South Yorkshire and Bassetlaw Pathology Transformation Programme
Transforming Patient Care through Leading Edge Pathology Services

NHS Barnsley Hospital · NHS Doncaster and Bassetlaw Teaching Hospitals · NHS The Rotherham · NHS Sheffield Children's · NHS Sheffield Teaching Hospitals

UK NEQAS
Leucocyte Immunophenotyping

Donation Consent Form Pack

UK NEQAS for **Leucocyte Immunophenotyping**

4th Floor
Pegasus House
463A Glossop Road
Sheffield
S10 2QD

Telephone: 0114 2673600
General email: admin@ukneqasli.co.uk
Web: https://www.ukneqasli.co.uk

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

PDF version of this consent form pack available for local printing at:
https://www.ukneqasli.co.uk/contact-us/help-to-source-patient-material-for-eqa-pt/

Contact the UK NEQAS LI Scientific team directly for non-urgent assistance, email: scientist@ukneqasli.co.uk

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Clinician/Healthcare Professional – Guidance Information

THE UK NEQAS ORGANISATION

The UK National External Quality Assessment Scheme (UK NEQAS) charitable consortium facilitates optimal patient care by providing a comprehensive External Quality Assessment (EQA)/Proficiency Testing (PT) service in laboratory medicine. Through education and the promotion of best practice, the organisation helps to ensure that the results of laboratory investigations are reliable and comparable wherever they are produced.

The UK Government Department of Health introduced the not-for-profit UK NEQAS in 1969. The aims of all UK NEQAS EQA/PT programmes are primarily educational. Our experienced scientific staff can support participating laboratories and/or individuals by providing clinically relevant assistance in method/technical troubleshooting and diagnostic interpretation across a variety of pathology disciplines.

ABOUT UK NEQAS FOR LEUCOCYTE IMMUNOPHENOTYPING

UK NEQAS for Leucocyte Immunophenotyping (UK NEQAS LI) was initially established in 1986 as a single regional EQA/PT programme with 20 participating laboratories. We now operate more than 25 programmes in the fields of molecular genetics based haemato-oncology and flow cytometry for haematological/immunological assays. UK NEQAS LI has over 2,000 active registrations worldwide.

UK NEQAS LI is hosted by, and is legally accountable to, Sheffield Teaching Hospitals NHS Foundation Trust. Responsibility for the organisation currently resides with Mr Stuart Scott, Acting Director of UK NEQAS for Leucocyte Immunophenotyping.

UK NEQAS FOR LEUCOCYTE IMMUNOPHENOTYPING EQA/PT PROGRAMMES

Haematological disorders span a large variety of conditions primarily affecting the blood from anaemia, bleeding and clotting disorders to malignancy. Laboratory based testing plays a crucial part in defining a diagnosis, prognostication and the treatment of affected patients. Relevant medical laboratory testing is performed in virtually all major hospitals. In a dynamic clinical field, it is important such laboratory tests are performed to a high standard, and that if a single patient sample was to be tested in a number of different laboratories, all laboratories would report similar results.

The aims of all UK NEQAS LI EQA/PT programmes are primarily educational. The distribution of identical samples to all participating laboratories allows inter-laboratory comparison. It also identifies the overall level of performance within the UK and permits benchmarking of your local laboratory service internationally. Corrective action taken as a result of unsatisfactory EQA/PT performance can lead to an improvement in proficiency within an individual laboratory. Learning from others, through UK NEQAS LI trial reports (describing the outcomes of distrubted exercises) and educational publications, leads to an improvement within the UK as a whole. By linking results with techniques and procedures; specific strengths and weaknesses can be identified, driving change. National guidelines are reinforced and the need for new best practice recommendations identified.

The EQA/PT programmes operated by UK NEQAS LI are overseen by a dedicated Steering Committee covering all programmes and by a Specialist Advisory Group with a focus on the molecular genetics based haemato-oncology programmes. This oversight ensures that the EQA/PT programmes operated are clinically relevant, fit for purpose and are developed in parallel to current clinical practice. UK NEQAS LI reports to relevant oversight bodies in the UK to support better governance and patient safety.

ENSURE PATIENTS RECEIVE THE BEST POSSIBLE CARE AND OUTCOMES

Please help us by facilitating the sourcing of EQA/PT material to meet the quality assurance needs of Laboratory Medicine

Clinicians (and other associated healthcare professionals) are in a unique position to support UK NEQAS LI by identifying suitable patients in your care. Please do get in touch with us as soon as possible if a potentially appropriate case presents in your laboratory, clinic or ward.

- **New diagnosis (or relapsed) leukaemia** AML (MDS), MPN, ALL and CLL
  Peripheral blood: WCC >50 x10^9/L or Bone marrow: >50% blasts, WCC ~100 x10^9/L
- **Lymphoma with liquid component** – please contact us to discuss
- **Paroxysmal Nocturnal Haemoglobinuria** >10% clone
- **Plasma Cell Myeloma** Bone marrow: WCC >50 x10^9/L

If sufficient patient diagnostic/treatment waste material is not salvageable, we may ask that clinical staff assist us in obtaining the additional sample(s) and establishing informed consent from the donating individual prior to venepuncture. **The donating patient is to have had no recent clinical history of infection with a class 2, 3 or 4 agent (COSHH hazard group).**

Forwarding Samples to UK NEQAS LI

It is highly recommended blood samples should arrive at UK NEQAS LI within 48 hours of collection. Please contact us to arrange specimen transport (at no cost to your centre).

Monday - Friday 8:30am to 4:30pm, Telephone: 0114 2673600

Outside of office hours, please ensure samples are refrigerated to 2-8°C immediately after collection.

Although UK NEQAS LI do not provide a 24 hour – 7 days/week laboratory service, by prior arrangement samples can be collected by courier outside of our core office hours. We endeavour to do our utmost to minimise any disruption to patient management or your working day.

For more information regarding suitable cases for referral, sample requirements and logistics please contact us or refer to our supporting documentation available on our website: https://www.ukneqasli.co.uk/contact-us/help-to-source-patient-material-for-eqa-pt/

Patient Information

Guidance for patients can be found in the proceeding pages of this document. The patient information sheet (PIS) has been designed to support clinicians during the consenting process and aims to inform potential donors regarding:

- Who UK NEQAS LI are and what we do as an organisation
- What making a blood sample(s) donation to UK NEQAS LI for EQA/PT purposes entails
- What will happen to the donated blood sample(s), including confidentiality aspects

We advise that a hardcopy of the PIS be taken away by the patient for their reference.

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Patient Donor – Information Sheet

Thank you for considering the donation of an extra sample(s) of your blood to allow us to check the quality of the laboratory tests used for the diagnosis, monitoring and management of various medical conditions.

WHAT IS UK NEQAS FOR LEUCOCYTE IMMUNOPHENOTYPING?

UK NEQAS for Leucocyte Immunophenotyping (UK NEQAS LI) is part of the UK National External Quality Assessment Service, which helps to ensure the continuing quality of medical laboratory tests and their use in the UK, parts of Europe and overseas. This may be done by distributing small quantities of a real patient specimen to each of the participating laboratories for testing to see if they each perform the test reliably and accurately to provide an appropriate result.

Our findings are made available to doctors, healthcare professionals and laboratories in the NHS; they are an important part of ensuring that standards of patient care are maintained and further improved. To do this, many of our educational Quality Assessment programmes rely on voluntary donations from real patients like you.

REASONS FOR ASKING YOU TO DONATE?

You have a relevant medical condition, which means that a sample of your blood could be used in our educational Quality Assessment exercises. Your doctor has approached you to ask you to consider donating. If you wish to do so, your sample(s) can be used to determine whether performance in medical laboratories is satisfactory. Using your donation this way can help to reveal whether there are any flaws in the testing methods, which make them unreliable or unsafe to use for the care of patients.

Our programmes are intended to help verify that the tests used in the NHS perform acceptably to support hospitals and GP practices to provide patients with the highest standards of care, and to ensure that standards are maintained and improved year on year. If you decide not to donate it will not affect your current or future medical care, and you are under no obligation to take part.

HOW WILL UK NEQAS LI USE MY DONATION?

At UK NEQAS LI, a blood sample donation from a suitable person, such as yourself, is sent to participating laboratories, which are asked to carry out certain medical tests. The results obtained by these laboratories are then returned to the UK NEQAS LI office based in Sheffield for analysis. Such Quality Assessment programme exercises help to maintain high and uniform standards in all laboratories participating in UK NEQAS LI programmes; this process is known as External Quality Assessment (EQA) or Proficiency Testing (PT). EQA/PT allows us to identify laboratories that are unable to perform tests reliably so that we can offer their staff assistance to improve their laboratory's performance. This in turn brings about improvements in the quality of clinical care provided to patients.

Each EQA/PT sample is specially coded and labelled before distribution (anonymised), so the identity of the donor (your identity) is not known. Samples produced from your donation will be sent to NHS and non-NHS medical laboratories participating in UK NEQAS LI programmes, both within the UK and worldwide.

Although UK NEQAS LI is a not-for-profit organisation, the costs of running our numerous educational EQA/PT programmes have to be met, and laboratories pay a fee to participate. However, no donated blood sample is ever sold by UK NEQAS LI to any commercial company or any other organisation.

WHAT WILL MAKING A DONATION INVOLVE?

If you agree to assist us, you can donate an extra sample(s) of blood at an opportune moment during your routine clinical care; typically around the time of diagnosis. Your sample(s) will be anonymised and securely stored by UK NEQAS LI until required for use.

Nobody will be asked to donate blood for use by UK NEQAS LI if there is any reason to think, on medical grounds, that blood donation is likely to be harmful in any respect. Advice will be sought from your doctor if there is any doubt about this. The blood sample(s) will be taken from your arm by a trained phlebotomist.

You are free to withdraw at any point if you decide later that you do not wish us to distribute anonymised samples prepared from your donated blood to laboratories participating in UK NEQAS LI educational Quality Assessment exercises.

WHAT WILL UK NEQAS LI DO WITH MY INFORMATION?

All information will remain confidential and be held securely by UK NEQAS LI. We will retain the minimal amount of clinical information required and personal details such as your age at donation and biological sex.

Records relating to your donation of blood for use by UK NEQAS LI will be held securely in the UK NEQAS LI office and made available only to those professional staff involved in the operation of our EQA/PT programmes in accordance with the current General Data Protection Regulations (GDPR).

UK NEQAS LI does not distribute any information, which allows a blood sample (or any other patient derived specimen) to be traced back to an individual patient. Your blood sample will be anonymised before it leaves UK NEQAS LI, and your identity will not be known by any participating laboratory.
Minimal information such as your age, biological sex and diagnostic indications required for a laboratory to perform a given medical test properly may be provided to participating laboratories/individuals. The results of the EQA/PT exercise will not be traceable to individual patients.

You can find out more about how we use your information by contacting UK NEQAS LI.
Telephone: 0114 2673600
Email: admin@ukneqasli.co.uk

For GDPR related information please see: https://www.sth.nhs.uk/about-us/gdpr

POTENTIAL BENEFITS

There are no direct benefits to you for donating blood for use as educational EQA/PT material by UK NEQAS LI. However, it is in the interests of us all, especially those of us who may need a blood disorder medical test carried out, that a high standard of practice should be maintained in all laboratories. Our Quality Assessment exercises facilitate this, and without donations from people like you, UK NEQAS LI would not be able to operate our educational programmes.

POTENTIAL RISKS AND DISCOMFORTS

It is mildly uncomfortable to have a needle for blood donation inserted into a vein and some people develop a small bruise at the puncture site. Rarely, people feel faint while blood is being taken. Provided normal good medical practice is observed, as it will be, the risk of a serious problem (such as major bruising) developing during or following blood donation is extremely rare.

REIMBURSEMENT OF EXPENSES

Any expenses which you may incur as a result of donating a blood sample(s) for use by UK NEQAS LI will be reimbursed.

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YOUR RIGHT NOT TO PARTICIPATE

You are under no obligation whatsoever to donate a blood sample for use by UK NEQAS LI. If you decide (now or later) not to donate, you need give no reason and your medical care will not be affected in any way.

You may withdraw your consent at any point if you decide later that you do not wish us to distribute anonymised samples prepared from your donated blood to laboratories participating in UK NEQAS LI educational Quality Assessment exercises - providing the samples have not already been used for EQA/PT purposes.

We will aim to act within 2 working days of receiving your instruction to withdraw your consent. Any stored material derived from your blood sample donation will be destroyed and disposed of appropriately.

WHAT IF I HAVE ANY FURTHER QUESTIONS?

Please contact us:
UK NEQAS for Leucocyte Immunophenotyping
4th Floor Pegasus House, 463a Glossop Road,
Sheffield S10 2QD
Telephone: 0114 2673600
Email: admin@ukneqasli.co.uk

Mr Stuart Scott (Acting Director of UK NEQAS for Leucocyte Immunophenotyping) or any of the UK NEQAS LI Programme Lead Scientists, will be glad to assist with any queries you may have now, and at any time in the future.

WHAT IF I WISH TO COMPLAIN ABOUT THE WAY IN WHICH MY BLOOD DONATION FOR UK NEQAS LI HAS BEEN CONDUCTED?

If you have any cause to complain about any aspect of the way in which you have been approached or treated during the course of donating a blood sample(s) to UK NEQAS LI, the normal National Health Service (NHS) complaints mechanisms are available to you. You are not compromised in any way because you have taken part in this donation programme.

If you are harmed as a result of donating blood for use by UK NEQAS LI, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action. If you have any concerns, please contact Mr Stuart Scott (Acting Director of UK NEQAS for Leucocyte Immunophenotyping.

If you prefer, you can contact:
Sheffield Teaching Hospitals NHS Foundation Trust, Patient Advice and Liaison Service (PALS)
Tel: 0114 271 2400
Email: sth.pals@nhs.net

or write to:
Kirsten Major, Chief Executive, Sheffield Teaching Hospitals NHS Foundation Trust, 8 Beech Hill Road, Sheffield S10 2SB

They will be able to assist you by putting you in touch with the appropriate person to best address your concern. The PALS team can also give you further advice on how to make a complaint.

THANK YOU!

All those involved with UK NEQAS for Leucocyte Immunophenotyping EQA/PT programmes are very much aware of the essential contribution donors like you make to the operation of our educational Quality Assessment exercises and we would like to express our appreciation for all the help received in this way.

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Donation of Blood to UK NEQAS LI

IMPORTANT: Please complete all sections of the consent form, parts 1, 2 and 3:

- **Part 1:** Retain within the patient's medical notes
- **Part 2:** Return to UK NEQAS for Leucocyte Immunophenotyping
- **Part 3:** Patient to keep for their reference

If unsure, please confirm sample requirements with UK NEQAS LI - Tel: 0114 2673600

- Volume required is dependent on recent WCC result and intended use of the donation
- Sample(s) to be acquired preferably before treatment: **EDTA - purple/pink/lavender**
- Label sample(s) as per local policy. Specimens to reach UK NEQAS LI ideally within 48 hours

Consent Form (Part 1) – Patient's Medical Notes

Please initial the box

1. I have read and understood the patient information provided (v3.0, issued October 2025). Any questions raised have been answered satisfactorily. ☐

2. I agree to give a sample(s) of blood and/or other tissues for External Quality Assessment (EQA)/Proficiency Testing (PT) purposes. I understand that samples of my blood, coded to conceal my identity, may be sent to both UK and non-UK participants in UK NEQAS LI educational Quality Assessment programmes. ☐

3. I understand how the sample(s) will be taken, that participation is voluntary and that I am free at any time to withdraw my permission for the storage and distribution of my sample(s) - providing they have not already been used for EQA/PT purposes. ☐

4. I agree that UK NEQAS LI staff can collect and store information from my health care records applicable to the EQA/PT exercises that use my donated material. I understand that UK NEQAS LI will keep my information confidential. Information will only be passed to researchers/programme participants in an anonymous way that protects my identity. ☐

Signed: ..... Date: .....

Name of patient (BLOCK CAPITALS): .....

I have discussed all the aspects above with this patient who has agreed to give informed consent.

IMPORTANT: There is no recent clinical history of infection with a class 2, 3 or 4 agent (COSSH hazard group) and thus there is minimal likelihood that such pathogens are present in the sample(s) obtained. **Please initial the box to indicate compliance and complete the section below.** ☐

Signed: ..... Date: .....

Name of person obtaining consent (BLOCK CAPITALS): .....

Position/Job Title: .....

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Donation of Blood to UK NEQAS LI

For UK NEQAS LI use only:

Received by (initials and date):

Estimated WCC (10^9/L):

Approx. total volume (mL):

Diagnosis comments: confirmed / pending

UK NEQAS LI Reference Number:

[ ] P:drive Sample Tracking spreadsheet completed

MTO/Scientist initials and date:

Material suitable for (tick):

[ ] Fix and irradiate (Flow) [ ] Lyophilise/non-stabilised (Mol) [ ] Review by UK NEQAS LI Director required - see form

Consent Form (Part 2) - UK NEQAS LI

Please initial the box

1. I have read and understood the patient information provided (v3.0, issued October 2025). Any questions raised have been answered satisfactorily. ☐
2. I agree to give a sample(s) of blood and/or other tissues for External Quality Assessment (EQA)/Proficiency Testing (PT) purposes. I understand that samples of my blood, coded to conceal my identity, may be sent to both UK and non-UK participants in UK NEQAS LI educational Quality Assessment programmes. ☐
3. I understand how the sample(s) will be taken, that participation is voluntary and that I am free at any time to withdraw my permission for the storage and distribution of my sample(s) - providing they have not already been used for EQA/PT purposes. ☐
4. I agree that UK NEQAS LI staff can collect and store information from my health care records applicable to the EQA/PT exercises that use my donated material. I understand that UK NEQAS LI will keep my information confidential. Information will only be passed to researchers/programme participants in an anonymous way that protects my identity. ☐

Signed: ..... Date: .....

Name of patient (BLOCK CAPITALS): .....

I have discussed all the aspects above with this patient who has agreed to give informed consent.

IMPORTANT: There is no recent clinical history of infection with a class 2, 3 or 4 agent (COSSH hazard group) and thus there is minimal likelihood that such pathogens are present in the sample(s) obtained. **Please initial the box to indicate compliance and complete the section below.** ☐

Signed: ..... Date: .....

Name of person obtaining consent (BLOCK CAPITALS): .....

Position/Job Title: .....

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THANK YOU

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If you have any questions or concerns, please contact us:

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Consent Form (Part 3) - Patient to retain

Please initial the box

1. I have read and understood the patient information provided (v3.0, issued October 2025). Any questions raised have been answered satisfactorily. ☐

2. I agree to give a sample(s) of blood and/or other tissues for External Quality Assessment (EQA)/Proficiency Testing (PT) purposes. I understand that samples of my blood, coded to conceal my identity, may be sent to both UK and non-UK participants in UK NEQAS LI educational Quality Assessment programmes. ☐

3. I understand how the sample(s) will be taken, that participation is voluntary and that I am free at any time to withdraw my permission for the storage and distribution of my sample(s) - providing they have not already been used for EQA/PT purposes. ☐

4. I agree that UK NEQAS LI staff can collect and store information from my health care records applicable to the EQA/PT exercises that use my donated material. I understand that UK NEQAS LI will keep my information confidential. Information will only be passed to researchers/programme participants in an anonymous way that protects my identity. ☐

Signed: ..... Date: .....

Name of patient (BLOCK CAPITALS): .....

I have discussed all the aspects above with this patient who has agreed to give informed consent.

IMPORTANT: There is no recent clinical history of infection with a class 2, 3 or 4 agent (COSSH hazard group) and thus there is minimal likelihood that such pathogens are present in the sample(s) obtained. **Please initial the box to indicate compliance and complete the section below.** ☐

Signed: ..... Date: .....

Name of person obtaining consent (BLOCK CAPITALS): .....

Position/Job Title: .....