UK NEQAS
Leucocyte Immunophenotyping

Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Paediatric Acute Leukaemia Translocations Programme

Distribution - 252601

Participant ID -

Date Issued - 16 June 2025

Closing Date - 18 July 2025

Trial Comments

This trial was issued to 65 participants; of which 61 (93.8%) returned results at the time of reporting. Of the non returns, one participant informed us of their intended non return. Overall, 59 participants returned results for t(12;21) (ETV6::RUNX1), 59 participants returned results for t(4;11) (KMT2A::AFF1) and 59 participants returned results for t(1;19) (TCF3::PBX1).

Sample Comments

Two vials of lyophilised cell line derived material (sample refs PALT 166 and PALT 167) were issued for t(12;21) (ETV6::RUNX1), t(4;11) (KMT2A::AFF1) and t(1;19) (TCF3::PBX1) analysis. PALT 166 was formulated to be negative for all rearrangements and PALT 167 was manufactured to be positive for the t(4;11) (KMT2A::AFF1) rearrangement.

Results and Performance

Your Results

PALT Identification	Your Results	Consensus Result
Sample PALT 166		
t(12;21) (*ETV6-RUNX1, TEL-AML1*)	No Rearrangement Detected	No Rearrangement Detected
t(4;11) (*KMT2A-AFF1, MLL-AF4*)	No Rearrangement Detected	No Rearrangement Detected
t(1;19) (*TCF3-PBX1, E2A-PBX1*)	No Rearrangement Detected	No Rearrangement Detected
Sample PALT 167		
t(12;21) (*ETV6-RUNX1, TEL-AML1*)	No Rearrangement Detected	No Rearrangement Detected
t(4;11) (*KMT2A-AFF1, MLL-AF4*)	Rearrangement Detected	Rearrangement Detected
t(1;19) (*TCF3-PBX1, E2A-PBX1*)	No Rearrangement Detected	No Rearrangement Detected

All Participant Results

	Rearrangement Detected (Returns)	No Rearrangement Detected (Returns)
Sample PALT 166		
t(12;21) (*ETV6-RUNX1, TEL-AML1*)	0	59
t(4;11) (*KMT2A-AFF1, MLL-AF4*)	2	57
t(1;19) (*TCF3-PBX1, E2A-PBX1*)	0	59
Sample PALT 167		
t(12;21) (*ETV6-RUNX1, TEL-AML1*)	0	59
t(4;11) (*KMT2A-AFF1, MLL-AF4*)	53	6
t(1;19) (*TCF3-PBX1, E2A-PBX1*)	0	59

Your Performance

Performance Status for this Trial	Performance Status Classification Over 3 Trial Period	
	Satisfactory	Critical
Satisfactory	3	0

N/A = Not Applicable

Sheffield Teaching Hospitals NHS Foundation Trust, a UKAS accredited proficiency testing provider No. 7804, operating UK NEQAS for Leucocyte Immunophenotyping.

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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	23	24	22
PCR for Next generation Sequencing	12	12	12
Single PCR	9	7	9
Multiplex PCR	9	11	11
Nested PCR	5	5	4
Droplet Digital PCR	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*)
In-house Assay	12	15	12
Hemavision 28Q Kit	12	12	12
Biomed 1	10	9	10
EAC Protocol	9	8	8
Modified EAC Protocol	4	3	4
Hemavision Kit	3	3	4
Oncomine Myeloid Research Assay	3	3	3
Archer FusionPlex Pan-Heme Kit	2	2	2
Archer FusionPlex Heme Kit	1	1	1
Archer Fusion Plex LLA Kit	1	1	1
Illumina TruSeq Stranded Total RNA	1	1	1
EntroGen One-Step Leukemia Translocation Panel	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	28	28	27
Agarose Gel Electrophoresis	16	16	16
NGS (Illumina)	8	8	8
NGS (ThermoFisher Ion Torrent)	4	4	4
NGS (Other)	1	1	1
Qiaxcel	1	1	1
Digital PCR (Biorad)	1	-	1
Capillary Electrophoresis	-	1	1

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Journal Reference for Assay

	Returns
Gabert et al (2003) Leukemia, 17(12), 2318-2357	20
Van Dongen et al (1999) Leukemia, 13(12), 1901-1928	14
In-house Designed	7
Jansen et al (2005) Leukemia, 19(11), 2016-2018	3
Pallisgaard et al (1998) Blood, 92(2), 574-588	2

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Final Comments

PALT 166

- All participants testing for t(12;21) (*ETV6*::*RUNX1*) (n=59) found PALT 166 to be negative for the rearrangement.
- All participants (n=59) testing for t(1;19) (*TCF3*::*PBX1*) reported the absence of the rearrangement in PALT 166.
- Fifty-seven participants out of 59 (96.6%) testing for t(4;11) (*KMT2A*::*AFF1*) reported the sample to be negative for the rearrangement.
- The two participants reporting a false positive result also reported an out of consensus false negative result for t(4;11) (*KMT2A*::*AFF1*) in PALT 167, suggesting a sample transposition event.

PALT 167

- All participants (n=59) testing for t(12;21) (*ETV6*::*RUNX1*) reported the absence of the rearrangement in PALT 167.
- All participants testing for t(1;19) (*TCF3*::*PBX1*) found PALT 167 to be negative for the rearrangement.
- In total, 53 out of 59 (89.8%) participants testing for t(4;11) (*KMT2A*::*AFF1*) reported the presence of the rearrangement in PALT 167.
- Two participants reporting a false negative result reported an out of consensus false positive result for the t(4;11) (*KMT2A*::*AFF1*) rearrangement in PALT 166, suggestive of a sample transposition.
- Of the remaining four participants reporting a false negative result, two utilised an in-house Next Generation Sequencing (NGS) assay (one ThermoFisher Ion Torrent and one NGS 'Other'), one utilised the Biomed 1 assay with agarose gel electrophoresis. The final participant utilised the Real-Time PCR EntroGen One-Step Leukemia Translocation Panel assay.

We would like to thank all participants for their continued engagement in the Paediatric Acute Leukaemia Translocations programme. If participants have any suggestions/ improvement ideas for this programme, please contact admin@ukneqasli.co.uk.

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
e-mail: amanda.newbould@ukneqasli.co.uk

4.8.2 b) The coordinator(s) of UK NEQAS LI programmes: Mr Stuart Scott (acting Director).

4.8.2 c) Person(s) authorising this report: Mr Stuart Scott (acting Director) of UK NEQAS LI.

4.8.2 d) Administration and shipping for this programme is provided by EQA International Limited.

4.8.2 d) Pre issue and post closure testing of samples for this programme is externally provided, although the final decision about sample suitability lies with the EQA provider; no other activities in relation to this EQA exercise were externally provided.

4.8.2 d) Where externally provided products or services are used in the delivery of EQA, a competent supplier is used, the EQA provider is responsible for this work and participants are informed accordingly.

4.8.2 g) The UK NEQAS LI Privacy Policy can be found at the following link: https://sheffield-ukneqas.ipassportqms.com/document_download/NjRlNTgxYzctMTI4ZS00MTg4LWI2ZDMtZDdkYzJhMTFlZTg3. Participant details, their results and their performance data remain confidential unless we are required by law to share this information. Where required by law or authorised by contractual arrangements to release confidential information, UK NEQAS LI will notify those concerned of the information released, unless prohibited by law. For UK participants, the relevant National Quality Assessment Advisory Panel is informed 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/

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