

Pilot Paediatric Acute Leukaemia Translocations Programme

Distribution - 151602

Participant ID -

Date Issued - 20 January 2016

Closing Date - 19 February 2016

Trial Comments

The trial was issued to 36 participants; 1 participant did not return any results. 35 participants returned results for t(12;21) (ETV6-RUNX1, TEL-AML1), and 32 participants returned results for t(4;11) (KMT2A-AFF1, MLL-AF4) and t(1;19) (TCF3-PBX1, E2A-PBX1). If your laboratory does not perform the full range of assays for the rearrangements encompassed by this pilot programme, please do get in contact with us (admin@ukneqasli.co.uk) to state your repertoire so as you are not unfairly penalised when we begin to apply performance monitoring to this trial.

Sample Comments

Two vials of lyophilised cell line derived material (sample refs PALT 114 and PALT 115) were issued for t(12;21) (ETV6-RUNX1*, TEL-AML1), t(4;11) (KMT2A-AFF1*, MLL-AF4) and t(1;19) (TCF3-PBX1*, E2A-PBX1) analysis. PALT 114 featured a t(12;21) (ETV6-RUNX1) rearrangement, while PALT 115 was negative for all three translocations. *Denotes the HGNC (HUGO Gene Nomenclature Committee, <http://www.genenames.org/>) approved gene symbols, which will be used throughout this report.

Results and Performance

Your Results

PALT Identification	Your Results	Consensus Result
Sample PALT 114		
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 115		
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)		No Rearrangement Detected

All Participant Results

	Rearrangement Detected (Returns)	No Rearrangement Detected (Returns)
Sample PALT 114		
t(12;21) (ETV6-RUNX1, TEL-AML1)	33	2
t(4;11) (KMT2A-AFF1, MLL-AF4)	0	32
t(1;19) (TCF3-PBX1, E2A-PBX1)	0	32
Sample PALT 115		
t(12;21) (ETV6-RUNX1, TEL-AML1)	1	34
t(4;11) (KMT2A-AFF1, MLL-AF4)	0	32
t(1;19) (TCF3-PBX1, E2A-PBX1)	0	32

Your Performance*

Performance Status for this Trial	Performance Status Classification Over 3 Trial Period	
	Satisfactory	Critical
N/A	N/A	N/A

* PLEASE NOTE: This is not currently a scored trial; however we are working towards accreditation for this programme.

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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	16	13	15
Single PCR	8	6	6
Nested PCR	6	5	5
Multiplex PCR	5	8	6

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	11	7	11
EAC Protocol	9	4	7
Hemavision Kit	6	6	7
In-house Assay	5	12	4
Modified EAC Protocol	3	2	2
Biomed 3	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	17	13	15
Agarose Gel Electrophoresis	17	16	16
Capillary Electrophoresis	1	2	1
Qiaxcel	-	1	-

Journal Reference for Assay

	Returns
Gabert et al (2003). Leukemia, 17, 2318-2357	18
Van Dongen et al (1999). Leukemia, 13, 1901-1928	17
In-house Designed	3
Jansen et al (2005) Leukemia, 19, 2016-2018	2
Pallisaard et al (1998). Blood, 92, 574-588	2

Pilot Paediatric Acute Leukaemia Translocation Identification Programme

Final Comments

Sample PALT 114:

- 33 of the 35 participants (94.3%) who returned results for sample PALT 114 correctly identified the t(12;21) (*ETV6-RUNX1*) rearrangement. Two laboratories reported a false-negative result for this translocation. One of these laboratories utilised an in-house designed single PCR and Agarose Gel Electrophoresis, the other utilised Real-Time PCR fluorescent detection as per EAC protocol.
- In line with sample formulation, all participants testing for the t(4;11) (*KMT2a-AFF1*) and t(1;19) (*TCF3-PBX1*) translocations found sample PALT 114 to be negative for these rearrangements.

Sample PALT 115:

- 34 of the 35 participants who test for t(12;21) (*ETV6-RUNX1*) translocation found sample PALT 115 to be negative for this rearrangement. The laboratory reporting a false-positive result utilised Real-Time PCR fluorescent detection as per EAC protocol.
- In line with sample formulation, all participants testing for the t(4;11) (*KMT2a-AFF1*) and t(1;19) (*TCF3-PBX1*) translocations found sample PALT 115 to be negative for these rearrangements.

Pilot Paediatric Acute Leukaemia Translocation Identification 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.