IgH/TCR Clonality Status Programme

Distribution - 202101

Participant ID -

Date Issued - 29 April 2020

Closing Date - 05 June 2020

Trial Comments

This trial was issued to 106 participants who were asked to analyse the samples for IG and TCR gene rearrangements . 100 (94.3%) participants returned results. Of the six participants who did not return results, two laboratories notified us of their intended non return and two laboratories submitted requests for an extension in results submission in light of the ongoing Covid-19 pandemic. 98 participants returned results for IG gene rearrangements and 98 participants returned results for TCR gene rearrangements. This is the final version of the report.

Sample Comments

Two samples were issued for this trial: IGH 151 and TCR 152. Sample IGH 151 manufactured to comprise 100% pooled buffy coat material and TCR 150 was manufactured from a T-Acute lymphoblastic leukaemia patient donation.

Results and Performance

Your Results

IgHTCR Clonality Status	Your Results	Consensus Result
Sample IGH 151	Polyclonal (Not Clonal)	Polyclonal (Not Clonal)
Sample TCR 152	Clonal	Clonal

All Participant Results

	Clonal	Pseudoclonal	Multiple Reproducible Peaks (n>=3)	Polyclonal (Not Clonal)
Sample IGH 151	4	0	0	94
Sample TCR 152	92	1	2	3

Your Performance

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

N/A = Not Applicable

The loci and reporting nomenclature in this report has been standardised to the Euroclonality/BIOMED 2 guidelines. Langerak, A. W. *et al.* (2012) EuroClonality/BIOMED-2 guidelines for interpretation and reporting of Ig/TCR clonality testing in suspected lymphoproliferations. *Leukemia* 26, 2159-71.

IgH/TCR Clonality Status Programme

IG Results by Loci

IG	IGH V_H-J_H	IGH D_H-J_H	IGK V_K-J_K	IGK Kde	IGL
Your Result	Polyclonal (Not Clonal)		Polyclonal (Not Clonal)	Polyclonal (Not Clonal)	
Returns	99	41	52	51	14
Clonal	2	1	0	2	0
Irregular Polyclonal (Not Clonal)	1	1	0	0	0
Multiple Reproducible Peaks (n>=3)	0	0	0	0	0
No (Specific) Product	2	0	0	1	0
Not Evaluable	0	1	0	0	0
Polyclonal (Not Clonal)	93	38	52	47	14
Pseudoclonal	1	0	0	1	0

TCR Results by Loci

TCR	TCRB Vβ-Jβ	TCRB Dβ-Jβ	TCRG Vγ-Jγ	TCRD
Your Result	No (Specific) Product	Clonal	Clonal	
Returns	57	53	98	23
Clonal	13	53	90	20
Irregular Polyclonal (Not Clonal)	2	0	0	0
Multiple Reproducible Peaks (n>=3)	0	0	4	1
No (Specific) Product	12	0	0	0
Not Evaluable	5	0	0	0
Polyclonal (Not Clonal)	24	0	3	2
Pseudoclonal	1	0	1	0

IgH/TCR Clonality Status Programme

Template Type

	IG Returns	TCR Returns
DNA	252	228
cDNA	3	0

PCR Type

	IG Returns	TCR Returns
Multiplex PCR	229	211
Single PCR	19	11
PCR for Next generation Sequencing	5	6
Nested PCR	1	0
Semi-Nested	1	0

Protocol Type

	IG Returns	TCR Returns
Invivoscribe Identiclone (IVD) Kit	113	109
In-House Method (BIOMED Primers)	114	62
Invivoscribe (RUO) Kit	16	34
In-House Method (Not BIOMED Primers)	5	10
LymphoTrack TRG Assay	0	6
Master Diagnostica	2	5
Invivoscribe LymphoTrack Dx TRB kit	0	4
LymphoTrack IGH FR1 FR2 FR3 IGK	8	0

Analysis Type

	IG Returns	TCR Returns
Capillary Electrophoresis	224	199
NGS (Other)	10	10
Acrylamide Gel Electrophoresis (PAGE)	8	8
Agarose Gel Electrophoresis	9	8
Microfluidic Electrophoresis	2	3
Radioactive Labelling	4	3
Heteroduplex Analysis	6	1
Other	0	1
Sequencing	1	0

IgH/TCR Clonality Status Programme

Trial Summary IGH:

- In line with sample formulation, 94/98 (95.9%) participants who returned results reported the Ig clonality status of sample IGH 151 to be 'Polyclonal (Not Clonal)'.
- Four participants reported the sample as 'Clonal'; one using the Invivoscribe Identiclone (IVD) Kit and Acrylamide Gel Electrophoresis (PAGE). One used an in-House Method (BIOMED Primers) and Capillary Electrophoresis. One used the Invivoscribe Identiclone (IVD) Kit and Capillary Electrophoresis and one used the Master Diagnostica kit and Agarose Gel Electrophoresis**.**
- One of the four participants found clonal peaks in IGH VH-JH and IG Kde having tested all relevant loci. One participant found a clonal peak in IG Kde only having tested all relevant loci. One participant found a clonal peak in IG DH-JH only having tested IGH VH-JH and IGH DH-JH only. One participant found a clonal peak in IG VH-JH only, testing only this locus.

Trial Summary TCR:

- In line with sample formulation, 92/98 (93.9%) participants who returned results reported the TCR clonality status of sample TCR 152 to be 'Clonal'.
- Three participants reported the sample as Polyclonal (Not Clonal). One used an In-House Method (Not BIOMED Primers) and Acrylamide Gel Electroporesis (PAGE); one used the Invivoscribe (RUO) Kit and Agarose Gel Electrophoresis and one used an In-House Method (BIOMED Primers) and NGS.
- One participant only tested the TCRG loci not in line with the Euroclonality/BIOMED-2 guidelines[1] which for suspected T cell proliferations advocates testing TCRG and TCRB, preferably in parallel, unless a TCRγδ+ T-cell proliferation is suspected when TCRG and TCRD PCR analysis is preferred.
- Two participants reported a Multiple Reproducible Peaks pattern. One used an In-House Method (BIOMED Primers) and Capillary Electrophoresis and one used the Master Diagnostica kit and Agarose Gel Electrophoresis. Both only tested the TCRG loci not in line with the Euroclonality/BIOMED-2 guidelines (see above)[1].
- One participant reported a Pseudoclonal pattern using an In-House Method (BIOMED Primers) and Capillary Electrophoresis. Again, they only tested the TCRG loci not in line with the Euroclonality/BIOMED-2 guidelines (see above)[1].

Reference(s)

1. Langerak, A. W. *et al.* EuroClonality/BIOMED-2 guidelines for interpretation and reporting of Ig/TCR clonality testing in suspected lymphoproliferations. *Leukemia* 26, 2159–71 (2012).

IgH/TCR Clonality Status 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/