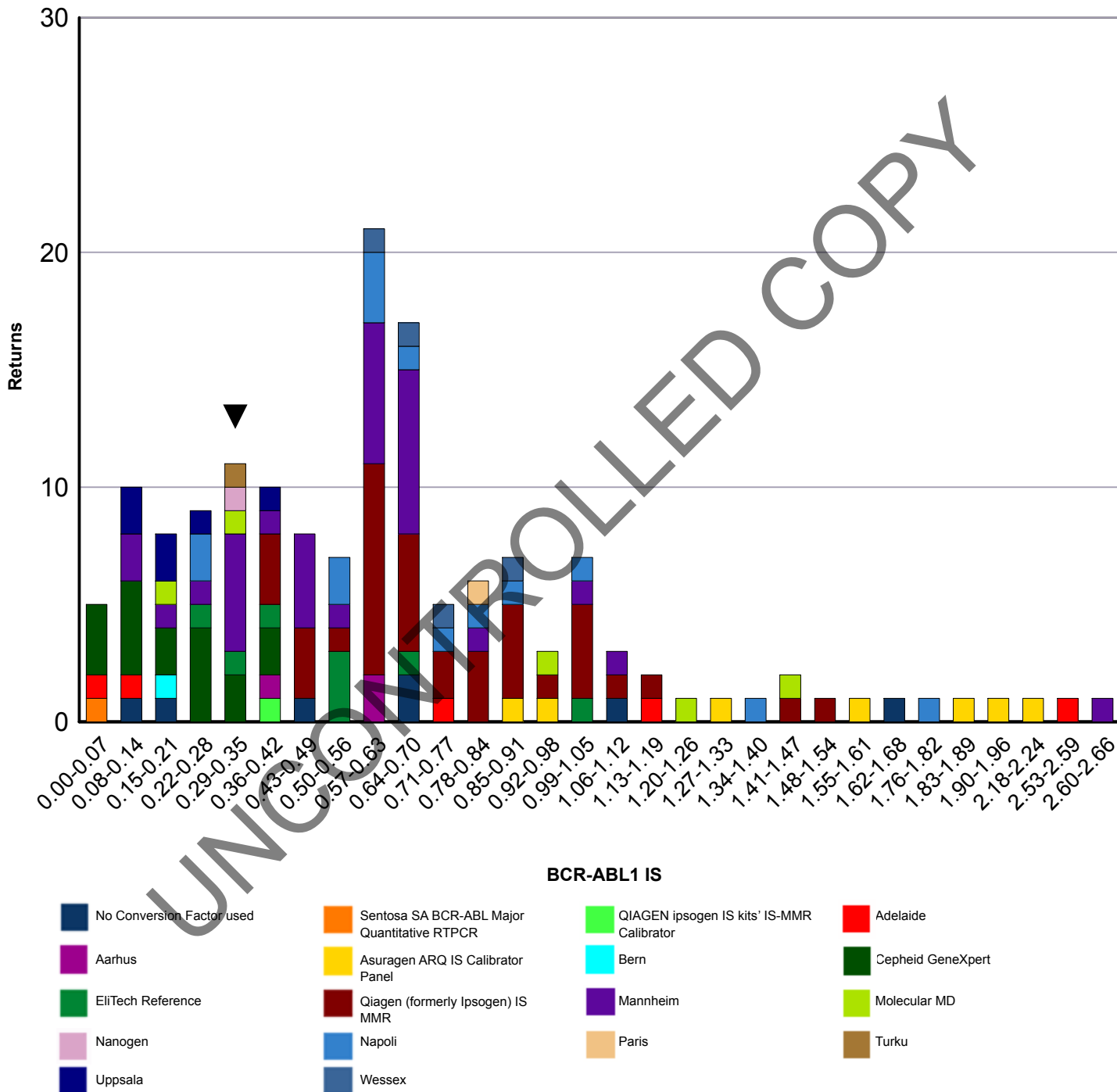
Method	Returns
ABL1	159
GUSB	12
G6PDH	3
BCR	2
ABL1 & GUSB & B2M	2

Source of Conversion to the IS Data Summary

Method	Returns
Qiagen (formerly Ipsogen) IS MMR	40
No Conversion Factor used	35
Mannheim	32
Cepheid GeneXpert	18
Napoli	14
EliTech Reference	8
Asuragen ARQ IS Calibrator Panel	7
Uppsala	6
Molecular MD	5
Adelaide	5
Wessex	4
Aarhus	3

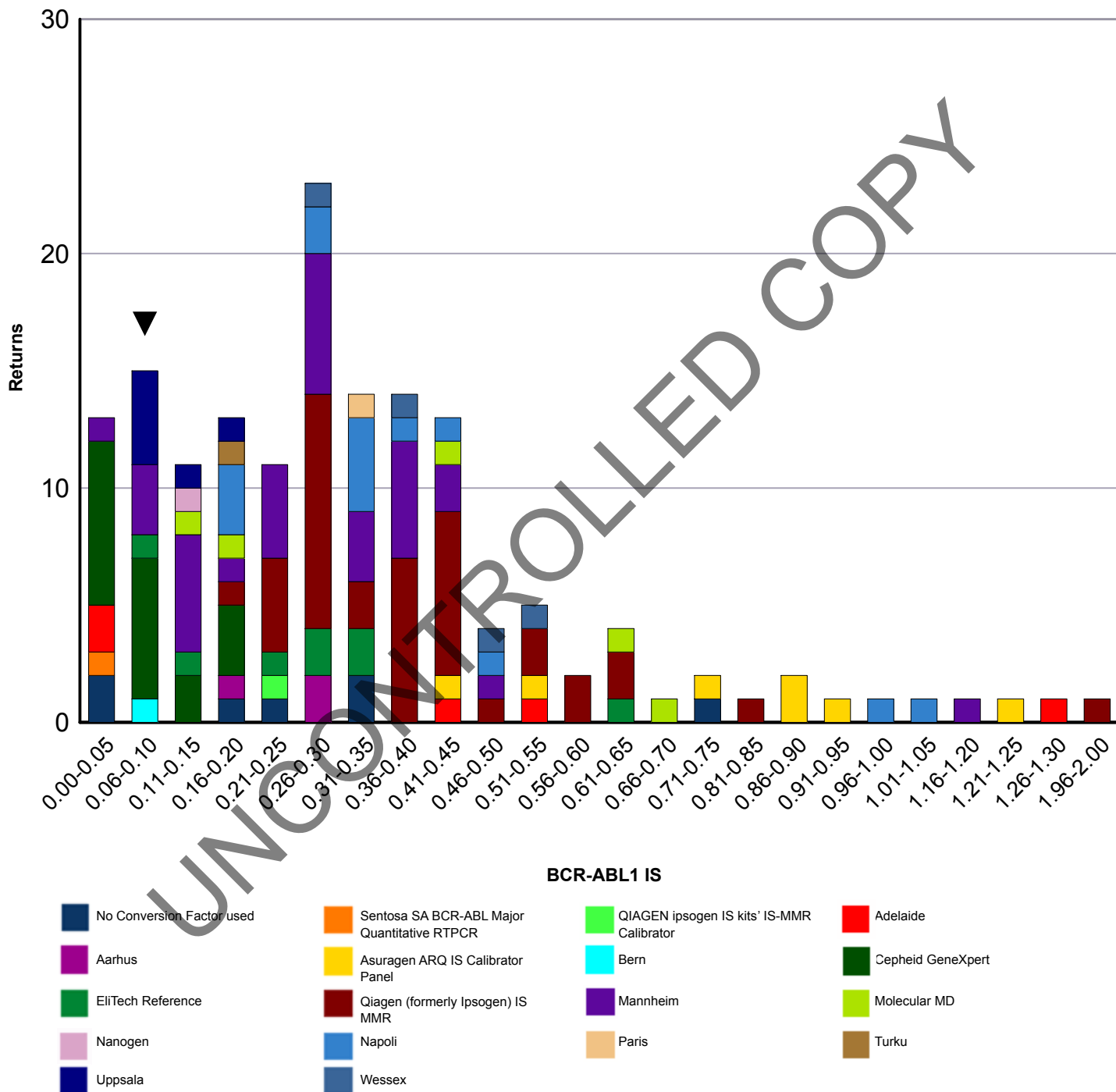
BCR-ABL1 Quantification Programme

Frequency distribution histogram showing participant BCR-ABL1/control gene results, classified by IS conversion method for sample 142



BCR-ABL1 Quantification Programme

Frequency distribution histogram showing participant BCR-ABL1/control gene results, classified by IS conversion method for sample 143



BCR-ABL1 Quantification Programme

Trial Comments (unconverted data)

- The robust mean unconverted log reduction between sample BCRQ 142 and BCRQ 143 was 0.30 with a robust SD of 0.08.
- 5 participants incurred a critical trial score: 2 used an in-house protocol, 1 used the Roche kit, 1 used the Sentosa SA kit and the other participant did not give us details of their protocol.

ABL1 Data

- The unconverted median for participants using *ABL1* as a control gene for sample BCRQ 142 was 0.81% *BCR-ABL1/ABL1*, with an IQR of 0.60.
- The unconverted median for participants using *ABL1* as a control gene for sample BCRQ 143 was 0.41% *BCR-ABL1/ABL1*, with an IQR of 0.29.
- Median *ABL1* control gene levels were 71,397 and 70,641 for samples BCRQ 142 and BCRQ 143, respectively.

GUSB Data

- Twelve participants used *GUSB* as a control gene in this trial.
- The unconverted median for participants using *GUSB* as a control gene for sample BCRQ 142 was 0.30% *BCR-ABL1/GUSB*, with an IQR of 0.07.
- The unconverted median for participants using *ABL1* as a control gene for sample BCRQ 143 was 0.15% *BCR-ABL1/GUSB*, with an IQR of 0.08.
- The robust mean unconverted log reduction between sample BCRQ 142 and BCRQ 143 for participants using *GUSB* as a control gene was 0.29 with a robust SD of 0.04.
- Median *GUSB* control gene levels were 151,725 and 191,134 for samples BCRQ 142 and BCRQ 143, respectively.

Trial Comments (IS data)

- The median *BCR-ABL1* IS for sample BCRQ 142 was 0.59 %, with an IQR of 0.52.
- The median *BCR-ABL1* IS for sample BCRQ 143 was 0.29 %, with an IQR of 0.26.
- The robust mean IS log reduction between sample BCRQ 142 and BCRQ 143 was 0.30 with a robust SD of 0.09.
- Seven participants incurred a critical trial score: 3 used an in-house methodology, 1 used the Roche kit, 1 used the Sentosa SA kit and 2 participants did not tell us what methodology they used.

Overall Trial Comments

- There are now 3 participants using digital PCR to quantify *BCR-ABL1*; all are using the Raindance Raindrop platform.
- There has been an increase in participants using the ERM-AD623 Certified Reference Material (n=29 vs. n=23 in trial BCRQ 151601).

BCR-ABL1 Quantification 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. 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/