

Measurable Residual Disease for ALL by Flow Cytometry

TRIAL No: 232403 **Participant:** **ISSUED:** 28-Nov-23 **CLOSING:** 18-Dec-23

Please note that this sample is from a B-ALL patient with a KMT2A rearrangement. A presentation sample is included for reference. This programme is designed to assess a laboratory's ability to detect levels of leukaemic B-ALL cells at measurable residual disease levels within a background of stabilised normal whole blood.

Samples 132 and 133 are manufactured from the same B-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. Sample 132 has a WBC $7.29 \times 10^9/L$ and sample 133 has a WBC $5.23 \times 10^9/L$.

Please analyse using your normal panel and report the percentage MRD population in sample 132 and sample 133 and give details of the antigens used in this case.

An educational electronic exercise has also been issued alongside this exercise, please note that this is NOT from the same case and that this educational exercise will not be performance monitored. The link for the electronic exercise is provided here <<https://form.jotform.com/233133502715345>>

Stability

The material is stabilised using an internationally patented method that preserves the leucocyte flow cytometric characteristics of scatter and fluorescence. It is suitable for use with whole blood lysis techniques and sequential gating strategies. These samples are stable at ambient temperature, but if storage of the sample is necessary it should be between 2°C and 8°C.

Processing of Samples

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. Because 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 material virologically tested and found negative for Hepatitis B, Hepatitis C, Hepatitis E, 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 Health & Safety practices. All samples contain the antibiotic Gentamycin and the antifungal Amphotericin.

In all cases the materials (patient samples, blood products etc) are provided under the conditions that they must be used only for the educational purpose of EQA. **Participants must only use the samples provided for the purpose intended.** Sheffield Teaching Hospitals, any of its employees or distributors (that are directly contracted to STH to provide UK NEQAS services) will not be held responsible for any misuse of samples issued once they have been shipped. UK NEQAS LI adhere to all IATA shipping regulations. The construction, performance, validity and all aspects of sample use shall be governed by English law and the parties submit to the exclusive jurisdiction of the English courts.

Packaging

UK NEQAS LI sample(s) are sent by first class post or courier according and all packaging is compliant with 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

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

contacted. If the packaging is broken and a spillage occurs please follow local protocols to deal with a small volume 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 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 by email (admin@ukneqasli.co.uk). Instructions of what to include in the request can be found 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. You 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.

"Please note, all data **saved** or submitted in the UK NEQAS data entry system will be downloaded and analysed at trial closure.

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).

Failure to return your results will be recorded as a non-return and for an accredited programme impact upon your performance status. If you have any queries with regards to online data entry, please do not hesitate to contact us. It is the responsibility of participants to ensure that their results have been received by UK NEQAS LI. Further information can be found in the associated trial issue email and on our website (www.ukneqasli.co.uk).

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 participant hub (using their web user details) to retrieve PDF 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. You 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.

Contact details

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