Policy

This policy describes the processes required for reporting deceased donor Human Leucocyte Antigen (HLA) results to NHSBT-Organ and Tissue Donation and Transplantation (NHSBT-OTDT) by Histocompatibility and Immunogenetics (H&I) laboratories.

Objective

The purpose of this document is to provide an overview of the processes available to H&I laboratories for reporting deceased donor HLA results to NHSBT OTDT Hub Operations. It outlines the requirements for submitting HLA information used in deceased donor characterisation and organ offering (i.e. offer types), as well as for reporting revised types and re-types (i.e. confirmatory types).

This document is intended to support local laboratory documentation.

Changes in this version

New document. This document replaces **SOP5038**.

Roles

- **H&I Scientist(s)** to provide accurate HLA results and to assist with the resolution of any HLA consistency failures. To provide the OAS with further instruction as necessary.

- **H&I Consultant(s)** to assist with resolution of OAS HLA queries via the H&I Scientist. May be locally delegated to a Senior Clinical Scientist.

- **Organ Allocation Specialist (OAS; NHSBT-OTDT Hub Operations)** to accurately enter deceased donor characterisation HLA offer types onto the National Transplant Database (NTxD) where DCERT automated input was not possible. To report any NTxD consistency failures to the submitting laboratory for resolution.

- **Specialist Nurse (SN)** to request HLA typing of potential deceased donors from H&I laboratories and provide clarification on any queries regarding patient (donor) identifiable data (PID). These tasks may be completed by a Specialist Nurse in Organ Donation (SNOD) or a Specialist Requestor (SR).

Introduction

HLA information reported to NHSBT-Organ and Tissue Donation and Transplantation (NHSBT-OTDT) is stored within the National Transplant Database (NTxD). Only the first HLA allele/antigen reported by the donor characterisation H&I laboratory is used by the organ offering algorithm. Additional HLA information submitted via DCERT, or **FRM4365**, is stored in a separate field within NTxD. A reference list of NTxD accepted alleles is available.

The H&I Scientist, in consultation with an H&I Consultant (or designated deputy) if required, is responsible for determining the appropriate HLA assignment to support the safe offering and

transplantation of organs. H&I Scientists submitting donor characterisation HLA information to NHSBT-OTDT must understand the clinical significance of the information reported. This includes recognition where the HLA typing string includes a rare lower denomination allele and/or has an ambiguous serological assignment (including null alleles) that could lead to inappropriate decisions in organ offering/acceptance. Examples of this include HLA-DQB1*03:02:02:01d/03:04:01:01/XX (i.e. DQ8 versus DQ7, respectively) and HLA-DRB4*01:03:28/01:03:01:02N/XX (i.e. DR53 versus DR53N).

Patient identifiable information (PID) for donor characterisation is provided by the Specialist Nurse (SN) to the H&I laboratory via the HLA Typing Request form (**FRM4279**) and entered onto the NHSBT IT system. The H&I laboratory must contact the SN using the information provided on the request form (**FRM4279**) where PID clarification is required. All PID provided on **FRM4279** should be included on the HLA report (DCERT or **FRM4365**) submitted to NHSBT-ODT.

Any issues with PID, failure of communication with the laboratories (e.g. not notified of sample) or issues with sample transport should be logged as a NHSBT Clinical Incident. Where the H&I laboratory is unable to fulfil donor characterisation HLA typing then follow the guidance in **SOP5546**.

This document provides information/guidance to assist with reporting:

1. Deceased Donor HLA results to NHSBT-OTDT for:

1.1 Donor characterisation (offer) HLA type via DCERT

1.2 Donor characterisation (offer) HLA type via FRM4365

1.3 Revised HLA offer type – identified by donor characterisation H&I laboratory

1.4 Revised HLA offer type – identified by recipient H&I Laboratory

1.5 Peri/post-transplant HLA re-typing (verification/confirmatory) via FRM4365

2. Additional guidance is provided for approaches to reporting ambiguous/unresolved HLA types:

2.1 HLA-DPB1 – unable to resolve

2.2 Rare allele – not accepted by NTxD

2.3 Serological ambiguity

2.4 Consistency check failure

Wherever possible, a copy of the laboratory analyser report should be provided to NHSBT-OTDT at the time of reporting a donor characterisation (offer), or revised offer type, to provide additional information for the recipient centre(s).

1. Deceased Donor HLA result reporting:

1.1 Reporting donor characterisation (offer) HLA type via DCERT:

PLEASE NOTE:

*The Donor Characterisation Electronic Results Transfer (DCERT) tool is only available for the submission of deceased donor characterisation (i.e. offer) HLA types. NTxD is only able to accept a single HLA result entry via DCERT. Any additions or amendments to a previously successful submission must be made manually by the Hub OAS via **FRM4365** [Section 1.3]. DCERT cannot be used to submit re-type HLA results*

Upon successful submission to DCERT, the HLA results PDF will be available to view on TransplantPath. However, in the event a revised report is submitted, the initial report remains on TransplantPath and cannot be removed, replaced or amended by NHSBT-OTDT Hub - deletion by the NHSBT Database Team will be requested by the Scientific Support team.

Following appropriate validation, DCERT files containing HLA results may be sent from donor characterisation H&I laboratories to NHSBT systems via Secure File Transfer Protocol (SFTP) or Secure Data Interchange (SDI). Upon receipt by NHSBT, automated checks are performed to verify appropriate format and content of the file. The Patient (Donor) Identifiable Data (PID) provided by the laboratory are then used to match with pre-registered deceased donor records in the NHSBT National Transplant Database (NTxD). Where content is accepted, PID is concordant, and HLA results are not already held in NTxD, the HLA results are automatically loaded into the NTxD database. Once the file is successfully loaded, a notification email and/or SMS is sent to the H&I laboratory, alongside a PDF copy of the results that were added to NTxD [**APPENDIX 4**].

If the DCERT file fails to load, a notification email is sent to the laboratory detailing the reason for the failure. Further information to help resolve these issues is available in the DCERT Troubleshooting Guide. **Please note: individual accounts for FutureNHS must be setup in advance to enable access this trouble shooting guide** – please ensure this is setup for all staff who may need future access out of hours by contacting the DCERT team (DCERT@nhsbt.nhs.uk).

H&I Scientist Guidance:

- Do not submit results to NHSBT until formal written consent has been confirmed by the Specialist Nurse (SN). A donor record is not created in NTxD until consent has been recorded in DonorPath. Any DCERT files received for non-consented donors will be auto-rejected.
- For any queries regarding patient (donor) identifiable data (PID), contact the SN to confirm how the data has been recorded in DonorPath. For DCERT submission to be successful, all PID details must be identical (including any middle names). For example, if “Anne-Marie” is held within NTxD then “Anne Marie” without the “-“ will not be accepted.
- When attaching PDF documents to DCERT (e.g. laboratory analyser output), ensure that the correct document is being attached. If an error does occur, then follow the steps outlined in Section 1.3 to provide NHSBT-OTDT Hub Operations with a revised offer type.
- Once HLA results have been submitted via DCERT and a confirmation email/text [**APPENDIX 4**] has been received then call NHSBT-OTDT Hub Operations (**01179 757580**) to advise that the

HLA data has been uploaded to NTxD. Failure to notify NHSBT-OTDT Hub Operations could lead to delay in the organ offering process.

- If an error message is received, refer to the DCERT Troubleshooting Guide for further information prior to resubmitting the file. If the file has failed due to a consistency check, then the scientist may resolve and re-send via DCERT. Contact NHSBT Service Desk on **0300 200 0173** for IT support, if needed. Please also report any issues via email to DCERT@nhsbt.nhs.uk with screenshots (if available) to be investigated by the NHSBT DCERT team the next working day.
- If the laboratory has not received a confirmation email/text within 15 minutes of submission, then the scientist should contact NHSBT-OTDT Hub Operations to confirm whether results were received into NTxD. If DCERT has been unsuccessful, and no error message(s) have been received, then the scientist must re-submit the HLA type using **FRM4365** [see Section 1.2].

1.2 Reporting donor characterisation (offer) HLA type via FRM4365:

PLEASE NOTE:

This process should be used for routine reporting of donor characterisation (offer) types where DCERT is not available.

***FRM4365** must always be used to submit revised offer or re-type HLA results. Ensure that the current version of **FRM4365** is used – this is available to download via: http://www.odt.nhs.uk/transplantation/pathology-services/histocompatibility-and-immunogenetics Where local versions of **FRM4365** are used, the format and content must correspond to the current NHSBT document controlled current version.*

H&I Scientist Guidance:

- Complete **FRM4365** (refer to guidance in **APPENDIX 1**) selecting "**Donor Centre OFFER TYPE**". This indicates to NHSBT-OTDT Hub Operations that this HLA type is required for the organ offering process.
- Submit a PDF/read-only version of the final/checked version of **FRM4365** via email to odthub.operations@nhsbt.nhs.uk alongside the laboratory analyser output report (scientist must confirm the correct files are attached to email prior to sending).
- Call NHSBT-OTDT Hub Operations to confirm that the email has been received (**01179 757580**).
- The ODT Hub OAS will aim to enter HLA results into NTxD within 20 minutes of receipt. The H&I scientist will be contacted by the OAS if there is a failure of the automated consistency checks [**APPENDIX 2 and APPENDIX 3**]. If applicable, the H&I Scientist must resolve any issues identified by the OAS; assistance from an H&I Consultant (or Senior Scientist) may be required.

OAS Process:

- To contact the H&I laboratory scientist if there is a failure of the automated consistency checks on the HLA type reported via **FRM4365**.

1.3 Reporting a revised HLA offer type via FRM4365 – identified by Donor Characterisation H&I Laboratory:

PLEASE NOTE:

This process should be used for reporting of revised donor characterisation types by the donor characterisation H&I laboratory. Recipient laboratories should follow process described in Section 1.4.

All revised HLA donor types will be checked by NHSBT-OTDT Scientific Support Services within five working days of submission. Any revised HLA types impacting on offering/compatibility will be logged as a potential Clinical Incident by the Scientific Support team. Information on revised HLA reports will be included in the H&I report for the NHSBT Clinical Audit, Risk and Effectiveness (CARE) Group and in the "HLA typing discrepancies pre and post allocation" annual paper.

Donor Characterisation H&I Scientist Guidance:

- Where the offer HLA type (including laboratory analyser report) requires amendment then advise NHSBT-OTDT Hub Operations (**01179 757580**) as soon as possible. The H&I Scientist must provide guidance to NHSBT-OTDT Hub Operations on the impact of the amendment (e.g. any impact on organ offering).
- Complete **FRM4365** (refer to guidance in **APPENDIX 1**) selecting "**Donor Centre REVISED TYPE**". This indicates to NHSBT-OTDT Hub Operations that a revised HLA type is being submitted and that further action may be needed.
- Enter an explanation of the reason(s) why a revised HLA type is being issued into the "Comments" box on **FRM4365** (e.g. "HLA-DPB1 results now available" or "PID updated") for recipient H&I laboratory information.
- Submit **FRM4365** via email to odthub.operations@nhsbt.nhs.uk alongside a copy of the laboratory analyser output. Call NHSBT-OTDT Hub Operations to confirm that the email has been received (**01179 757580**).

OAS Process:

- Contact the H&I laboratory scientist if there is a failure of the automated consistency checks on the HLA type reported via **FRM4365**.
- If the revised donor type is received within 18 hours of the original type, then consider re-initiating the offering algorithm as per the NHSBT-OTDT Hub Operations Manual.
- NHSBT-OTDT Hub Operations to inform all organ recipient centres (where relevant) of the updated HLA report and email a copy to recipient H&I laboratories.
- To forward copies of the revised type to Scientific Support for checking during routine hours.

1.4 Reporting a revised HLA offer type via FRM4365 – identified by Recipient H&I Laboratory:

PLEASE NOTE:

This process should be used for reporting a discrepancy between the offer HLA type and the results obtained by a recipient H&I laboratory.

*A revised HLA type is only required where HLA confirmatory data identifies an allele that was not present in the donor characterisation laboratory analyser report. Please refer to **APPENDIX 5** for worked examples. Scientific Support (ScientificSupportOTDT@nhsbt.nhs.uk) may be contacted for guidance.*

All revised HLA donor types will be checked by NHSBT-OTDT Scientific Support Services within five working days of submission. Revised HLA types impacting on offering/compatibility will be logged as potential Clinical Incident by the Scientific Support team. Information on revised HLA reports will be included in the H&I report for the NHSBT Clinical Audit, Risk and Effectiveness (CARE) Group and in the "HLA typing discrepancies pre and post allocation" annual paper.

Recipient H&I Scientist Guidance:

- Contact the donor characterisation H&I laboratory to discuss and attempt to resolve the identified discrepancy.
- If the discrepancy is confirmed with the donor characterisation H&I laboratory, then complete **FRM4365** (refer to guidance in **APPENDIX 1**) selecting the "**Recipient Centre REVISED TYPE**" option and email to NHSBT-OTDT Hub Operations.
- Enter an explanation of the need for a revised HLA type into the "Comments" box (e.g. "HLA-A results updated")
- Submit **FRM4365** via email to odthub.operations@nhsbt.nhs.uk.

Donor Characterisation H&I Scientist Guidance:

- Inform NHSBT-OTDT Hub Operations (**01179 757580**) that a revised report has been agreed and will be submitted via **FRM4365**.
- Complete **FRM4365** (refer to guidance in **APPENDIX 1**) selecting the "**Donor Centre REVISED TYPE**" option.
- Enter an explanation of the need for a revised HLA type into the "Comments" box (e.g. "HLA-A results updated as agreed with recipient laboratory XX")
- Submit **FRM4365** via email to odthub.operations@nhsbt.nhs.uk.

OAS Process:

- If the revised donor type is received within 18 hours of the original type, then consider need to re-run the offering algorithm as per the NHSBT-OTDT Hub Operations Manual.
- To forward copies of the revised types to Scientific Support for checking during routine hours.

1.5 Reporting a deceased donor HLA re-type (verification/confirmatory) via FRM4365:

PLEASE NOTE:

No immediate action will be taken by NHSBT-OTDT Hub Operations upon receipt of an HLA re-type report. These are reviewed periodically by Scientific Support.

This process should be used for reporting a re-type (verification/confirmatory) deceased donor HLA type to NHSBT-OTDT Hub Operations.

H&I Scientist Guidance:

- Complete **FRM4365** (refer to guidance in **APPENDIX 1**) selecting "**HLA RE-TYPE**".
- Submit **FRM4365** via email to odthub.operations@nhsbt.nhs.uk indicating that this is an HLA re-type.

OAS Process:

- To forward the re-type to Scientific Support for checking during routine hours.

2 Guidance for ambiguous/unresolved HLA types (including rare HLA-DPB1 results):

2.1 HLA-DPB1 deceased donor characterisation – unable to resolve:

As per **SPN1439**, HLA-A, -B, -C, -DRB1, -DRB3/4/5 (or -DR51/52/53) and -DQ reporting are mandatory for 100% of deceased donor characterisation types. Whilst HLA-DP reporting is also mandatory, it is acknowledged that it is not always possible to resolve HLA-DPB1 results within the target reporting turnaround time and therefore HLA reports will be accepted without HLA-DPB1, by exception (target >95%).

If HLA-DPB1 cannot be satisfactorily resolved, then the donor characterisation offer HLA report may be submitted without HLA-DPB1 results to avoid delays in organ offering. Any useful information related to HLA-DPB1 should be captured in the comments box (DCERT or **FRM4365**) for the recipient laboratories. If results become available later, these results can be submitted to NHSBT-OTDT Hub Operations using **FRM4365** following the "**revised HLA offer type**" instructions [Section 1.3].

2.2 Rare allele – not accepted by NTxD:

The current NTxD HLA database has limited capacity. Rarer HLA alleles may not be present in the database and therefore not reportable to NHSBT-OTDT. For deceased donor HLA characterisation, this may cause the HLA type to be auto rejected (by DCERT) or by the OAS at the point of input (**FRM4365**). A reference list of NTxD accepted alleles is available online at https://dcertrefdataprod.blob.core.windows.net/refdata/DCERT-hla-type-reference-data.html.

Rare allelic results rejected by NTxD should be redacted to an acceptable HLA equivalent (e.g. HLA-A*01:168 to be reported as HLA-A*01; HLA-DQB1*03:170 to be reported as HLA-DQB1*03) and resubmitted via DCERT**/FRM4365**. A comment should be added to highlight that a rare allele has been identified but cannot be reported.

For rare HLA-DPB1 alleles rejected by NTxD, it has been agreed by H&I Consultant consensus that HLA-DPB1 results should not be submitted. The following standard comment must be added to the report (DCERT/**FRM4365**):

> ***"IMPORTANT - HLA-DPB1 results have not been uploaded to NTxD due a rare/novel allele having been identified. Please refer to the attached analyser output for further details"***

2.3 Serological ambiguity:

Where a serological ambiguity has been identified in an HLA typing result, or the potential combination of alleles crosses more than one broad/split antigen (or serological equivalent) then it is the responsibility of the laboratory H&I Scientist, in conjunction with the H&I Consultant (or Senior Scientist) to make a decision regarding how the HLA results should be reported in order to support the safe offering and transplantation of organs to national recipients.

2.4 Consistency check failure:

If an inconsistency error [**APPENDIX 2**] is generated for an offer type received via **FRM4365** then NHSBT-OTDT Hub Operations OAS will contact the H&I laboratory and request that the laboratory resolve the error and submit a revised HLA type to NHSBT-OTDT following the process described in Section 1.3.

If the laboratory H&I scientist is unable to resolve the error, they must contact their H&I Consultant (or designated deputy) for advice and resolution. If the HLA type is correct (e.g. with an unusual HLA association), then the Head of Laboratory (or designated deputy) may provide written authorisation (i.e. email) to authorise the OAS to over-ride the consistency check and initiate the organ offering process with the HLA type as reported.

Definitions

- **DCERT** = Donor Characterisation Electronic Results Transfer
- **H&I** = Histocompatibility and Immunogenetics
- **HLA** = Human Leucocyte Antigen
- **NHSBT** = NHS Blood and Transplant
- **NTxD** = National Transplant Database
- **OAS** = Organ Allocation Specialist
- **ODT** = Organ Donation and Transplant
- **OTDT** = Organ Donation, Tissue and Transplantation
- **PID** = Patient (Donor) Identifiable Information
- **SN** = Specialist Nurse
- **SNOD** = Specialist Nurse for Organ Donation
- **SR** = Specialist Requestor
- **WHO** = World Health Organization

Related Documents / References

- **SPN1439** – Donor Characterisation Commissioning Service Specification
- **SOP5546** – H&I/Virology laboratory – operational disruption
- **INF1466** – Back-up Laboratories for Deceased Donor Tissue Typing Testing
- **INF1713** – Out of hours contact details for back-up laboratories
- **FRM4279** – HLA Typing Request *[internal document]*
- **DAT2885** – Minimum Resolution Requirements for Donor and Patient HLA types
- **HLA conversion chart for organ allocation**
- **INF1766** – Unacceptable Antigen Mapping Chart
- **FRM4365** – National Transplant Database HLA Report

Email addresses:

- **ODT Hub Operations (24-7)** – odthub.operations@nhsbt.nhs.uk (**T: 01179 757580)**
- **DCERT team (office hours only)** – DCERT@nhsbt.nhs.uk
- **Scientific Support team (office hours only)** – ScientificSupportOTDT@nhsbt.nhs.uk

Useful Links

- **DCERT FutureHealth page**
  https://future.nhs.uk/donorcharacterisationert
  [Please note it is necessary setup an individual account in advance to gain access to this website]
- **NHSBT-ODT Clinical H&I webpage**
  https://www.odt.nhs.uk/transplantation/pathology-services/histocompatibility-and-immunogenetics/
- **NHSBT-ODT Clinical Incident reporting**
  https://www.odt.nhs.uk/odt-structures-and-standards/clinical-governance-and-patient-safety/tell-us-about-an-incident/
- **NHSBT-ODT Clinical Procedural documents**
  https://www.odt.nhs.uk/deceased-donation/best-practice-guidance/procedural-documents/
- **NTxD Allele List (DCERT)**
  https://dcertrefdataprod.blob.core.windows.net/refdata/DCERT-hla-type-reference-data.html
- **NTxD Hospital Code list**
  https://dcertrefdataprod.blob.core.windows.net/refdata/DCERT-hospital-code-reference-data.html

Appendices

- **APPENDIX 1** – H&I Scientist guidance for completion of FRM4365
- **APPENDIX 2** – NTxD HLA Automated Consistency Checking Process
- **APPENDIX 3** – Examples of consistency checking process failures
- **APPENDIX 4** – DCERT Examples
- **APPENDIX 5** – Revised HLA type guidance

APPENDIX 1 – H&I Scientist guidance for completion of FRM4365:

- Enter H&I laboratory/centre information and contact details.
- Enter donor demographic information (please enter all PID provided on **FRM4279**).
- Identify and select the appropriate report type:
    - Donor Centre OFFER TYPE [Section 1.2]
    - Donor Centre REVISED TYPE [Section 1.3]
    - Recipient Centre REVISED TYPE [Section 1.4]
    - Peri/post-transplant HLA RE-TYPE (i.e. confirmatory) [Section 1.5]
- Enter date and time of report submission/completion.
- Enter the donor HLA type in compliance with the minimum typing requirements (as specified in **DAT2885**) including:
    - ensure that any HLA information entered in the “broad”, “split” and “allele” sections is appropriate [**APPENDIX 3**].
    - only molecular information may be entered into the “allele” box. The asterix “*” is not required.
    - valid (current) WHO HLA nomenclature must be used.
    - HLA-DQA1* and HLA-DPA1* results may be provided but this information is not entered into NTxD and is for recipient H&I information only.

  Please note that:
    - NTxD will “map” alleles to the antigens used in the organ allocation process as per the “HLA Conversion Chart for Organ Allocation”.
    - Bw4 and Bw6 information is only required in relation to the HLA-B locus for HLA typing. HLA-A antigens with the Bw4 motif (as per **INF1766**) are excluded at the point of offering where the recipient has Bw4 listed as an unacceptable antigen.
- Enter method(s) used for HLA typing.
- Include any additional information in the “comments” box that would be helpful for recipient H&I laboratories. This information cannot be entered into NTxD or included in organ offering but provides supporting information.
- Once finalised, make the form read only (e.g. print to PDF) ready for submission.

APPENDIX 2 – NTxD HLA Automated Consistency Checking Process:

The NTxD automated process checks HLA consistency according to the following six rules:

Rule 1	**There is consistency between HLA broad/split antigens/alleles** [**APPENDIX 3 - EXAMPLE 1**] **Valid HLA WHO nomenclature is used** [**APPENDIX 3 - EXAMPLE 2**] *If there is inconsistency between broad antigens/split antigens/alleles or invalid nomenclature is used, then the HLA type cannot be entered into the NTxD database.*
Rule 2	**No more than two antigens/alleles can be reported at a single locus** *If more than two antigens or alleles are reported at a single locus, the HLA type cannot be entered into the database.*
Rule 3	**Bw4/Bw6 antigen associations must be consistent with HLA B locus antigens/alleles** [**APPENDIX 3 - EXAMPLE 3**] *Unsuccessful consistency checking via **FRM4365** submission generates the following error message for ODT-Hub OAS:* *"The reported HLA type displays an unlikely Bw4/Bw6 association with reported B locus antigens. Please check HLA type*"
Rule 4	**DR51/51N/52/53/53N antigen associations must be consistent with HLA-DR locus antigens/alleles** [**APPENDIX 3 - EXAMPLE 4**] *Unsuccessful consistency checking via **FRM4365** submission generates the following error message for ODT-Hub OAS:* *"The reported HLA type displays an unlikely DR51/52/53 or DRB3*/4*/5* association with reported DR locus antigens. Please check HLA type"*
Rule 5	**DRB3/4/5 allele associations must be consistent with HLA-DR locus antigens/alleles and DR51/51N/52/53/53N antigens.** [**APPENDIX 3 - EXAMPLE 5**] *Unsuccessful consistency checking via **FRM4365** submission generates the following error message for ODT-Hub OAS:* *"The reported HLA type displays an unlikely DR51/52/53 or DRB3*/4*/5* association with reported DR locus antigens. Please check HLA type"*
Rule 6	**At least one specificity must be reported at the HLA- A, B, C, DRB1 and DQB1 loci** *Unsuccessful consistency checking via **FRM4365** submission generates the following error message for ODT-Hub OAS:* *"At least one allele/antigen must be declared at the HLA-XXXX locus"*

APPENDIX 3 – Examples of consistency checking process failures

APPENDIX 3 – EXAMPLE 1 – Rule 1: There is consistency between HLA broad antigens/split antigens/alleles.

HLA donor characterisation (offer) type submitted**:**

HLA TYPE

HLA	HLA broad specificity	HLA split specificity	HLA allele(s)	HLA broad specificity	HLA split specificity	HLA allele(s)	Bw4/Bw6	DR51/51N/52/53/53N
-A	2		02	9	25	25		
-B	8		08	35		35	Bw6	
-DR	103		01:03	3	17	03		DR52
-Cw	4		04	7		07		
-DQB1	1	5	05:01-04	2		02:01-04		
-DRB3 alleles	01-03			-DRB4 alleles				
-DRB5 alleles								
-DPB1			01:01			02:01		

The OAS will be unable to enter this type as there is **inconsistency between A9/A25/A*25**.

The HLA type was reviewed by laboratory and a revised type emailed to NHSBT-OTDT Hub Operations:

HLA TYPE

HLA	HLA broad specificity	HLA split specificity	HLA allele(s)	HLA broad specificity	HLA split specificity	HLA allele(s)	Bw4/Bw6	DR51/51N/52/53/53N
-A	2		02	10	25	25		
-B	8		08	35		35	Bw6	
-DR	103		01:03	3	17	03		DR52
-Cw	4		04	7		07		
-DQB1	1	5	05:01-04	2		02:01-04		
-DRB3 alleles	01-03			-DRB4 alleles				
-DRB5 alleles								
-DPB1			01:01			02:01		

APPENDIX 3 – EXAMPLE 2 – Rule 1: Valid WHO nomenclature is used

HLA donor characterisation (offer) type submitted**:**

HLA TYPE

HLA	HLA broad specificity	HLA split specificity	HLA allele(s)	HLA broad specificity	HLA split specificity	HLA allele(s)	
-A			01			02	
-B			08			62	Bw4/Bw6: 6
-DR			04				DR51/51N/52/53/53N: DR53
-Cw			03:03/11/13			07	
-DQB1			0301			03:02	
-DRB3 alleles				-DRB4 alleles	01		
-DRB5 alleles							
-DPB1			02:01			04:01	

The OAS will be unable to enter this type as **B*62 is invalid nomenclature**. Please note that **DQB1*0301** would be accepted as outdated WHO HLA nomenclature is currently still valid in the NTxD database, however, the donor laboratory would be contacted by Scientific Support retrospectively to advise that the incorrect nomenclature was used.

The HLA type was reviewed by laboratory and a revised type emailed to NHSBT-OTDT Hub Operations:

HLA TYPE

HLA	HLA broad specificity	HLA split specificity	HLA allele(s)	HLA broad specificity	HLA split specificity	HLA allele(s)	
-A			01			02	
-B			08			15:01/04/05/06	Bw4/Bw6: 6
-DR			04				DR51/51N/52/53/53N: DR53
-Cw			03:03/11/13			07	
-DQB1			03:01			03:02	
-DRB3 alleles				-DRB4 alleles	01		
-DRB5 alleles							
-DPB1			02:01			04:01	

APPENDIX 3 – EXAMPLE 3 - Rule 3: Bw4/Bw6 antigen associations must be consistent with HLA-B locus antigens/alleles

HLA donor characterisation (offer) type submitted**:**

HLA TYPE

HLA	HLA broad specificity	HLA split specificity	HLA allele(s)	HLA broad specificity	HLA split specificity	HLA allele(s)	
-A			02:01			11:01	
-B			39:01			44:02	Bw4/Bw6: 6
-DR			01:01			04:01	DR51/51N/52/53/53N:
-Cw			05:01			12:01	
-DQB1			05:01			03:01	
-DRB3 alleles				-DRB4 alleles	01		
-DRB5 alleles							
-DPB1			02:01			04:02	

HLA-B44 is not consistent with Bw6 and therefore an error message will be auto generated: *"The reported HLA type displays an unlikely Bw4/Bw6 association with reported B locus antigens. Please check HLA type"*

The HLA type was reviewed by laboratory and a revised type emailed to NHSBT-OTDT Hub Operations:

HLA TYPE

HLA	HLA broad specificity	HLA split specificity	HLA allele(s)	HLA broad specificity	HLA split specificity	HLA allele(s)	
-A			02:01			11:01	
-B			39:01			44:02	Bw4/Bw6: 4,6
-DR			01:01			04:01	DR51/51N/52/53/53N:
-Cw			05:01			12:01	
-DQB1			05:01			03:01	
-DRB3 alleles				-DRB4 alleles	01		
-DRB5 alleles							
-DPB1			02:01			04:02	

APPENDIX 3 – EXAMPLE 4 - Rule 4: DR51/51N/52/53/53N antigen associations must be consistent with HLA-DR locus antigens/alleles

HLA donor characterisation (offer) type submitted**:**

HLA TYPE

HLA	HLA broad specificity	HLA split specificity	HLA allele(s)	HLA broad specificity	HLA split specificity	HLA allele(s)	
-A	1		01	2		02:01	
-B	7		07	17	57	57	Bw4/Bw6: Bw4,6
-DR	2	15	15:01	4		04:01	DR51/51N/52/53/53N: DR53
-Cw	6		06	7		07	
-DQB1	1	6	06	3	7	03:01	
-DRB3 alleles				-DRB4 alleles			
-DRB5 alleles							
-DPB1			03:01			04:01	

DR15(2) is not consistent with DR53 (DR51 expected) and therefore an error message will be auto generated:
"The reported HLA type displays an unlikely DR51/52/53 or DRB3/4*/5* association with reported DR locus antigens. Please check HLA type"*

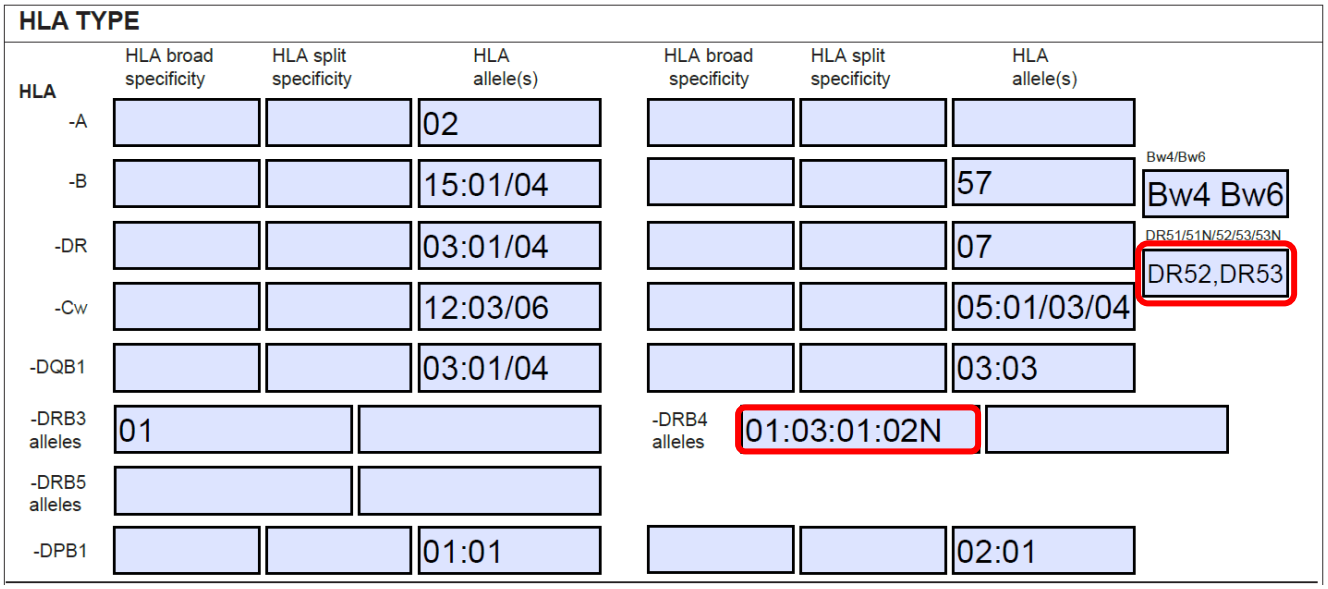
The HLA type was reviewed by laboratory and a revised type emailed to NHSBT-OTDT Hub Operations:

HLA TYPE

HLA	HLA broad specificity	HLA split specificity	HLA allele(s)	HLA broad specificity	HLA split specificity	HLA allele(s)	
-A	1		01	2		02:01	
-B	7		07	17	57	57	Bw4/Bw6: Bw4,6
-DR	2	15	15:01	4		04:01	DR51/51N/52/53/53N: DR51,53
-Cw	6		06	7		07	
-DQB1	1	6	06	3	7	03:01	
-DRB3 alleles				-DRB4 alleles			
-DRB5 alleles							
-DPB1			03:01			04:01	

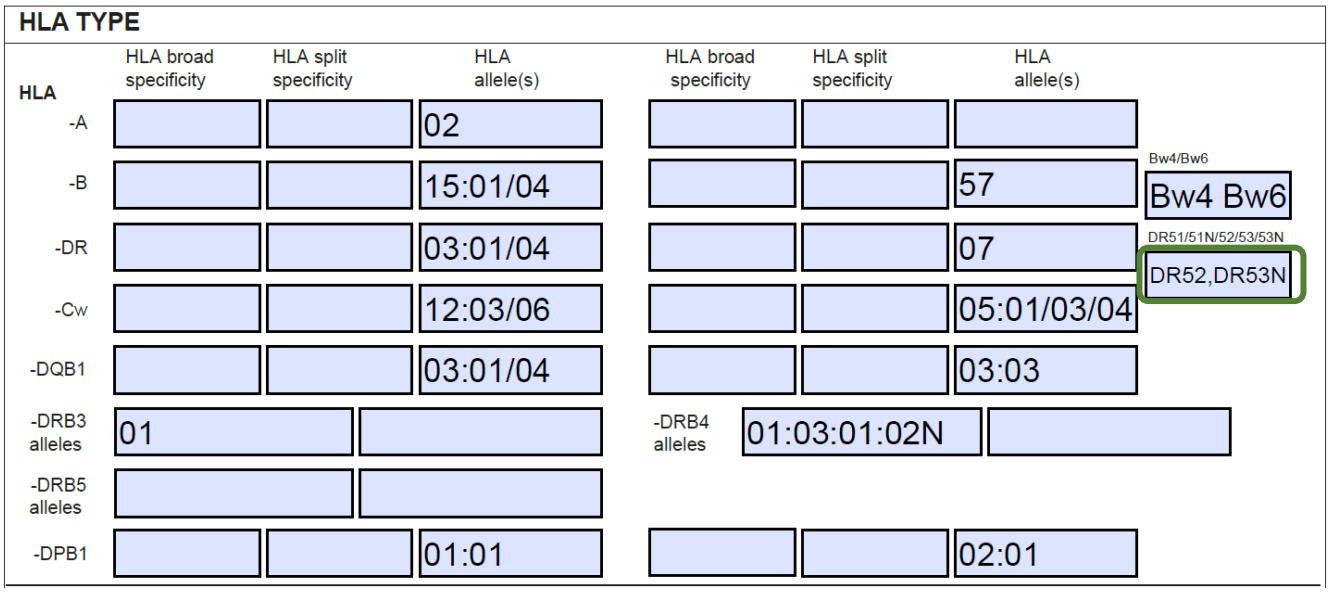
APPENDIX 3 – EXAMPLE 5 - Rule 5: DRB3/4/5 allele associations must be consistent with HLA-DR locus antigens/alleles and DR51/51N/52/53/53N antigens

HLA donor characterisation (offer) type submitted**:**



DRB4*01:03:01:02N is not consistent with DR53 and therefore an error message will be auto generated:
"The reported HLA type displays an unlikely DR51/52/53 or DRB3/4*/5* association with reported DR locus antigens. Please check HLA type"*

The HLA type was reviewed by laboratory and a revised type emailed to NHSBT-OTDT Hub Operations:



APPENDIX 4 – DCERT Examples

APPENDIX 4a – Example of the DCERT generated PDF report

Donor Characterisation - HLA Test Result

Patient Information

Test Subject Code	Deceased Organ Donor
First Name	AUTOLKTAR
Surname	DCERT
Date of Birth	26/09/1978
NHS/CHI/H&C Number	7027230151
Donor ID	[redacted]
Hospital Code	HE0101

HLA Test Results

Please note, only the 1st alleles in a likely string of alleles are displayed for each locus. See detailed analyser report attached for all possible alleles.

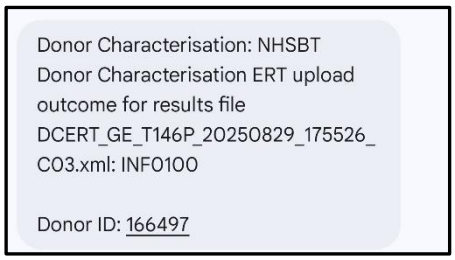
Lab Sample Identifiers	[redacted]
Results Complete Timestamp	
Results Type	HLA Donor Centre Offer Type
Comments	Detailed analyser output including results for DPA1 and DQA1 are attached at the end of this document.

HLA Locus	Broad 1	Split 1	Allele 1	Broad 2	Split 2	Allele 2
A			A*31:01			A*32:01
B			B*42:01			B*44:02
Bw						
C			C*05:01			C*17:01
DRB1			DRB1*10:01			DRB1*13:03
DRB3/4/5			DRB3*01			
DR51/52/53						
DQB1			DQB1*03:01			DQB1*05:01
DPB1			DPB1*02:01			DPB1*05:01

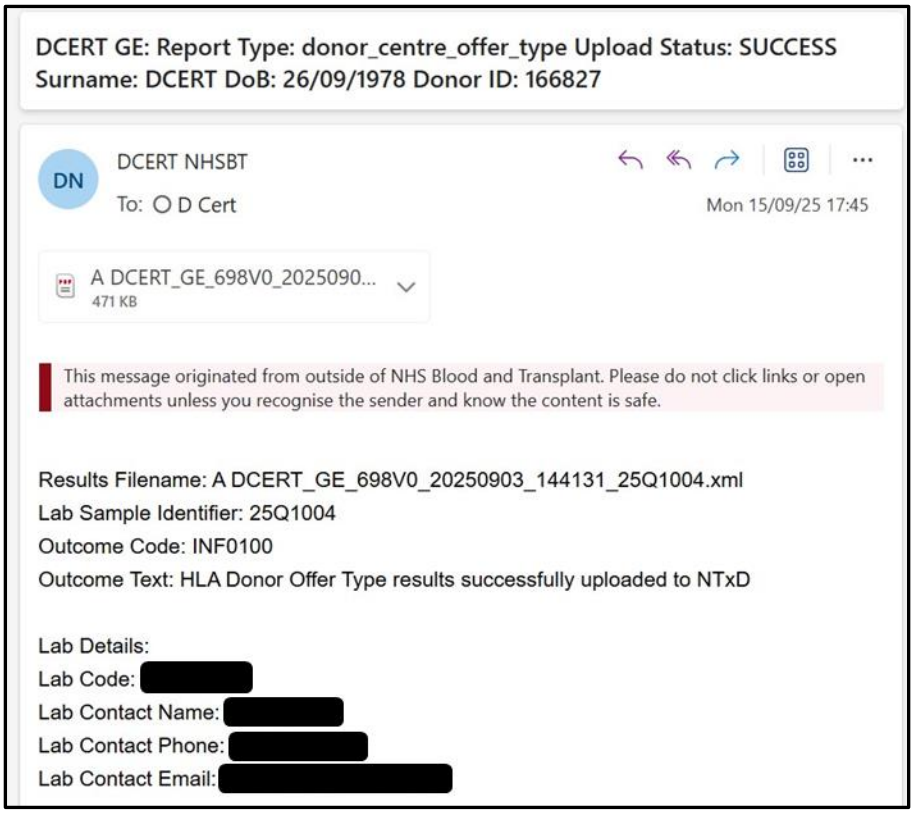
Testing Lab

Lab ID	[redacted]
Lab Name	[redacted]
Tested by	[redacted]
Results Signatory Name	[redacted]
Lab Contact Name	[redacted]
Lab Contact Email	[redacted]
Lab Contact Phone	[redacted]

APPENDIX 4b – Example of DCERT SMS Confirmation text:



APPENDIX 4c – Example of DCERT email confirmation:



APPENDIX 5 – Revised HLA type guidance

A revised HLA type investigation and report is only required where the re-type HLA results indicate the presence of an antigen/allele that was not present in the donor characterisation laboratory analyser report, or is inconsistent with the serological equivalent of the first allele reported in the allele string.

APPENDIX 5 – EXAMPLE 1 – No action needed – to be reported as a re-type (Section 1.5).

The following DCERT report was provided by the donor characterisation laboratory. This donor was reported as HLA-DPB1*03:01, -DPB1*04:01.

	HLA broad specificity	HLA split specificity	HLA allele(s)†	HLA broad specificity	HLA split specificity	HLA allele(s)†
HLA-A	2		*02:01/02/XX	19	29	*29:01/02/XX
HLA-B	7		*07:02/XX	12	44	*44:02/03/XX
HLA-DR	1		*01:01/02/XX	6	13	*13:03/07/XX
HLA-C	3	10	*03:02/04/XX	5		*05:01/XX
HLA-DQB1	3	7	*03:01/XX	1	5	*05:01/02/XX
HLA-DRB3	*01			HLA-DRB4		
HLA-DRB5						
HLA-DPB1			*03:01			*04:01

A recipient laboratory re-type indicated that the donor type was HLA-DPB1*04:01, -DPB1*124:01. Upon examination of the laboratory analyser output from the donor characterisation laboratory, the HLA-DPB1*124:01 was present in the -DPB1*03:01 string.

EPITYPE	ALLELES	HVR-A	HVR-B	HVR-C	HVR-D	HVR-E	HVR-F
EDP03	**DPB1*03:01:01:01**; DPB1*03:01:01:02e-DPB1*03:01:34e / DPB1*104:01:08e / DPB1*111:01e / DPB1*124:01e / DPB1*221:01e / DPB1*222:01e / DPB1*270:01e / DPB1*293:01e / DPB1*329:01e / DPB1*391:01e / DPB1*404:01e / DPB1*405:01e / DPB1*439:01e / DPB1*472:01e / DPB1*509:01e / DPB1*548:01e / DPB1*568:01e / DPB1*610:01e / DPB1*645:01e / DPB1*664:01e /	VYQL	EEFV	DED	LLEEK	V	DEAV

Therefore, the re-type is not in conflict with the donor characterisation type and not considered as discrepancy. It should be reported as a re-type following process in **Section 1.5**.

APPENDIX 5 – EXAMPLE 2 – Investigation required – follow process described in Section 1.4.

The following DCERT report was provided by the donor characterisation laboratory. This donor was reported as HLA-B*35:29 via DCERT with the accompanying laboratory analyser report:

HLA Locus	Broad 1	Split 1	Allele 1	Broad 2	Split 2	Allele 2
A			A*01:01			A*30:02
B			B*18:01			B*35:29
C			C*04:01			C*05:01
DRB1			DRB1*01:01			DRB1*03:01
DRB3/4/5			DRB3*02			
DQB1			DQB1*02:01			DQB1*05:01
DPB1			DPB1*02:02			DPB1*04:01

Group	Allele tolerance range: (0)	Serological eq.
B*18	**B*18:01:01:01**, 18:01:01:02-18:01:01:11, 18:01:01:12Q-18:01:01:41, 18:01:01:42Q-18:01:15, 18:01:17, 18:01:19-18:01:27, 18:01:29-18:01:35, 18:01:38-18:01:40, 18:01:43-18:01:49, 18:01:51-18:01:54, 18:01:56-18:01:60, **18:03:01:01**, 18:03:01:02-18:03:02, 18:05:01:01-18:06, 18:08, 18:18:01:01, 18:18:01:02, 18:24, 18:28, 18:31, 18:32, 18:34, 18:38, 18:39, 18:42, 18:45-18:47, 18:49, 18:51, 18:53, 18:55, 18:59, 18:60, 18:62-18:65, 18:70, 18:71, 18:73, 18:75-18:78, 18:80-18:85, 18:87-18:93, 18:95, 18:96, 18:98:01-18:100, 18:103, 18:104, 18:108, 18:111, 18:112, 18:114-18:121, 18:123, 18:124, 18:126-18:135:01:02, 18:137, 18:139-18:142, 18:144-18:147, 18:155-18:163, 18:167, 18:171-18:177, 18:180, 18:181, 18:183-18:188, 18:190, 18:192, 18:193, 18:196-18:198, 18:200-18:203, 18:206-18:209, 18:211-18:216, 18:218-18:226, 18:228, 18:230, 18:231Q-18:234, 18:237-18:239, 18:242-18:244, 18:246, 18:247, 18:249-18:251, 18:253, 18:256, 18:261-18:268	B18, -
	B*18:17N, 18:23N, 18:74N, 18:94N, 18:154N, 18:245N, 18:248N, 18:258N, 18:269N	Null
B*35	B*35:29:01-35:29:03, 35:497	B35, -

However, upon re-typing by the recipient laboratory the donor was typed using NGS by a recipient centre as HLA-B*35:01:01:02, with HLA-B*35:29:01 having been excluded:

	Allele 1	*Allele 2*
HLA-A	**01:01:01:01**	**30:02:01:01**
HLA-B	**18:01:01:01**	**35:01:01:02**
HLA-C	**04:01:01:01**	**05:01:01:01**
DRB1	**01:01:01:01**	**03:01:01:01**
DRB3	**02:02:01:01**	
DQB1	**02:01:01:01**	**05:01:01:03**
DQA1	**01:01:01:01**	**05:01:01:01**
DPB1	**02:02:01:01**	**04:01:01:01**
DPA1	**01:03:01:01**	**01:03:01:04**

Whilst this does not impact on the offering algorithm (both alleles are offered as HLA-B35), it identifies a potential technical issue and requires investigation by the donor characterisation laboratory and should be reported as a revised type following the process outlined in **Section 1.4**.