

To: Pathology Network Directors
cc. Jane Mills, Professor Jo Martin

NHS England
Wellington House
133-155 Waterloo Road
London
SE1 8UG

4 September 2023

Dear Colleague,

Preparations for blood group genotyping for people with sickle cell, thalassaemia and rare anaemia

NHS England (NHSE) has invested in a new national programme of work to better match blood groups for all current patients in England (circa 18,000) living with inherited anaemias including Sickle Cell Disorder and Thalassaemia. The NHS in England will soon be able to offer blood group and HLA genotyping for the current cohort of people with sickle cell, thalassaemia and transfusion dependent rare anaemias, which will be funded by NHS England, free of charge to hospital trusts until March 2024.

In preparation for the start of patient sampling for the [National Blood Group Genotyping Programme](#) delivered by NHS Blood and Transplant, all pathology services should prepare by implementing the following actions:

- 1) **Add the test to your LIMs and/or other Information Management Systems. The [request form](#) can be used in three ways:**
 - a. Embedded within hospital order comms so the majority of fields can be auto-filled.
 - b. An electronically editable PDF, then printed.
 - c. Printed and filled in by hand – note NHS Blood and Transplant, who are delivering the work will not be supplying paper forms.

Please ensure your haematology clinic/laboratories are familiar with the test request form, as shown in annex 1, and add it to information systems to enable submission of testing requests on commencement.

- 2) **Inform clinical and laboratory colleagues about this programme and the plans for sampling and recruiting patients using the information available on the [NHS Blood & Transplant website](#), including a set of Frequently Asked Questions for [hospital & lab staff](#) and [patients](#).**
- 3) **Identify eligible patients**, outlining the benefit, invite them for testing as part of routine appointments, discuss and note consent on the request form.
- 4) **Develop a local strategy to collect and submit samples** once patient sampling formally starts.



NHS Blood and Transplant anticipate commencing sample collection in England from October 2023– you will be formally notified of the start date. **Please do not send samples until notified that the programme has commenced.**

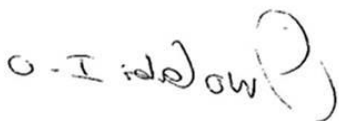
The programme aims to use a DNA testing array, developed by the Blood transfusion Genomics Consortium to provide extended blood group genotyping and HLA typing for all patients with sickle cell, thalassaemia and transfusion dependent rare anaemias. Once we notify you of the start date, please ensure that all patients with these conditions attending hospital are invited to have a blood group genotype DNA based test alongside their routine blood test, even if they have had an extended red cell genotype/phenotype before.

With this programme, alongside a related programme that is being rolled out to increase blood donations, it will be possible to identify better matched blood for transfusion and so reduce antibody formation. For those that already have antibodies it will be easier to find suitable blood for transfusion and so will improve overall care of patients receiving blood transfusions.

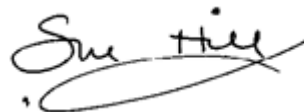
Further information on this programme for hospitals and patients can be found [here](#). If you have any questions please contact molecular.diagnostics@nhsbt.nhs.uk

With our grateful thanks for your support

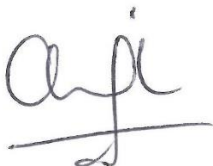
Yours sincerely,



Professor Bola Owolabi
Director of National Healthcare Inequalities Improvement
NHS England



Professor Dame Sue Hill
Chief Scientific Officer, England, Senior Responsible Officer for Genomics
NHS England



Dr Gail Miflin
Chief Medical Officer
NHS Blood and Transplant



Professor David Roberts
Medical Director, Pathology
NHS Blood and Transplant

Annex 1 – Test Request Form

Place labelled specimen in bag, remove protective strip, fold flap onto bag and seal firmly.

4A	MOLECULAR DIAGNOSTICS	Blood and Transplant
	Red Cell (HEA) and HLA typing for patients <small>Sickle cell, thalassaemia and rare inherited anaemia blood group genotyping programme https://www.nhsbt.nhs.uk/what-we-do/clinical-and-research/blood-group-genotyping/ See reverse of forms for sample labelling criteria</small>	

IMPORTANT: Ensure that the three points of identification used on this form and all samples match. Use BLOCK CAPITALS to complete. Refer to reverse of form for sample labeling criteria.

Essential information included in this box must be completed, or the sample may not be tested.

Patient Details	Requester Details
Surname <input style="width: 90%;" type="text"/>	Name of Requester <input style="width: 90%;" type="text"/>
Forename <input style="width: 90%;" type="text"/>	Department <input style="width: 90%;" type="text"/>
NHS No. <input style="width: 20%;" type="text"/> <input style="width: 20%;" type="text"/> <input style="width: 20%;" type="text"/> <input style="width: 20%;" type="text"/>	Hospital Name, Full Address and ODS code† <input style="width: 95%;" type="text"/> <input style="width: 95%;" type="text"/> <input style="width: 95%;" type="text"/>
Hospital number <input style="width: 20%;" type="text"/> <input style="width: 20%;" type="text"/> <input style="width: 20%;" type="text"/> <input style="width: 20%;" type="text"/> <input style="width: 20%;" type="text"/> <input style="width: 20%;" type="text"/>	
Male <input type="checkbox"/> Female <input type="checkbox"/>	
Sex at birth: <input style="width: 90%;" type="text"/>	
DOB DD/MM/YY <input style="width: 10%;" type="text"/> <input style="width: 10%;" type="text"/> <input style="width: 10%;" type="text"/> <input style="width: 10%;" type="text"/> <input style="width: 10%;" type="text"/> <input style="width: 10%;" type="text"/>	
Sample date DD/MM/YY <input style="width: 10%;" type="text"/> <input style="width: 10%;" type="text"/> <input style="width: 10%;" type="text"/> <input style="width: 10%;" type="text"/> <input style="width: 10%;" type="text"/> <input style="width: 10%;" type="text"/>	
<i>This service is for NHS patients only.</i>	
Tick to confirm that the patient has consented to the tests being undertaken <input type="checkbox"/> (see reverse for further information) I acknowledge that by making this referral, I am agreeing to NHSBT's terms and conditions, [#] subject to NHSBT's acceptance of the contents of this request form.	

Hospital sample ID <input style="width: 90%;" type="text"/>	Name of Consultant <input style="width: 90%;" type="text"/>
Sample time taken <input style="width: 10%;" type="text"/> : <input style="width: 10%;" type="text"/>	Contact Email address <input style="width: 90%;" type="text"/>
Ethnicity*: Please select ethnicity <input style="width: 90%;" type="text"/>	Additional relevant clinical information: <input style="width: 95%; height: 100%;" type="text"/>
<i>*Please indicate if not provided</i>	
Complete for potential sibling stem cell donors (Name of sibling and DoB) <input style="width: 90%;" type="text"/> <input style="width: 90%;" type="text"/>	

Samples included - Please supply relevant information as required

6ml EDTA – Adult/ child over 12 years 2ml EDTA – 6 months to 12 years 1-2ml EDTA – under 6 months

Regular transfusion programme: Yes No

If Yes, please indicate if simple transfusion or exchange transfusion

Please select one option: Sickle Cell Rare inherited anaemia Thalassaemia

For urgent red cell genotyping, use FRM4738 <https://tinyurl.com/5n8bn4cf>

For urgent HLA typing for stem cell transplantation, use form 3C <https://tinyurl.com/h-i-forms>

NHSBT use only

FRM7257/2	ISBT 128 label (Molecular)	ISBT 128 label (Serological)	Number of each sample received <input style="width: 30px;" type="text"/> EDTA Comments:	Signature Date Received

For Your Information: Send all samples at ambient temperature

Address all samples to **"Molecular Diagnostics - Diagnostic Specimens"** and use the correct address for the laboratory.

NHSBT CENTRE	ADDRESS	Phone - LAB
Filton	500 North Bristol Park, Northway, Filton, Bristol, BS34 7QH	0117 921 7572

These tests are being made available for patients with sickle cell, thalassaemia and rare inherited anaemias (where the patient is transfusion dependent) ONLY at this time. Results will not be available immediately. For urgent testing send samples via the established routes. These tests are being provided free of charge for NHS patients, funded by NHSE. More information can be found at <https://www.nhsbt.nhs.uk/what-we-do/clinical-and-research/blood-group-genotyping/>

Consent

Where consent is required for an investigation or to comply with the Human Tissue Act (2004) legislation it is the responsibility of the requester submitting a sample, to ensure that any patient has been informed of, and has provided valid consent to all the tests being requested including genetic tests in accordance with current guidance and legislation. The requester may be asked to provide a copy of this valid consent. Consent for the use of any data and investigations using surplus sample for scheduled purposes (quality assurance, education or training relating to human health or ethics committee approved research) should be obtained by the requester. If one or more tests are declined this must be made clear on the accompanying request form.

Patients should be informed that a sample may be stored as part of required archiving protocols or to enable further investigation for the benefit of the individual. Surplus sample or data may be used anonymously for quality assurance, education or training relating to human health or ethics committee approved research. If the patient refuses consent for the use of surplus sample for these purposes, such refusal of consent must be properly recorded by the requester on the request form and communicated to NHSBT at the time the sample is sent to NHSBT.

The primary reason for testing is to determine blood group and Human Leucocyte Antigen (HLA) types. Relevant findings will be reported to the NHS referring team for clinical care and added to electronic patient records. The British Society for Genetic Medicine and Royal College of Pathologists Guidance on Consent and Confidentiality in Genomic Medicine will be followed (<https://www.rcpath.org/static/d3956d4a-319e-47ca-8ece8a122949e701/Consent-and-confidentiality-in-genomic-medicine-July-2019.pdf>).

IMPORTANT: Sample labelling / completion of request form

Three points of identification must be used on the form and on the sample tubes (tube and form details must agree):

1. Forename AND surname **2.** Date of birth **3.** NHS number (mandatory requirement and **must** be provided).

Further copies of this form can be obtained from: <https://tinyurl.com/5n8bn4cf>

Sample Requirements

Blood:

6ml EDTA for Adults/children over 12 years

2ml EDTA 6 months-12 years

1-2ml EDTA for under 6 months

Note: Additional samples may be requested to perform supplemental tests for complex cases. The laboratory will contact you if necessary.

Blood sample integrity, storage & transportation

Samples should be transported at ambient temperature and delivered to the laboratory in a timely manner preferably within 24 hours of collection to ensure sample age is not a limitation factor for testing.

Prior to transportation, samples can be stored at 4°C before sending. Samples must be labelled and packaged as Biological Substance Category B, UN 3373 and must meet PI650. Samples must reach the laboratory in time to be processed during laboratory working hours: Monday to Friday 07:00-18:00 and Saturday 07:00-16:00.

Further information

All information provided to NHS Blood and Transplant is used in accordance with the General Data Protection Regulation (GDPR) and all other applicable privacy legislation. For more information on how we look after personal details or to find out more about privacy rights visit www.nhsbt.nhs.uk/privacy or call 0300 123 23 23.

NHSBT is committed to keeping data safe and confidential.

NHSBT H&I information can be found at <https://tinyurl.com/y4xre49f>

*ODS code refers to the NHS Hospital location code, previously known as the NACS organisation code or NHSIA location code eg RJ701 or RQ8MY.

*NHSBT terms and conditions <https://tinyurl.com/yc4jddcj>