
Objective

This Commissioning Service Specification covers the provision of laboratory characterisation (HLA typing and microbiological screening) of eligible deceased organ donors to permit safe and legal transplantation of all solid organs.

This is not a legally binding document; the intention behind this document is to provide background information and to outline the commissioning requirements for a deceased donor characterisation service, for example, in the event of commissioning a new laboratory.

Changes in this version

Removal of the requirement for EFI accreditation for H&I laboratories.

Removal of the requirement for repeat testing for H&I and microbiology laboratories.

Removal of the requirement for annual contract review meetings.

Remove requirement to have a formal arrangement with a back-up laboratory.

Amend HLA blood volumes to reflect reduction.

Under 2.1 Pathway, included the requirement to record the time samples were received in the laboratory

2.2 Consent/Authorisation – new section added to outline the different testing requirements following implementation of deemed consent

3. Activity data removed – recent data and activity projections can be made available on request to OTDT Commissioning

6.1 Definitions of “Partial” and “Final” included

Annex B updated with requirement to test for SARS-COV-2

Annex E removed, Annex F re-labelled as Annex E (Further Information) accordingly, and updated with links, definitions and contact details

Minor aesthetic and grammatical changes made throughout for accuracy.

THE DONOR CHARACTERISATION SERVICE SPECIFICATION:

- 1. Scope**
- 2. Pathways and Dependencies**
- 3. Population and Evidence Base**
- 4. Quality and Outcomes**
- 5. Applicable Service Standards**
- 6. Clinical Standards and Performance**
- 7. Informatics Standards**

1. Scope

1.1. Scope

This [Commissioning Service Specification](#) covers the provision of laboratory characterisation (HLA typing and microbiological screening) of eligible [deceased](#) organ donors to permit safe and legal transplantation of all solid organs.

The laboratories undertaking [deceased](#) donor characterisation, working collaboratively, will support the delivery of the strategic aims and objectives of the [OTDT NHSBT Strategy](#) and meet the future demands of the organ donation and transplantation programme.

Laboratories will deliver a nationally defined testing service for all consented/authorised eligible organ donors.

1.2. In/Out Scope

The laboratories' responsibilities include, but are not limited to, activities relating to the following:

- Eligible donor sample receipt management, sample processing, DNA extraction, storage and subsequent transportation in accordance with regulations and guidelines
- Test provision and results generation
- Reporting, including interpretation of results, as appropriate
- Return of results to the SNOD/ODT Hub Operations/Donor Records Department
- Collection, sharing and submission of data
- Maternal microbiology testing for paediatric/infant donors

Any tests related to transplant recipients are out of scope. This includes, for example:

- Microbiology screening of transplant recipients
- HLA typing of transplant recipients and crossmatch testing
- Confirmatory microbiology testing and HLA retyping of eligible organ donors by recipient centres
- HLA typing and microbiology screening of living donors
- Histopathology

1.3. Rationale

The prescribed Services outlined in this Service Specification cover eligible organ donors of all ages.

Organs from DBD and DCD donors can transmit disease; a minimum repertoire of microbiological screening tests is undertaken as mandated by the European Union Organ Donation Directive¹ and recommended by The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO)². Additional testing may be performed when specific risks have been identified e.g. through epidemiological or travel history.

The donor Human Leukocyte Antigen (HLA) type is crucial for the safe allocation of organs. It is required for donor and recipient HLA matching and in ensuring safe transplantation of

¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32010L0053>

² https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/876161/SaBT_O-microbiological-safety-guidelines.pdf

patients with pre-existing HLA antibodies. The minimum resolution required for reporting donor and patient HLA types is published by [OTDT NHSBT](#).³

To ensure compliance with legislation all eligible organ donors must be characterised⁴. Donor characterisation is the process of collecting relevant information about the donor to evaluate suitability for organ donation. The information provided [contributes to](#) recipient patient safety, minimises the risk of disease transmission, enables risk mitigation and through allocation processes ensures equity of access to organs.

Information relating to the donor is used by transplant clinicians in making the decision to either accept or decline an organ and by the potential recipient to inform a decision to either consent to or refuse a transplant from a particular donor.

This specification will be subject to [annual](#) review. If changes are made, a link to the revised document will be circulated to the donor characterisation laboratories.

2. Pathways and Dependencies

2.1. Pathway

The pathway for the collection, transportation, testing and reporting of blood samples from DBD and DCD donors can be summarised as follows. Referral of a potential organ donor to the Specialist Nurse for Organ Donation (SNOD)

- Consent/authorisation for organ donation is established [by the SNOD](#)
- Blood samples taken [by the SNOD](#) from the potential donor – please see 2.2 below for details about consent/authorisation arrangements in each of the four UK nations.
- [The SNOD will routinely send the following volumes of donor blood for adult donor characterisation testing \(in cases of very small/paediatric or blood diluted donors, the SNOD will call the laboratory to establish the volume of blood that can be taken\):](#)
 - Microbiology screening total volume 26 ml: 14ml clotted and 12 ml EDTA
 - HLA typing total volume 6 ml EDTA
- [Where possible, donor bloods sent for paediatric patients under 30 kg will be:](#)
 - Microbiology screening total volume 2ml
 - HLA typing total volume 3 ml
- Blood samples [labelled by the SNOD](#) with a minimum of three identifiers (these currently include the patient's name, date of birth, hospital/NHS number – please refer to MPD1086 for the full list of acceptable identifiers).
- Laboratory [request](#) forms (FRM 4278 and 4279) completed and included with blood sample(s) and packaged according to agreed standard.
- Laboratory informed about potential organ donor with instructions on whether samples can be tested immediately upon receipt or [when instructed by the Specialist Nurse \(see 2.2 for arrangements for different sample types in each of the UK countries\)](#).
- Transport organised [by OTDT](#) with clear instructions to the driver about the point of delivery
- Samples received by the laboratory [and time of receipt recorded](#)

³ <https://nhsbtbe.blob.core.windows.net/umbraco-assets-corp/16945/dat2885-minimum-resolution-for-reporting-donor-recipient-hla-types-table-1.pdf>

⁴ <https://www.legislation.gov.uk/ukxi/2012/1501/contents/made>

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- Virology laboratory to review form to establish whether samples can be tested immediately, or whether they are to be held until formal consent has been obtained in line with the guidance below (2.2 Consent/Authorisation).
 - Samples tested

Pre-Electronic Results Transfer:

- HLA results reported to ODT Hub Operations/Microbiology results reported to the SNOD
- SNOD enters microbiology results onto DonorPath for review by Transplant Centres. ODT Hub Operations enters HLA results onto NTxD

Post-Electronic Results Transfer:

- Data is uploaded by the laboratories direct from the LIMS or analyser into a file that is sent to OTDT.
- Results from additional testing not reported at the time of donation reported to OTDT Hub Operations/Donor Records Department as soon as they are available.

2.2 Consent/Authorisation

Following implementation of deemed consent in the UK, arrangements for testing can differ depending on the type of sample, and the country. Please note the following:

In England, Wales and Northern Ireland:

- Microbiology - bloods can be taken and sent if the donor has expressed decision, family expressed decision or on ODR but cannot be tested until agreement from the family has been obtained or as part of completion of consent. Microbiology laboratories should check the form on receipt of the sample to establish whether testing can proceed immediately, or whether to wait for a call from the SNOD.
- HLA - bloods can be taken and processed if donor has expressed decision, family expressed decision or on ODR to donate.
- If the donor has opted out or has met the criteria for deemed (ie. Has not made a decision) then the blood sample cannot be taken before discussion and agreement with the family for either microbiology or HLA.

In Scotland:

- Blood samples cannot be taken for HLA or microbiology testing without discussion with the donor's family, or before authorisation has been obtained.

2.3 Core Requirements of the Service:

- The laboratory must have adequate numbers of appropriately trained and qualified staff to meet peaks in demand and provide 24/7 continuous service
- 24/7 consultant advice for the resolution and interpretation of results in the context of organ donation must be available.
- Laboratories must have a business continuity plan including or specifically covering DBD and DCD donor characterisation.
- Laboratories must be able to record the electronic user identifications at each stage of the data transfer process
- Laboratories must not manually transcribe results. However, if the electronic file transfer service (SFTP) provided by NHSBT is not in service, as a contingency, laboratories may send the electronic results data file as an attachment by secure email to an email address to be specified by NHSBT.
- Laboratories must report all results to OTDT electronically. The requirements for the electronic transfer of data are presented in Annex A;

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- If laboratories plan to make any changes that may impact upon the electronic transfer of data as presented in Annex A, they must:
 - a) notify [OTDT Commissioning](#) immediately upon becoming aware of the change and in advance of making any such change; and
 - b) the parties shall consult together on the form and content of any such changes made to the electronic transfer of data to ensure continued service delivery.

2.4. Interdependencies with other Services and Organisations

Laboratories will be responsible for the performance, including quality oversight of their service.

Laboratories will work with [OTDT Commissioning](#) and Transplant Centres to ensure delivery of a quality service for donor characterisation by compliance with nationally agreed testing requirements and minimum datasets, [key performance indicators as outlined in the Contract/Agreement](#), external quality assessment, benchmarking and review of activity.

Laboratories will participate and collaborate with other stakeholders to share best practice and quality improvements. Laboratories will implement requirements as set out by the Advisory Committee for the Safety of Blood, Tissues and Organ (SaBTO) and the NHSBT [Organ Advisory Groups](#).

3. Population and Evidence Base

3.1. Population covered by this Specification

This Service Specification covers DBD and DCD organ donors of all ages.

3.2. Population Needs and Evidence Base

Transplantation is an effective and cost-efficient treatment for end stage organ failure. Since the publication of the Organ Donation Taskforce Report⁵ in 2008 the number of organ donors and therefore transplants have continued to rise.

Donor characterisation is an absolute requirement for safe organ allocation and is mandated in law under the Quality and Safety of Organs Intended for Transplantation Regulations (2012)⁶. The majority of organs cannot be offered or allocated to recipients until the results for the donor HLA type and microbiology screen are reported. A robust and efficient laboratory service providing donor characterisation is essential to support organ offering and subsequent transplantation.

4. Quality and Outcomes

4.1. Quality management and assurance of both processes and data

Laboratories undertaking DBD and DCD donor characterisation testing will provide a 24/7 continuous testing service with access to relevant and appropriate consultant advice for the resolution and interpretation of results.

⁵<https://nhsbtdeb.blob.core.windows.net/umbraco-assets-corp/4245/organsfortransplants/theorgandonortaskforce1streport.pdf>

⁶ <https://www.legislation.gov.uk/uksi/2012/1501/contents/made>

Laboratories will establish, undertake and regularly monitor local quality control and assurance processes, in line with ISO15189 requirements.

Laboratories will participate and achieve satisfactory performance in relevant external quality assurance schemes such as United Kingdom National External Quality Assessment Service (UK NEQAS). The laboratory will inform [OTDT Commissioning](#) of any unsatisfactory performance for these schemes and the [acceptance of proposed corrective action by the scheme organisers](#).

The laboratory will share performance data against Key Performance Indicators (KPI) [as outlined in the Contract/Agreement](#), where appropriate, and from EQA schemes with the Commissioners.

Laboratories will have a business continuity plan specifically for the provision of DBD and DCD donor characterisation testing.

The laboratories performing donor characterisation testing will share best practice and improve standards through collaboration.

4.2. Outcomes

The laboratory will participate in the [performance](#) review process and will collect and submit data [as requested](#) to support the assessment of compliance with this Service Specification.

5. Applicable Service Standards

5.1. Applicable Obligatory National Standards

The laboratory will:

- [Show compliance with](#)
 - [The Human Tissue Act 2004](#)
 - [The Human Tissue Scotland Act 2006](#)
 - [The Human Transplantation \(Wales\) Act 2013](#)
- [Work in compliance with the requirements of:](#)
 - [The Human Tissue Authority \(Code F part two: Deceased Organ and tissue donation\)](#)
- Have accreditation from UKAS and ensure all tests and the technologies utilised for both microbiology screening and HLA typing are included within the scope of their ISO15189 accreditation; [to notify OTDT Commissioning if accreditation is lost or suspended](#).
- Work in compliance with *The Quality and Safety of Organs Intended for Transplantation Regulations 2012*⁷ and *The Human Tissue (Quality and Safety for Human Application) Regulations 2007*⁸
- Work within agreed and published commissioning policies and policy statements, as directed by the commissioners
- Work within published operational standards for NHS diagnostic services

⁷ <https://www.legislation.gov.uk/uksi/2012/1501/contents/made>

⁸ <https://www.legislation.gov.uk/uksi/2007/1523/contents/made>

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- Inform **OTDT Commissioning** of any change in accreditation or **Regulatory** status to any part of its service and implement an action plan with timescales to achieve full compliance
 - Report test results using nomenclature as **agreed with OTDT NHSBT**
 - Follow applicable SaBTO and NHSBT Advisory Group guidance
 - Be compliant with Data Protection Legislation
 - Be compliant with the relevant Best Practice Guidelines of the Royal College of Pathologists⁹ and applicable guidelines from all other Royal Colleges and, where relevant, in line with **OTDT/NHSBT Advisory Group** guidance, and international bodies
 - Be responsible for the security of and access to electronic data which it holds in line with Records Management and Code of Practice 2021¹⁰
 - **Raw data must be retained, retrievable and made available to NHSBT for at least six years post-transplant. Reported results must be retained, retrieval and made available to NHSBT for 30 years post-transplant or the life of the recipient (whichever is longer).**

⁹ <https://www.rcpath.org/profession/guidelines.html>

¹⁰ <https://www.nhsx.nhs.uk/information-governance/guidance/records-management-code/records-management-code-of-practice-2021/>

6. Clinical Standards and Performance

6.1: DBD and DCD Donor Microbiology Screening Service

Pathogens tested

A laboratory report must be issued for all pathogens set out in **Annex B** as per SaBTO guidance prior to donation. Laboratories **are** responsible for sending blood samples for Hepatitis E testing to **MSL (NHSBT) or SNBTS (Scotland)**. The specification for specialised reference testing can be found in **Annex C**.

Result Reporting

- All laboratory **diagnostic** reports must be marked “**Partial**” (interim/preliminary) or “**Final**” (the report is complete and verified by an authorised person). In the context of positive or unresolved results, comprehensive and clear interpretive advice for the non-specialised healthcare professional must be provided on the report.
- Initially reactive/positive results must be resolved prior to donation/transplantation.

Key Performance Indicators

- Turnaround time:
 - 90% of the initial results reported to **OTDT** within two hours of receipt of the sample in the laboratory OR within two hours of the call from the Specialist Nurse to confirm consent/authorisation has been obtained.
 - 95% of initially reactive results resolved within an additional two hours.
- Compliance with the required repertoire:
 - SaBTO requirements: 100% compliance.
- Discrepancy rate:
 - Discrepancy rate less than 1.0%.
- Response to incidents:
 - Full investigation of incidents to be completed within 2 calendar weeks of date of notification from OTDT.
 - Implementation of corrective and preventive measures within a defined target date or period commensurate with the risk posed.

Notification of high-risk incidents to OTDT immediately upon discovery. All other incidents should be reported as soon as safely possible
<https://www.odt.nhs.uk/odt-structures-and-standards/governance-and-quality/tell-us-about-an-incident/>

- Support investigation of incidents, including:
 - Timely provision of information on assays used and results obtained.
 - Onward referral of samples as per OTDT's instruction.
 - Performance of further testing, following appropriate discussion with OTDT.

Sample storage

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- As advised by Royal College of Pathologists, the central reference laboratory (MSL, Colindale) will be responsible for archiving a 2mls serum/plasma sample from each donor according to current guidelines¹¹.
 - As of 2019/20, the SaBTO and RCP guidelines state samples should be stored for ten years.

6.2: DBD and DCD Donor HLA Typing Service

Standards

To test results in line with the following repertoire – HLA -A, B, C, DRB1, DRB3/4/5, DQA1, DQB1, DPA1, DPB1 **Annex D**.

Result reporting

- DNA nomenclature must be used to report results on all HLA loci in DAT2285 for minimum resolution.
- Report must include, as a standard, the minimum resolution; any additional information provided in addition to the minimum resolution must comply with IMGT and EFI standards for HLA reporting.

Key Performance Indicators

- Turnaround time:
 - 90% of the initial results reported to OTDT within four hours of receipt of the sample in the laboratory.
- Compliance with the required repertoire:
 - HLA-A, B, C, DRB1, DRB3/4/5, DQA1, DQB1, DPA1, DPB.
 - 100% compliance for HLA-A,B,C; DRB1, DRB3/4/5, DQA1, DQB1;
 - 95% for HLA – DPA1, DPB1
- Discrepancy rate less than 0.5%

The requirements for compliance with the repertoire and the discrepancy rates will be subject to review. Laboratories will be expected to achieve 100% compliance and a less than 0.5% discrepancy rate.

- Response to incidents:
 - Full investigation of incidents to be completed within 2 calendar weeks of date of notification from OTDT
 - Implementation of corrective and preventive measures within a defined target date or period commensurate with the risk posed
- Notification of high-risk incidents to OTDT immediately upon discovery. All other incidents should be reported as soon as safely possible.
<https://www.odt.nhs.uk/odt-structures-and-standards/governance-and-quality/tell-us-about-an-incident/>
- Support investigation of incidents, including:

¹¹ <https://www.rcpath.org/uploads/assets/049ea966-df5c-4a9f-9353ba24a69bb808/The-retention-and-storage-of-pathological-records-and-specimens-5th-edition.pdf>

- Timely provision of information on assays used and results obtained
- Onward referral of samples as per OTDT's instruction
- Performance of further testing, following appropriate discussion with OTDT

Sample storage

- As advised by the Royal College of Pathologists, laboratories will be responsible for archiving DNA from DBD and DCD donors according to guidelines¹².

¹² <https://www.rcpath.org/uploads/assets/049ea966-df5c-4a9f-9353ba24a69bb808/The-retention-and-storage-of-pathological-records-and-specimens-5th-edition.pdf>

7. Informatics Standards

The laboratory will comply with the standards or demonstrate working towards compliance within a defined timescale, with such timescale **as required by OTDT Commissioning**. Information Standards and Service Standards are set out below (all may be amended, replaced, updated or added to from time to time).

The laboratory or its parent NHS organisation must have completed a Full NHS Digital Data Security and Protection assessment within the last year, and:

- Been assessed as “Standards Met” or “Standards Exceeded”, or
- If assessed as “Standards Not Met”, then an Improvement Plan must have been agreed and shared with **OTDT**.

The laboratory or its parent NHS organisation must have support for the relevant standards in the NHS Interoperability Framework including:

- HL7 messaging (**version 2.3 or later**) and FHIR (**version 3 or later**)
- SNOMED-CT or **SaBTO naming of Microbiology tests**
- Conformance to IMGT naming conventions for HLA results data

When sending personal identifiable data by email or email attachment, the laboratory or its parent NHS organisation must use:

- NHSmail;
- Or an email system conformant to DBC1596¹³
- Or an email system that uses TLS 1.2 or later for encrypting email transmission and uses SPF, DKIM and DMARC for email authentication;
(See <https://www.gov.uk/government/publications/email-security-standards> for more information).

To ensure data can be transferred electronically:

- Laboratories must be able to record the electronic user identifications at each stage of the data transfer process.
- Laboratories must not manually transcribe results. However, if the electronic file transfer service (SFTP) provided by NHSBT is not in service, as a contingency, laboratories may send the electronic results data file as an attachment by secure email to an email address to be specified by NHSBT.
- Laboratories must report all results to OTDT electronically. The requirements for the electronic transfer of data are presented in Annex A.
- If laboratories plan to make any changes that may impact upon the electronic transfer of data as presented in Annex A, they must:
 - a) notify **OTDT Commissioning** immediately upon becoming aware of the change and in advance of making any such change; and
 - b) the parties shall consult together on the form and content of any such changes made to the electronic transfer of data to ensure continued service delivery.

¹³ <https://digital.nhs.uk/services/nhsmail/the-secure-email-standard>

ANNEX A: Requirements to support electronic results transfer

Principles
There should be no manual transcription of results data at any stage.
Data must be secured against unauthorised access or tampering, when stored or when being transmitted.
Any changes to the data which is the outcome of local validation must have a full audit trail.
Relevant, established standards for data definitions, encoding, transmission protocols and information security will be utilised where appropriate.

Process
Data for tests for an individual must be sent in a single data file.
Data must be electronically sent to ODT in a structured format to be specified by ODT or in a structured format which can be automatically and unambiguously converted to the ODT specified format.
The encoding of individual test results must conform to the ODR specified standard.
For HLA typing data this structure and encoding will be based on the NHSBT National Transplant Database HLA report form.
The sending of data must use a mechanism which guarantees transmission within a specified time.

SPN1439/3 – Donor Characterisation Commissioning Service Specification



Blood and Transplant

Copy No:

Effective date: 16/03/2022

ANNEX B: MICROBIOLOGY ONLY – Tests Mandated by SABTO

Agent	Marker	Screen before donation	Work up of reactive results before donation (laboratories permitted to use local algorithms)	Resolution of reactive results locally, after donation/event (labs permitted to use local algorithms)
HBV	HBsAg	YES	YES	N/A
	anti-HBcore Ab	YES	YES	72 hours to include HBV DNA
	anti-HBsAg (discretionary) ¹	in current or past HBV infection	YES (if HBsAg or anti-core reactive)	N/A
	HBV DNA (discretionary) ¹	N/A (not a screening marker)	NO (post donation testing currently permitted)	72 hours from receipt of sample
HCV	HCV Ab	YES	YES	72 hours from receipt of sample
	HCV Ag	see note ²	YES	72 hours from receipt of sample
HIV	HIV Ag/Ab	YES	YES	72 hours from receipt of sample
HTLV	HTLV Ab	YES	NO ^{3, 4}	N/A
CMV	CMV IgG	YES ⁵	NO ⁶	72 hours from receipt of sample
EBV	EBV IgG	YES ⁵	NO ⁶	72 hours from receipt of sample
T gondii	Toxoplasma Ab	YES ⁵	NO ⁶	72 hours from receipt of sample
T pallidum	Syphilis Ab	YES ⁵	NO ⁶	72 hours from receipt of sample

NB: testing for SARS-COV-2 is required for all deceased organ donors

¹ Discretionary means that anti-HBsAg and HBV DNA is done if anti-HBcore is reactive	² Laboratories use different screening and confirmatory strategies for HCV. Laboratories will establish protocols to determine the infectious HCV status of the donor *. This can be done by incorporating HCV Ag or RNA in local protocols. * see notes in the NAT section above	³ Under the current testing structure (as of April 2018), local testing of initially reactive samples is limited. Samples are usually sent to a reference laboratory; this must be done on the same or next working day with a request for prompt resolution. ⁴ Use of reflex testing by applying a second antibody test locally is already done in some laboratories and may become an option in the future. Laboratories will still be required to refer samples for final confirmation.	Relates to standard week days (as normal working hours arrangements differ between laboratories), from specimen arrival in the laboratory	Relates to standard week days (as normal working hours arrangements differ between laboratories), from specimen arrival in the laboratory
	⁵ Markers not required for D/R matching or donor selection but completion of whole screening with issue of report pre- donation is required for other quality and safety reasons	⁶ Any marker may give rise to results that may require verification; situations requiring further testing are identified on an individual basis and according to local laboratory algorithms.		

ANNEX C: Specialised Reference testing – for information

Agent	Marker	Screen before donation	Resolution of significance of reactive results before donation (labs permitted to use local algorithms)	Screening TAT	Resolution of reactive results after donation/event (labs permitted to use local algorithms)
Hepatitis E Virus	HEV RNA	NO	N/A	4 calendar days	7 calendar days from receiving the sample
Plasmodium sp	Plasmodium Ab+/- DNA	NO	N/A	4 calendar days	7 calendar days from receiving the sample
T cruzi	T cruzi Ab	NO ¹	N/A	4 calendar days	7 calendar days from receiving the sample
Blood Borne Virus (HIV, HCV, HBV)	NAT (discretionary)	NO	N/A	4 calendar days	7 calendar days from receiving the sample
HTLV8		NO			
Other as per relevant active guidance	variable	variable	variable	variable	variable

¹ In the event of need to test for other agents (ie emerging infectious agents, outbreaks), guidances produced in response to those needs will apply	² Under the current testing structure (as of April 2018), it is not feasible to do any local screening. Samples are sent to a reference laboratory on the same or next working day for testing. Pre-donation testing may be possible and required in future	relates to standard week days (as normal working hours arrangements differ between laboratories), from specimen arrival in the laboratory	³ These requirements are only mandatory for reference laboratories. However, as part of this exercise we wish to understand whether any other laboratories have the capability to carry out any/all of these functions.
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ANNEX D: HLA ONLY Repertoire of testing

To test results in line with the following repertoire – HLA -A, B, C, DRB1, DRB3/4/5, DQA1, DQB1, DPA1, DPB1.

Controlled if copy number stated on document and issued by QA

(Template Version 03/02/2020)

ANNEX E – FURTHER INFORMATION

Additional Documents

These documents can be made available on request:

- **MPD1086** - Minimum Operating Standards – Patient Identifiable Data - Hub Operations
- **FRM4278** - Virology/Microbiology Request Form
- **FRM4279** - HLA Typing Request
- **DAT2885** - Minimum Resolution for Donor and Patient HLA Types:

Definitions

- Service Specification – where referenced in SPN1439/3 and in the Contract/Agreement, “Service Specification” refers to this commissioning document (SPN1439)
- “OTDT Commissioning” means the Coordinating Commissioner of the Service.
- “Laboratories” means all laboratories or providers delivering deceased donor characterisation with whom OTDT NHSBT holds a Contract/Agreement.
- “NHSBT” means NHS Blood and Transplant (Coordinating Commissioner)
- “SNOD” means the Specialist Nurse in Organ Donation
- “OTDT” means Organ and Tissue Donation and Transplantation, a Directorate within NHSBT.
- “Contract/Agreement” means the document outlining the terms and conditions of the Service

Useful Contacts

OTDT Hub Operations (for reporting disruption to services): odthub.operations@nhsbt.nhs.uk

OTDT Commissioning: odt.commissioningteam@nhsbt.nhs.uk

OTDT Clinical Governance and Quality Incident Reporting: <https://www.odt.nhs.uk/odt-structures-and-standards/governance-and-quality/tell-us-about-an-incident/>