Measurable Residual Disease for ALL by Flow Cytometry

TRIAL No: 242502 **Participant:** **ISSUED:** 23-Jul-24 **CLOSING:** 12-Aug-24

A presentation sample is included for reference that contains approximately 2.5% blasts, this programme is designed to assess a laboratory's ability to detect levels of leukaemic ALL cells at measurable residual disease levels within a background of stabilised normal whole blood or PBSC harvest.

Samples 136 and 137 are manufactured from the same ALL case and are designed to represent different stages post treatment to assess the ability of a centre to detect leukaemic cells at MRD levels. The white cell count is approximately 7.0 x 10^9/L. For the MRD-ALL programme you are required to provide Limit of detection (LOD) and Limit of quantification (LOQ) of your assay.

Please analyse using your normal panel and report the percentage MRD population in sample 136 and sample 137 and give details of the antigens used in this case.

Please note: An educational electronic exercise has been issued alongside this exercise, this may be found at https://form.jotform.com/241911100058342 this is a separate case to the samples issued and is not performance monitored.

Stability
The material is stabilised using an internationally patented method that preserves the leucocyte flow cytometric characteristics of scatter and fluorescence. Whilst the samples should ideally be stored at 2°C and 8°C, they are stable across a range of temperatures for the duration of transit, even for extended transit periods. However, if samples appear to have visibly deteriorated or do not pass local QC, please contact UK NEQAS LI to arrange repeat samples-see below for details.

Processing of Samples
These samples are suitable for use with flow cytometric methods only, using whole blood lysis techniques and sequential gating strategies.

Upon processing these samples with your current methodology, please treat them as routine samples, adhering to local quality controls/guidelines as stated in your Standard Operating Procedures. As the material is stabilised some minor adjustments may be required to the Forward Scatter (FSc) and Side Scatter (SSc) Photo Multiplier Tube (PMT) voltages. This is normal and does not affect the staining characteristics.

Owing to the stabilisation process, the cells are not viable. UK NEQAS LI therefore recommends that viability dyes are either not used or, if used, all cells are included in the viable cells gate. In addition, the stabilisation process allows for haemoglobin to leach out of the red blood cells. As a result of this the samples may have a haemolysed appearance. This is normal and the samples can be tested.

There are no specific environmental conditions that need to be considered for this EQA trial.

COSHH
This cell preparation has been produced from human material virologically tested and found negative for Hepatitis B, Hepatitis C, HIV1 and HIV2, Syphilis and HTLV1 and judged as having a minimal likelihood that pathogens are present. No material is knowingly used that is positive for these pathogens. However, as the material is derived from human sources it should be handled in accordance with local laboratory practices. The material is only designed for the purpose it is intended. All samples contain the antibiotic Gentamycin and the antifungal Amphotericin. Participants must only use the samples for the purpose intended. UK NEQAS, Sheffield Teaching Hospitals NHS Foundation Trust and any of its employees will not be responsible for any misuse of samples issued in this programme.

Packaging
UK NEQAS LI sample(s) are sent by first class post or courier accordingly. Packaging is guided by Package Instruction P650. These samples have been classified as ADR 'Exempt human specimen'.

Disposal/Spillage of Material
The sample(s) cannot be assumed to be free from infectious agents therefore the material should be assessed as potentially infectious and disposed of accordingly. In the event of a spillage the packaging has sufficient absorbent capacity to absorb the sample(s) and if found the packaging and samples should be disposed of in an appropriate manner and UK NEQAS LI should be contacted. If the packaging is broken and spillage occurs, please follow local protocols to deal with a small volume of blood spillage. If no protocol is available UK NEQAS LI suggests liberally covering the area with a suitable disinfectant. Clean the area with paper towel, then rinse the area with water and dry thoroughly. Dispose of all material used to deal with spillage in an appropriate manner and contact UK NEQAS LI.

Repeat Samples
Requests for repeat samples should be made online at the UK NEQAS LI website by selecting the 'Request a Repeat Sample' icon on the homepage (www.ukneqasli.co.uk). Should this not be possible please telephone our Administration team on the number provided below. Please make a repeat sample request as soon as possible. If following repeat sample(s) processing, results obtained still do not pass local internal QC please contact UK NEQAS LI.

Results submission
The data entry webpage for this trial can be accessed online at the UK NEQAS LI website via the Participant Hub (www.ukneqasli.co.uk). Participants are required to log into this area of the website using their Lab number (also known as PRN, participant reference number), Identity and Password.

Please only submit results applicable to the scope of this EQA programme.

UK NEQAS LI website hosted results submission pages have been designed to facilitate local independent checking of trial results prior to final submission. Once data has been entered into the relevant fields a participant can chose to click the [Save] button to permit independent checking by a second operative before final submission to UK NEQAS LI. The date and time will appear in the corresponding field to indicate data has been successfully saved. Subsequent editing of the data fields is still possible at this stage. The [Submit] button must be clicked for data to be locked (preventing further editing) and transferred to UK NEQAS LI. The date and time will appear in the corresponding field to indicate the trial data has been successfully submitted. Additionally, the date of successful results submission will also appear in the 'completed' column of the relevant programme trial list. Please note, all data saved or submitted in the UK NEQAS data entry system will be downloaded and analysed at trial closure.

For results returned via the Participant Hub using an externally hosted data entry system (e.g. JotForm) the UK NEQAS LI website functionality outlined above is unfortunately not currently available. Participants are encouraged to carefully read and follow the instructions provided on the individual results submission pages.

Please note, all numerical fields must be completed using only decimal points to separate numbers, and not commas (e.g. enter 6.3 not 6,3).

If you experience any problems submitting your trial results, please do contact us (see contact details section) for assistance. Participants can make changes to existing laboratory contact details, request a password reminder, or add a new contact at any time via the Participant Hub. Alternatively, please email (admin@ukneqasli.co.uk) or telephone the number provided below for assistance.

Report Distribution
The trial report for this programme will be available online at the UK NEQAS LI website (www.ukneqasli.co.uk). Participants are required to log into the relevant area of the website using their web user details to retrieve report(s). Participants will be notified regarding the availability of an issued report by email. To ensure you receive such emails please check the contact details we hold for your laboratory are accurate and current at re-registration. If you wish to update your laboratory contact details at any time, please contact our Administration team for assistance via the UK NEQAS LI website using the 'Contact us' tab on the left-hand side of the home page and then selecting the 'General enquiries' option. Alternatively, please telephone the number provided below.

Contact details.
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Please state PRN (participant reference number) on all correspondence.