Paediatric Acute Leukaemia Translocations Programme

Distribution - 202101

Participant ID - 4XXXX

Date Issued - 24 June 2020

Closing Date - 31 July 2020

Trial Comments

FINAL REPORT: This trial was issued to 51 participants; of which 45 (88.2%) returned results. Of the non returns, three laboratories notified us of their intended non return. Overall, 44 participants returned results for t(12;21) (ETV6-RUNX1*, TEL-AML1), 43 participants returned results for t(4;11) (KMT2A-AFF1*, MLL-AF4) and 44 participants returned results for t(1;19) (TCF3-PBX1*, E2A-PBX1). *Denotes the HGNC (HUGO Gene Nomenclature Committee, http://www.genenames.org/) approved gene symbols, which will be used throughout this report.

Sample Comments

Two vials of lyophilised cell line derived material (sample refs PALT 136 and PALT 137) were issued for t(12;21) (ETV6-RUNX1), t(4;11) (KMT2A-AFF1) and t(1;19) (TCF3-PBX1) analysis. PALT 136 was manufactured to be positive for the t(12;21) (ETV6-RUNX1) rearrangement and PALT 137 was formulated to be positive for the t(1;19) (TCF3-PBX1) rearrangement.

Results and Performance

Your Results

PALT Identification	Your Results	Consensus Result
Sample PALT 136		
t(12;21) (*ETV6-RUNX1, TEL-AML1*)		Rearrangement Detected
t(4;11) (*KMT2A-AFF1, MLL-AF4*)		No Rearrangement Detected
t(1;19) (*TCF3-PBX1, E2A-PBX1*)		No Rearrangement Detected
Sample PALT 137		
t(12;21) (*ETV6-RUNX1, TEL-AML1*)		No Rearrangement Detected
t(4;11) (*KMT2A-AFF1, MLL-AF4*)		No Rearrangement Detected
t(1;19) (*TCF3-PBX1, E2A-PBX1*)		Rearrangement Detected

All Participant Results

	Rearrangement Detected (Returns)	No Rearrangement Detected (Returns)
Sample PALT 136		
t(12;21) (*ETV6-RUNX1, TEL-AML1*)	44	0
t(4;11) (*KMT2A-AFF1, MLL-AF4*)	0	43
t(1;19) (*TCF3-PBX1, E2A-PBX1*)	0	44
Sample PALT 137		
t(12;21) (*ETV6-RUNX1, TEL-AML1*)	0	44
t(4;11) (*KMT2A-AFF1, MLL-AF4*)	0	43
t(1;19) (*TCF3-PBX1, E2A-PBX1*)	44	0

Your Performance

Performance Status for this Trial	Performance Status Classification Over 3 Trial Period	
	Satisfactory	Critical

N/A = Not Applicable

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PCR Type

	Returns		
	t(12;21) (*ETV6-RUNX1, TEL-AML1*)	t(4;11) (*KMT2A-AFF1, MLL-AF4*)	t(1;19) (*TCF3-PBX1, E2A-PBX1*)
Real-Time PCR	20	19	19
Single PCR	10	9	11
Nested PCR	7	7	6
Multiplex PCR	5	7	6
Droplet Digital PCR	1	-	1
PCR for Next generation Sequencing	1	1	1

Protocol Type

	Returns		
	t(12;21) (*ETV6-RUNX1, TEL-AML1*)	t(4;11) (*KMT2A-AFF1, MLL-AF4*)	t(1;19) (*TCF3-PBX1, E2A-PBX1*)
Biomed 1	14	13	13
Hemavision Kit	8	8	9
EAC Protocol	8	8	9
Modified EAC Protocol	7	3	5
In-house Assay	5	9	6
Leukemia Fusion Gene (Q30) QuanDx kit	1	1	1
Oncomine Myeloid Research Assay	1	1	1

Analysis Type

	Returns		
	t(12;21) (*ETV6-RUNX1, TEL-AML1*)	t(4;11) (*KMT2A-AFF1, MLL-AF4*)	t(1;19) (*TCF3-PBX1, E2A-PBX1*)
Real-Time PCR Fluorescent Detection	23	22	22
Agarose Gel Electrophoresis	16	17	17
Capillary Electrophoresis	2	2	2
NGS (ThermoFisher Ion Torrent)	1	1	1
NGS (Illumina)	1	1	1
Digital PCR (Biorad)	1	-	1

Journal Reference for Assay

	Returns
Gabert et al (2003). Leukemia, 17, 2318-2357	21
Van Dongen et al (1999). Leukemia, 13, 1901-1928	20
In-house Designed	3
Pallisgaard et al (1998). Blood, 92, 574-588	3
Jansen et al (2005) Leukemia, 19, 2016-2018	2

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Final Comments

Sample PALT 136

- Forty-four (44) participants (100%) testing for the t(12;21) (*ETV6-RUNX1*) translocation correctly identified the rearrangement in sample PALT 136.
- In line with sample formulation, all participants testing for the t(4;11) (*KMT2A-AFF1*) and t(1;19) (*TCF3-PBX1*) translocations (43 and 44 participants, respectively) found sample PALT 136 to be negative for these rearrangements.

Sample PALT 137

- Forty-four (44) participants (100%) testing for the t(1;19) (*TCF3-PBX1*) translocation correctly identified the rearrangement in sample PALT 137.
- In line with sample manufacture, all participants testing for the t(4;11) (*KMT2A-AFF1*) and t(12;21) (*ETV6-RUNX1*) translocations (43 and 44 participants, respectively) found sample PALT 137 to be negative for these rearrangements.

Paediatric Acute Leukaemia Translocations 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 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) Pre issue testing of samples for this programme is subcontracted, although the final decision about sample suitability lies with the EQA provider; no other activities in relation to this EQA exercise were subcontracted. Where subcontracting occurs it is placed with a competent subcontractor and the EQA provider is responsible for this work.

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/