

BCR-ABL and AML Translocation Identification Programme

Participant: 

Trial No: 151602 

Date Issued: 02/09/2015 

Date Closed: 02/10/2015 

Two lyophilised cell line preparations were distributed for analysis:

- Sample BCR 136: Participants were requested to analyse the sample for the presence of a *BCR-ABL1* translocation.
- Sample AML 137: Participants were requested to analyse the sample (subject to their laboratory repertoire) for the presence of the t(8;21) *RUNX1-RUNX1T1*, t(15;17) *PML-RARA* and inv(16) *CBFB-MYH11* translocations associated with AML.

This trial was issued to 126 participants; 122 participants returned results; 4 participants did not return results.

Your Results

	Sample 136	Sample 137		
	BCR-ABL Assay	Inv(16) Assay	t(8;21) Assay	t(15;17) Assay
Your Results 				
Consensus/Expected Result 	Y	N	N	Y
Transcript 				

Key: Y = transcript detected, N = no transcript detected, N.T. = not tested

Overall Results

	Sample 136	Sample 137		
	BCR-ABL Assay	Inv(16) Assay	t(8;21) Assay	t(15;17) Assay
No. labs performing assay 	118	96	97	105
Transcript detected	117	0	0	99
Transcript not detected	1	96	97	6
% with consensus result	99%	100%	100%	94%

Issue Date: 08 December 2015 

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

Method Breakdown

Assay	Method	Number of Participants
BCR-ABL	Single PCR	23
	Multiplex PCR	40
	Nested PCR	12
	Real-time PCR	43
Inv(16)	Single PCR	18
	Multiplex PCR	18
	Nested PCR	25
	Real-time PCR	25
t(8;21)	Single PCR	20
	Multiplex PCR	16
	Nested PCR	24
	Real-time PCR	45
t(15;17)	Single PCR	19
	Multiplex PCR	18
	Nested PCR	23
	Real-time PCR	37

Please note: Figures in the above table do not tally with the number of participants returning results due to some participants using a combination of two different techniques

Summary

Sample BCR 136

In line with sample formulation 117 (99.2%) participants returning a result for this sample detected a *BCR-ABL1* transcript. 113 (96.6%) laboratories reported identification of a major *BCR-ABL1* transcript (p210, e14a2, b3a2). The only participant who failed to detect a rearrangement utilised a single PCR methodology, no further details known.

Sample AML 137

In line with sample formulation 92 (4.3%) participants performing the relevant assay detected a t(15;17) *PML-RARA* translocation. All participants commenting on the transcript type detected a bcr1 (long) type as the predominant *PML-RARA* fusion form; additional transcript types were also noted by some participants.

Of the 6 laboratories who failed to detect this rearrangement, 4 participants utilised Real Time PCR, 1 nested PCR and another single PCR based methodology. The proportion of participating laboratories detecting the *PML-RARA* translocation has improved compared to the 141503 trial distribution; possibly facilitated by the increased overall cell numbers provided in sample AML 137 (12 x10⁶) compared to sample AML 133 (7 x10⁶).

No participants returning a result for this sample detected a t(8;21) *RUNX1-RUNX1T* or inv(16) *CBFB-MYH11* rearrangement.

Further Remarks

We remind participants to please test each sample for all the relevant assays available in their laboratory repertoire. For example, if a t(8;21) *RUNX1-RUNX1T1* transcript is detected in the AML sample, please do continue to analyse the sample for t(15;17) *PML-RARA* and inv(16) *CBFB-MYH11* rearrangements wherever possible. We acknowledge this approach may not reflect your strategy for a clinical case; however, it is important all results are returned for trial scoring purposes.

If you have not already informed us of the relevant assays offered by your laboratory please do email this information to debbie.travis@ukneqasli.co.uk to avoid a non return designation and an adverse impact on your laboratory performance status.

Website only: Uncontrolled

BCR-ABL and AML Translocation Identification Programme

Participant:

Trial No: 151602

Date Issued: 2nd September 2015

Date Closed: 2nd October 2015

Results summary: Sample BCR 136 (BCR-ABL1)

	Consensus Result	Your Result	Performance Status for BCR-ABL
BCR-ABL1 Detected	Yes		
Transcript Type	Not Applicable		

Results summary: Sample AML 137

	Consensus Result	Your Result	Performance Status for AML
Inv(16) Detected	No		
t(8;21) Detected	No		
t(15;17) Detected	Yes		

Your Overall Performance Status for Trial 151602



Running Performance Status for this Programme



The scoring system is a rolling scheme designed to identify unsatisfactory performance or persistent unsatisfactory performance of any participant. This is in order that UK NEQAS LI can provide support and guidance where needed, and ensure that the Genetics National Quality Assurance Advisory Panels (NQAAP) are informed as appropriate.

Running performance status:

- Satisfactory Performance = no action required.
- Unsatisfactory Performance = a single incidence of unsatisfactory performance (critical trial performance status) in the last three trials; action required.
- Persistent Unsatisfactory Performance = 2 or more incidences of unsatisfactory performance (critical trial performance status) in the last three trials; immediate action required.

The specific scoring system for this trial is available online at www.ukneqasli.co.uk

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.