Clinical Microbiology Manual

Index

Responsibilities:

Specialist Nurse (SN) Responsibilities:
SNs must understand the rationale and importance of clinical microbiological screening. The responsibility of the SN is to ensure that appropriate tests are requested according to the agreed protocol and when available, to ensure the results are available to the retrieval and recipient teams. It is NOT the role of the SN to interpret these tests, and it is NOT the role of the SN to give advice as to the clinical implications of the results. The SN should ensure the transplanting team is provided with the contact details of the Clinical Microbiologist in the testing lab whenever the need arises. The aim of this manual is to aid the SN in fulfilling their responsibilities.

Tissue and Eye Services - Clinical Support Nurse Team (TES CSNT) Responsibilities:
TES CSNT must understand the rationale and importance of clinical microbiological screening. It is NOT the role of the TES CSNT to interpret these tests, and it is NOT the role of the TES CSNT to give advice to the clinical implications of the results. If CSNT receive communication from an individual following receipt of a letter; they can seek further support from TES Medical Consultant or Consultant Virologist for further advice. The aim of this manual is to aid TES CSNT in fulfilling their responsibilities.

Summary of changes

- Correction of characterisation manual **SOP6504** number p12 point 1.6
- Removal of the number of the MASH questions to a less prescriptive advice for BBV Nat testing p15
- Change of documentation area for BBV Nat results to investigation tab to match with Hep A and Parvo B19 management of result p17
- Change from child's mother to child's birth parent and/ or individual who breast fed the child p22 point 1.32 to match MASH changes and in cases where patient receives milk from a different person than the birth parent
- Addition of research is considered if non proceeding donation p22 point 1.33
- Removal of Birmingham email access flow p 24.
- Addition of an advice box to complete an incident form for the patient safety team and not to change the result on DonorPath pathway, in cases where a test result from a blood sample sent with an organ is discrepant to the characterisation test result p29
- Removal of DCERT process throughout the document.

Purpose and Objective - Clinical Microbiology in Deceased Organ Donors

Transplantation is a well-established treatment of choice for most patients with end stage organ failure. Transmission of infection through the transplanted organ/tissue is one of the associated risks that cannot be eliminated but must be managed.

To manage the risk of infection transmission, potential organ/tissue donors undergo a comprehensive patient assessment. The SN is required to obtain a detailed medical, behavioural and travel history and instigate clinical microbiological testing of the potential donor. Most organ transplants are lifesaving. There remains a significant mortality risk for those on the waiting list, the risks associated with organ transplantation are different to those associated with tissue transplantation.

The Quality and Safety of Organs Intended for Transplantation Regulations (2012) stipulates that minimum data should be available to support decision making in accepting an organ for transplant. This includes the results of specific microbiological investigations. Review of clinical microbiology results are a mandatory requirement for the acceptance of tissue for transplantation, in accordance with the Human Tissue (Quality and Safety for Human Application) Regulations (2007).

In support of these regulations, further advice on suitability and potential contraindications to organ/tissue donation is identified in the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) Guidance on the Microbiological Safety of Human Organs, Tissue and Cells used in Transplantation.

Relevant infections may spread in a variety of ways. If the donor has evidence of current or past infection, the family or contacts may have been at risk because they may have been infected by the donor, or they may have been the source of infection or exposed to the same environment or risks. Duty of Care places an obligation on the health care professional to inform the family where appropriate.

These infections are often chronic and asymptomatic until the onset of organ failure. Advances in treatments mean that most cases of Hepatitis C (HCV) are curable, and Hepatitis B (HBV) and Human Immunodeficiency Virus (HIV) are treatable, and complications may be prevented.

This document aims to provide guidance for Organ Donation Services Teams (ODST) to work to best practice guidelines, thereby minimising donor-related risk of infection to organ recipients and maximising the quality and safety of organs/ tissue for transplantation. **This manual is to be utilised by a qualified and trained SN. Expert advice must be sought for any area of practice in which the SN does not have the necessary experience, knowledge and training. If the SN is in training, this manual is to be utilised under supervision.**

Clinical Microbiology screening assesses whether the person has been infected with a transmissible agent and whether that agent is still actively replicating. Some viruses are never cleared from the body and after an infection will lie dormant in the tissues until reactivated. Once infection has occurred, the individual is infected for life, The virus remains dormant in the white blood cells and may reactivate from time to time.

The laboratories can look for antibody or the actual pathogen (antigen or nucleic acid) in the blood (or other) sample:

Antigen	An antigen is part of the infectious agent that provokes an immune response from the body
Antibody	An antibody shows that the body has recognised an antigen: this means that infection has taken place. An antibody does not always indicate that the infection has been cleared.
	IgM and IgG: following a new infection, the body first makes IgM antibody then IgG antibody; so, the presence of IgM usually (but not always) implies recent infection.
	Immunisation will also induce an antibody response, so a positive IgG to Hepatitis B surface antigen (anti-HBsAg) may mean either successful immunisation or previous infection with the virus.
RNA + DNA	Shows current infection (whether DNA or RNA depends on the agent) This can be detected by Nucleic Acid Tests (NAT) with Polymerase Chain Reaction (PCR) being one such test.

N.B. HBV vaccine contains just HBV surface antigen, eliciting anti-HBsAg only, whereas natural infection will induce antibodies to both surface and core antigen - therefore, look for anti-HBsAg and anti-HBcore Ag

Current tests are generally precise but there are many factors that can affect accuracy, so it is important to understand the following:

1.	Tests done on patient blood may give false positive or false negative readings as no test is perfect. Results may be affected by certain substances present in the blood or following large volumes of transfusion.
2.	False-positive results is a positive result unrelated to the infection being tested for. In these instances, there may be cross-reaction between different antigens and antibodies, i.e. proteins that look similar and lead to a false-positive result. An example of a false-positive result can be seen in the presence of an auto immune disease. This is usually resolved by doing further tests. Some are molecular tests and may not be completed before donation takes place. That is why sometimes, an initial result may change after the lab performs further investigations.
3.	Indeterminate results occur when it is not possible to be a 100% sure if the sample is positive or negative for a particular marker. Further tests usually help confirm one way or another. Final results may or may not be available before donation and transplantation takes place.
4.	False negative result (the test has not identified an infection): No test is 100% sensitive and there is always a theoretical chance of missing an infection. For all infections, there is a window period where the infection is present but there is not sufficient antibody or antigen to be detected in the blood, giving a negative test result This may be a problem if there has been an infection in the preceding days or weeks, that is why it is important to note a recent risk. Long-standing, established infections are unlikely to be missed by screening tests.
5.	Confirmation of screening results: For many tests, an initial positive result must be confirmed. Sometimes the lab will be able to do that straight away.

Glossary

Roles and NHSBT Specific

BMS – Biomedical Scientist

MSL – Microbiology Services Laboratory

NHSBT – National Health Services Blood and Transplant

NRC – National Referral Centre for Tissues

NTMRL – National Transfusion Microbiology Reference Laboratory

OM On Call - Operational Manager on call (e.g. Regional Head of Nursing)

ODST – Organ Donation Services Team

OLN – Operational Lead Nurse

RCPoC – Recipient Centre Point of Contact

SN - Specialist Nurse

SNBTS – Scottish National Blood Transfusion Service

TES CSNT – Tissue and Eye Services Clinical Support Nurse Team

Terminology

CMV – Cytomegalovirus

DNA – Deoxyribonucleic Acid

Donor Family - Includes NOK/nearest relative

DP – Donor Path

EBV – Epstein-Barr Virus

EDTA – Ethylenediaminetetraacetic acid

E, W & NI – England Wales and Northern Ireland

GDRI – Geographical Disease Risk Index

HBcAb - Hepatitis B Core Antibody

HBsAg - Hepatitis B Surface Antigen

HBV - Hepatitis B Virus

HCV - Hepatitis C Virus Antibody

HEV – Hepatitis E Virus

HHV-8 – Human Herpes Virus-8 (Kaposi's sarcoma associated)

HIV – Human Immunodeficiency Virus 1 + 2

HTLV - Human T-Lymphotropic Virus

ICU – Intensive Care Unit

IgG - Immunoglobulin G

IgM - Immunoglobulin M

JPAC - Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee

MaSH – Medical and Social History

NAT - Nucleic acid test

NOK – Next of Kin/first person of significance to the donor

PCR - Polymerase chain reaction

PID – Patient Identifiable Data

RNA – Ribonucleic Acid

SABTO – Advisory committee on the Safety of Blood, Tissues and Organs

SARs CoV2 RNA – Severe Acute Respiratory Syndrome Coronavirus 2 Ribonucleic Acid

SoE – Sequence of Events

TDSG-DD – Tissue Donor Selection Guidelines – Deceased Donors

TxP – Transplant Path

WNV – West Nile Viru

Related Documents/References

FRMs:
FRM5025 - Additional Testing Request Form
FRM5037 – Reporting of Reactive/Discrepant Microbiology Result
FRM5814 – BBV Screen/Malaria/WNV/T.Cruzi request form
FRM7029 - HHV8 Request Form (Scotland)
FRM7233 – Microbiology Services Laboratory Specialist Referral Form

INFs:
INF947 - Rationale Document for medical & social History Questionnaire
INF958 - Statutory Notifiable Diseases England and Wales
INF960 - Statutory Notifiable diseases Scotland
INF961 – Statutory Notifiable diseases Northern Ireland
INF1746 – Implementation of HHV8 screening in deceased Organ Donation

MPDs:
MPD897 – Authorisation of Tissue Donor Files
MPD865 - Obtaining Coroner/Procurator Fiscal Decision

SOPs
SOP3649 - Voice Recording of Organ Donor Clinical Conversations
SOP3925 - Manual Organ Donation Process for a Potential Organ and/or Tissue Donor in the Event of DonorPath/IT Network Unavailability
SOP4938 - Sharing Clinical Information
SOP5049 – Donor Family Care Service (DFCS) Process Manual
SOP5869 - SARS-CoV-2 Deceased Organ Donor Screening
SOP5874 - Paediatric manual
SOP6405 - Characterisation Manual

Dats
DAT2792 - Recipient Centre Point of Contact – List of email addresses
DAT4135 - Researchers contact list/email addresses.

LETs:
LET428 - Letter to Communicate Positive Virology with Organ Donor Families / NOK

The Quality and Safety of Organs Intended for Transplantation Regulations (2012):
https://www.legislation.gov.uk/uksi/2012/1501/made

1 – Clinical Microbiology: The Characterisation Phase – Medical and Social History (MaSH), Diagnostic Blood Tests, Considerations

Medical and Social History Questionnaire (MaSH)

1.1 MaSH will be completed by the SN prior to donation.

1.2 SN must be able to recognise and document when to expand questions to obtain more details. Extensive details of social and behavioural habits are essential especially in high-risk donors.

1.3 Some infections can only be acquired abroad, either through living or visiting countries where infectious diseases are common.

1.4 Relevant details of travel history are essential. Whilst there is no need to document all details of residency/nature of travel and other risks for all countries, it is important to enter each country into the JPAC GDRI to see if there is any risk associated with that country.

1.5 To identify the nature of the risk; location, specific details of location, i.e. rural or city/town accommodation, duration of travel and date of return to the UK should always be documented. If exact dates not known, SN must try to ascertain approximate timings i.e. start/middle/end of month. This allows the SN to check JPAC GDRI.

1.6 For further clarification on MaSH process, please refer to Characterisation Manual **SOP6405** and the rational document related to MaSH **INF947**.

Diagnostic Blood Tests – Universal Blood Tests

1.7 SN must understand the rationale and importance of microbiological screening. The responsibility of the SN is to ensure that the appropriate tests are requested at the characterisation phase of donation, according to the agreed protocol.

1.8 SN will be required to undertake the following universal blood tests for ALL Donors:

Universal Blood Tests for ALL Donors
Hepatitis B Surface Antigen - HBsAg
Hepatitis B Core Antibody - HBcAb
Hepatitis C Virus Antibody - HCV
Human Immunodeficiency Virus 1 + 2 – HIV
Cytomegalovirus – CMV
Epstein Barr Virus – EBV
Human T-Lymphotropic Virus 1 + 2 antibody - HTLV
Toxoplasma – Toxo
Treponema pallidum antibodies - Syphilis
Hepatitis E Virus RNA – HEV
Human Herpes Virus Type 8 - HHV-8 Ab
Hepatitis A (SNBTS only)
Parvovirus B19 (SNBTS only)

1.9 HEV and HHV-8 testing is now performed routinely on all donors, post donation.

1.10 For every donor in England, Wales, and Northern Ireland (E, W & NI), please continue to collect an EDTA sample for HEV and HHV-8.

1.11 **HEV Scotland only:** no additional sample required for HEV, as this is included within the mandatory BBV NAT testing with completed **FRM5814.**

1.12 **HHV-8 (Scotland only)** For every donor in Scotland, collect and additional EDTA sample for HHV-8 and complete **FRM7029.**

1.13 Samples from West of Scotland Hospitals:

- Package blood sample in separate box addressed to WoSSVC 'out of hours' box together with completed **FRM7029**.
- Send packaged blood sample with Microbiology samples to WoSSVC.
- Inform laboratory of pending samples as per normal process.

Samples from East of Scotland Hospitals:

- Package blood sample in separate box addressed to WoSSVC "out of hours" box together with completed **FRM7029**.
- Inform laboratory of pending samples by sending an email to west.ssvc2@nhs.scot with the following details: PID (including donor number), donating hospital, date & time sample dispatched.
- In subject box add – Request to process HHV-8 sample - Organ Donation.
- Document in DonorPath SoE.
- Send packaged blood sample to WoSSVC.

1.14 Hepatitis A and Parvovirus B19 Scotland only testing/result Scotland National Blood Transfusion Service (SNBTS) **ONLY**

- SNBTS have commenced testing for Hepatitis A and Parvovirus B19. We expect positive results to be rare as the incidence of Hepatitis A is low in the UK. Parvovirus B19 is much more common but particularly so in young children.
- All Organ and Tissue donors in Scotland, and pancreas sent to Edinburgh for islet isolation from anywhere in the UK, will have NAT bloods tested for Hepatitis A and parvovirus B19. The testing will be based on PCR testing and not serology i.e. it will pick up current active infection and not historical infection

Diagnostic Blood Tests – Additional Blood Tests

1.15 SN must be able to recognise from medical notes, GP history or MaSH Questionnaire when a patient may have been exposed to high risk factors. If exposed, additional blood tests may be required to ensure safe transplantation.

1.16 **E, W & NI** – If high risk factors are identified during the behavioural risk and sexual history assessment (excluding alcohol, cannabis use and tobacco consumption) then BBV NAT section is indicated (See next section).

For guidance on how to collect and send bloods please check the Characterisation Manual SOP6405

BBV NAT Testing

- BBV NAT testing is indicated for individuals where behavioural and sexual history is considered high risk
- During Characterisation and MaSH, **if there is clinical evidence and/ or the donor family provided evidence suggestive of the donor participating in recreational and non-prescribed drug use** (excluding alcohol, cannabis and tobacco consumption), **has been in juvenile detention/ prison in the past 12 months or there is evidence of behavioural/ sexual practices that may have exposed them to higher risks of sexually transmitted or blood borne diseases** – please request BBV NAT testing with rationale documented in SoE and **FRM5025**.
- SN should note that **alcohol, cannabis use, and tobacco consumption do not trigger BBV NAT Testing**
- E, W & NI – In circumstances of positive virology during characterisation or donation process but BBV NAT has not been triggered then SN must notify MSL Virology via e-mail to process BBV NAT testing on HEV Sample. **Additional sample is not required.**
- Scotland – BBV NAT testing is performed routinely on all donors. Complete **FRM5814** and send together with packaged blood samples, to Scottish National Blood Transfusion Service (SNBTS)
  - **If sample is sent prior to completion of MaSH, MSL/SNBTS MUST be updated by email with complete rational for additional testing requirement.**

1.17 SN should obtain travel history from family using MaSH - **FRM4211**.

1.18 Geographical Disease Risk Index (GDRI) A-Z Search "transfusionguidelines.org" should be used to search for each individual country to identify potential requirement for additional testing. SN must identify location of travel, duration of travel and date of return to the UK.

1.19 If an infection is flagged, following a GDRI check, refer to General Principles (transfusionguidelines.org) to identify if patient meets criteria for further testing. List relevant travel on **FRM5025** or **FRM5814** (Scotland). Consider specific details of location, i.e., rural or city/town accommodation, duration of travel and date of return to the UK when performing GDRI checks. If exact dates not known, ascertain approximate timings i.e. start/middle/end of month.

1.20 If BBV/NAT testing is requested the SN is to update this on DonorPath > Past Medical History > General comments. This is to ensure RCPoCs are aware of testing and then to expect subsequent results. See flow chart on page 17.

BBV/NAT Post Donation Result - attached to DonorPath by DFCS and regional SN PoC informed that it is available for checking.

Check PID of report against donor record. Update result DonorPath > Investigations > Infection tab.

RESPONSIBILITY/ ACTION KEY
- DFCS
- SN- Organ Donation
- Receiving Centre

New Positive BBV/NAT Result

- Escalate to LN for awareness.
- Check Organ Outcome Summary for receiving centres
- **Telephone RCPoCs/Research centres/ NRC (Appendix 1)**
- Email centres (**DAT2792 DAT4135**) *do not attach result to email*

Subject: Organ Donor NEW INFORMATION Test Name (mark as High Priority) FINAL REPORT or INTERIM REPORT (SN to delete as appropriate)

Body of Email FINAL REPORT or INTERIM REPORT (SN to delete as appropriate)
'Dear.., please refer to Transplant Path for a final BBV/NAT report for Donor ODT, DOB and Donating Hospital' **or**
There is an interim BBV/NAT report for *Donor ODT, DOB and Donating Hospital' and therefore not visible on TransplantPath. Please refer to Past Medical History> General Comments on TxP Final Report to follow*

Process is to be repeated with the final report

New Negative Result BBV/NAT Result

- Check Organ Outcome Summary for receiving centres
- Email **RCPoCs/Research centres/ NRC** (**DAT2792 DAT4135**) *do not attach result to email*

Subject: Organ Donor NEW INFORMATION Test Name (mark as High Priority) FINAL REPORT or INTERIM REPORT (SN to delete as appropriate)

Body of Email FINAL REPORT or INTERIM REPORT (SN to delete as appropriate)
'Dear.., please refer to Transplant Path for a final BBV/NAT report for Donor ODT, DOB and Donating Hospital' **or**
This is an interim BBV/NAT for *Donor ODT, DOB and Donating Hospital' report and therefore not visible on TransplantPath. Please refer to Past Medical History> General Comments on TransplantPath*
Final Report to follow

Process is to be repeated with the final report

If BBV/NAT testing is requested the SN is to update this on DonorPath > Past Medical History > General comments

RCPoC to check new results on Transplant Path

Malaria and Trypanosoma Cruzi (T. Cruzi)

- A GDRI search A-Z Search “transfusionguidelines.org” is required in every country visited to identify requirement for possibility of additional testing.
- If Malaria and T.Cruzi are identified following a GDRI check, refer to TDSG-DD General Principles (transfusionguidelines.org) to identify if patient meets criteria for further testing.
- If Malaria and T Cruzi indicated complete **FRM5025**, Scotland complete **FRM5814**. **SN Must ensure the rationale for testing is communicated to MSL Virology or SNBTS on the referral form.**

West Nile Virus

- A GDRI search A-Z Search “transfusionguidelines.org” is required in every country visited to identify requirement for additional testing.
- Testing is indicated if travel to a high-risk area has occurred during Mosquito season and patient is **within 28 days** of return from travel. Travel outside these criteria, in completely asymptomatic individuals, is **NOT** required.
- If West Nile Virus is indicated complete **FRM5025**, Scotland complete **FRM5814**. **SN must ensure the rationale for testing is communicated to MSL Virology on the referral form.**
- **If sample is sent prior to completion of MaSH, MSL/SNBTS must be updated by email with complete rational for additional testing requirement.**

Tropical Viruses (Including Chikungunya, Dengue, Yellow Fever and Zika)

- A GDRI search A-Z Search "transfusionguidelines.org" is required in every country visited to identify requirement for additional testing.
- Testing is indicated if travel to a high-risk area has occurred, and patient is **within 28 days** of return from travel.
- E, W & NI If testing is indicated complete **FRM5025**. **SN must ensure the rationale for testing is communicated to MSL Virology on the referral form.**
- Scotland: If testing indicated, complete "**Other testing required**" section on **FRM7029**. SN must ensure the rationale for testing is communicated to MSL Virology on the referral form, follow up request to MSL with complete rationale for additional testing requirement.
- **If sample is sent prior to completion of MaSH, MSL/SNBTS must be updated by email with complete rational for additional testing requirement.**

N.B: If requesting any additional testing, ensure that details such as:

1. Residency/ travel/ other risk
2. Countries visited
3. Date of travel (approximate as near as possible if exact dates not known. e.g., start/middle/end of month)
4. Date of last entry into the UK from countries visited (approximate as near as possible if exact dates not known e.g., start/middle/end of month)
5. Any other relevant notes

If testing is indicated please complete **FRM5025**, Scotland complete **FRM7029**. ***If sample is sent prior to completion of MaSH*** or new information from the donor becomes available***, MSL MUST be updated by email with complete rational for additional testing requirement***, contact the relevant laboratories by email.

Contacting the laboratories.

1.21 MSL Virology in Colindale is the reference laboratory for England, Northern Ireland and Wales.

1.22 SNBTS is the reference laboratory for Scotland.

1.23 In circumstances where bloods have been sent for processing and a subsequent risk factor has been identified following completion of MaSH, email MSL Virology or SNBTS (Scotland).

- 3 points of PID (NHS/Hospital/CHI number, ODT number, date of birth and full name).
- Additional marker request (for example: Malaria).
- Rationale for the request (for example, travel throughout South America for 6 months returning to the UK 2 weeks ago).
- Do NOT send a second form.
- Do NOT send further blood samples.

MSL Virology: Email **NTMRL@nhsbt.nhs.uk -** Always advise local testing laboratory that SN is sending sample. Clearly state which ODST.

SNBTS: Telephone SNBTS on **0131 314 5535**. Always advise local testing laboratory that SN is sending sample. Clearly state which ODST.

1.24 If additional testing has been requested by the SN and this is deemed not clinically required by labs i.e. MSL/SNBTS. The SN must contact the recipient point of contact by email to inform them that these tests will not be completed. The SN must document in visible sections in DonorPath.

Haemodilution

1.25 SN must be aware of when large volume blood loss requiring intravenous fluid replacement therapy, may result in false negative screening test results due to dilution of specific antibodies or antigens below the lower limit of detection.

1.26 The volume of fluid that may be infused before false negative results may occur depends on the size of the individual, amount of blood loss and the nature of the infused fluid.

1.27 If required, SN to perform haemodilution calculation. If >50%, a pre-dilution sample must be sought. If this sample cannot be found, then the Microbiology laboratory, RCPoCs and TES must be informed and documented in DonorPath within a Core Donor Data field (indicated by Wi-Fi symbol) to ensure this is visible in Transplant Path. Indicate haemodilution calculation percentage in the laboratory request form.

1.28 Implement caution when calculating haemodilution in circumstances of mass transfusion and specifically ECMO due to additional circulation.

1.29 Haemodilution calculations for 12 years and under, the following JPAC calculation / assessment tool should be completed and the results documented on DonorPath, in line with the paediatric manual **SOP5874**. DO NOT use the one on DonorPath.

1.30 If a pre-transfusion sample is required, ensure that Coroner/Procurator Fiscal's permission has been sought if applicable – refer to **MPD865**. SN should ensure sufficient samples remain should Coroner/Procurator Fiscal require these. Ensure date, time and hospital location is clearly written on the sample tube.

Passively Acquired Antibodies

1.31 When blood components and blood products are transfused, antibodies present in these units can be detected when testing the donor sample. These antibodies can remain detectable for approximately 3 to 4 weeks, sometimes longer. This information about transfusion must be entered in the relevant section of MaSH.

Maternal Microbiology

1.32 For patients under 18 months and any child who has been breast-fed in the last 12 months, microbiological samples, including a sample to accompany tissue donation if applicable, will be required for testing from the child's birth parent and/or individual who breast fed the child.

Non-Proceeding Donation

1.33 In the event of a non-proceeding organ donor, please see Characterisation Manual **SOP6405** (Blood testing in non-proceeding organ donors), for blood testing stand down process and consideration of research and tissues.

2 – Clinical Microbiology documentation and reporting at time of donation

Receipt and Management of Clinical Microbiological Blood Results at the Time of Donation

2.1 Receive Clinical Microbiology blood results in a PDF format. Results are received via secure email in the regional microbiology inbox.

2.2 Confirm correct report has been received, check demographics and content of report

2.3 Upload PDF through 'Attach File' to DP ensuring accurate file type (interim / final result). Document in attachment comments that the results are checked against 3 PID. Label results as per report heading. No requirement to Print results

2.4 If results not received in PDF format alert DFCS on **FRM5499** and DFCS will convert to PDF as per **SOP5049**.

2.5 Enter the Microbiology blood results directly onto DonorPath. Check results entered onto DonorPath for accuracy.

2.6 A EQUIVOCOL or INDETERMINATE result, must be entered as INDETERMINATE into Donor Path and NOT recorded as POSITIVE.

2.7 A provisional positive or initial reactive result must be entered into DonorPath as a positive result until the confirmatory testing has been complete. If unable to record on DonorPath follow **SOP3925**.

2.8 If offering has been commenced prior to microbiology results being available, contact HUB operations to inform them of changes.

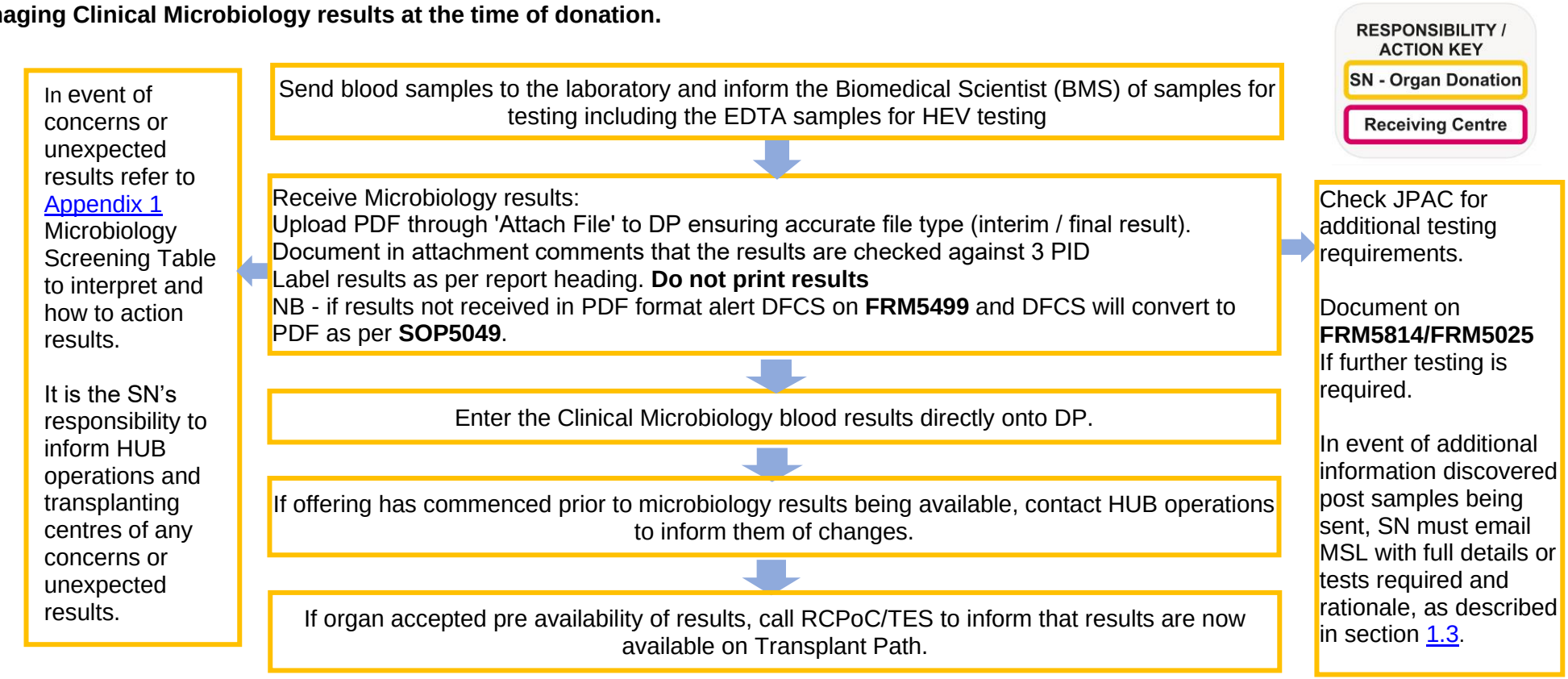
2.9 If organ accepted pre availability of results, call RCPoC/TES to inform that results are now available on Transplant Path.

2.10 For the process of sharing microbiology results to Europe/ Republic of Ireland please refer to **SOP4938** Sharing Clinical Information.

2.11 For immediate actions that must be taken for any intermediate or positive results, refer to Appendix 1.

2.12 HEV and HHV-8 results will be available from MSL/SNBTS 12-14 days post donation and results will be emailed to DFCS. On receipt of results follow Appendix 1. **HEV** **HHV-8**

Managing Clinical Microbiology results at the time of donation.



3 – Positive Clinical Microbiology – Considerations for unexpected results

3.1 Upon receiving positive or indeterminate clinical microbiology results consult Appendix 1 Microbiology Screening Table.

3.2 If required obtain interpretation from the testing laboratory Consultant. Discuss with OLN or OM On Call if you have concerns or require clarity regarding the Clinical Microbiology results.

3.3 Discuss with local testing laboratory to enquire what other tests should / can be undertaken to confirm the Clinical Microbiology results.

3.4 SN to ascertain if further tests can be done locally and when will the results be ready.

3.5 If further testing is not available locally or testing is required to be performed by MSL/SNBTS, consult Appendix 1. Discuss case with NHSBT consultant microbiologist at MSL/SNBTS as soon as possible during working hours. Send sample to MSL/SNBTS at earliest opportunity.

3.6 Out of hours, consult Appendix 1 and if required, SN must send the sample to MSL/SNBTS at earliest opportunity. SN must also email MSL/SNBTS marked as high importance and attach completed **FRM5025 / FRM5814** (Scotland). SN to contact NHSBT Consultant Microbiologist at MSL/SNBTS to discuss case / results during normal working hours.

3.7 SN should discuss case with OLN or OM On Call. Appendix 1 should be used to assess if a process may need to be paused.

4 – *Clinical Microbiology documentation and reporting Post Donation*

RESPONSIBILITY/ ACTION KEY
- DFCS
- SN- Organ Donation
- Receiving Centre

Post Donation Result - attached to DonorPath by DFCS and regional SN PoC informed that it is available for checking as per **SOP5049**

Check PID against donor record and check each individual pre donation result documented on DonorPath against the final microbiology laboratory report.

No New Information
Confirmed NEGATIVE / POSITIVE Result
(**EXCLUDING confirmed POSITIVE HHV-8 –** see next page)
- Document in comments under attachment "Checked against 3 x PID. No new information. No further action"

RCPoC/Research centres/NRC aware that results will be available post donation but receive no alert to check them.

ADVICE
In rare cases it may not be possible to ascertain a confirmed positive or negative result. Final indeterminate results should follow the positive results pathway.

New Positive Result
(**EXCLUDING POSITIVE HHV-8** – see next page)
- Update microbiology section in DonorPath with the result
- Escalate to LN for awareness
- Check Organ Outcome Summary for receiving centres
- **Telephone RCPoCs/Research centres/ NRC (Appendix 1)**
- Email centres (**DAT2792 DAT4135**) *do not attach result to email*
  Subject: ORGAN DONOR: NEW INFORMATION
  Microbiology Report/Test Name (mark as High Priority)
  FINAL REPORT or INTERIM REPORT (SN to delete as appropriate)
  Body of Email FINAL REPORT or INTERIM REPORT (SN to delete as appropriate)
  'Dear.., please refer to Transplant Path for a final Microbiology/Test Name report for Donor ODT, DOB and Donating Hospital' **or**
  An interim Microbiology/Test Name result is available for *Donor ODT, DOB and Donating Hospital' documented in the results section on TransplantPath.Full Report is NOT visible on TransplantPath. Final report to follow.*

Process is to be repeated with the final report

New Negative Result
(Including NEGATVE HHV8)
- Update microbiology section in DonorPath with the result
- Check Organ Outcome Summary for receiving centres
- Email **RCPoCs/Research centres/ NRC** (**DAT2792 DAT4135**) *do not attach result to email*
  Subject: ORGAN DONOR: NEW INFORMATION
  Microbiology Report/Test Name (mark as High Priority)
  FINAL REPORT or INTERIM REPORT (SN to delete as appropriate)
  Body of Email FINAL REPORT or INTERIM REPORT (SN to delete as appropriate)
  'Dear.., please refer to Transplant Path for a final Microbiology/Test Name report for Donor ODT, DOB and Donating Hospital' **or**
  An interim Microbiology/Test Name result is available for *Donor ODT, DOB and Donating Hospital' documented in the results section on TransplantPath..Full Report is NOT visible on TransplantPath. Final report to follow.*

Process is to be repeated with the final report

RCPoC to check new results on TransplantPath

Document on DonorPath under attachment in the comments "Checked against 3 x PID" and actions taken

HHV-8 Post Donation Result (interim OR final) - attached to DonorPath by DFCS as per **SOP5049**
Regional SN PoC informed that it is available for checking

Document on DonorPath under attachment in the comments "Checked against 3 x PID" and actions taken

New or confirmed POSITIVE / INDETERMINATE HHV-8 Result

- Check 3x PID against donor record
- Update microbiology section in DonorPath with the result
- The SN must escalate to LN for awareness
- Check Organ Outcome Summary for receiving centres
- Telephone RCPoCs/Research centres/NRC to inform them that a new (or confirmed) positive/indeterminate result is on TxP.
- If interim result, inform RCPoC/Research Centres that the result is on TxP, a full report is **not** visible on TxP but a final report will be uploaded and centres will be alerted. If centres require the report immediately escalate to LN/ OM
- Email centres (use as per **DAT2792 DAT4135**) mark as High Priority attaching **FRM7233** and **INF1746 *do not attach result to email***

Subject: ORGAN DONOR: NEW INFORMATION HHV-8 POSITIVE (or INDETERMINATE) antibody result
Body of email: Donor ODT number, DOB, Date of Donation, Donating Hospital, Transplant Centre, Organ donated.
(mark as High Priority) FINAL REPORT or INTERIM REPORT (SN to delete as appropriate)

Dear…. HHV-8 antibody reactivity was **DETECTED** in the above donor's blood. Please see final results and comments in the report uploaded onto TxP
Or (for interim) Dear… HHV-8 antibody reactivity was **DETECTED** in the above donor's blood. An interim result has been uploaded to TxP, the report is **not** visible on TxP but a final report will follow.
Please liaise with Virology so that testing and reporting of results are optimally co-ordinated.
Short notes on HHV-8 and the follow up protocol can be found on attached **INF1746**. Recipient follow up samples must be sent to NHSBT via your Laboratory, with the attached request form **FRM7233** Please liaise with Virology when submitting a sample in order to avoid incorrect referral.
Please kindly acknowledge receipt of this communication and do not hesitate to contact us as required.
SN name and contact details.
*Above process to be repeated with the final report (if interim was initially actioned) *

- Call RCPoCs/Research centres/NRC to make them aware, check they have received the above email.
- SN to facilitate discussion between microbiologist and transplanting surgeon if required.
- Document on DonorPath under attachment in the comments "Checked against 3 x PID" and actions taken.

RCPoC/Research centres/NRC to check new results on TransplantPath

RESPONSIBILITY/ ACTION KEY
DFCS
SN- Organ Donation
Receiving Centre

ADVICE
In rare cases it may not be possible to ascertain a confirmed positive or negative result. Final indeterminate results should follow the positive results pathway.

4.1 Locate results within DonorPath and check each individual result against the final microbiology laboratory report. By stating the report has been checked, the SN is confirming that the final report has been compared against the results already documented on DonorPath and checked against 3 points of PID.

4.2 Acceptable PID references must be checked; ODT number if included on the report plus 2 of the following 3 additional identifiers- donor's name, DoB and NHS/CHI number.

4.3 Compare individual results on DonorPath against the final report to ensure no discrepancies in results.

4.4 Uploaded results that have not previously been received at the time of donation will include, but is not limited to, HEV, HHV-8, Malaria, WNV and T-Cruzi and any other additional anticipated microbiology results triggered during donor characterisation.

4.5 In the event of positive microbiology/virology (excluding CMV, EBV and Toxo), discuss with LN/ OM On Call who will advise if it is appropriate to seek specialist advice. Refer to Appendix 1. If appropriate escalate to MSL/SNBTS. **FRM5037** must only be completed if, after discussion with LN, the SN is seeking advice on a particular donor result. This form is not needed to report every positive case where advice is not being sought.

4.6 For any new final microbiology, including new negative results, the SN must contact ODT Hub operations to review organ outcome summary.

4.7 When Hub Ops is called to confirm organ outcomes, the SN should confirm if the pancreas was isolated and where so that the isolating lab can be included in dissemination of the micro results report.

4.8 SN is to then email RCPoC/TES/Research via NHSBT email and mark with 'high importance' – and to refer to TransplantPath for final microbiology. Use **DAT2792** to source transplant unit email addresses and **DAT4135** for research centres (do not attach result to email) **There is not a requirement to email confirmed negative results.**

- Ensure subject line on email includes:
  - ORGAN DONOR: NEW INFORMATION Test Name (mark as High Priority)
    OR
  - ORGAN DONOR Maternal Final Microbiology Laboratory report-urgent attention

- Include following information in the body of the email:
  - ODT number
  - Donor DOB
  - Donor hospital
  - Date of donation

4.9 In the event of positive microbiology/virology (excluding CMV, EBV and Toxo), SN to contact RCPoC/TES/Research points of contact to alert them of microbiology/virology results and ensure receipt of microbiology results via email following **DAT1435** and **DAT2792**.

4.10 Document notes, in the attachments section on DonorPath, pertaining to the uploaded laboratory report, that the attached results have been checked (as per section 4.1) and what actions have been taken e.g. Transplant centre/TES has been notified of the final report including which organ has been transplanted. Date and time RCPoC(s)/TES notified and the name of the RCPoC(s)/TES if alerted by telephone.

4.11 The process of sharing microbiology results to Europe/ Republic of Ireland please refer to **SOP4938** Sharing Clinical Information.

ADVICE

If a receiving centre performs additional microbiology testing (on blood accompanying the organ), and these results are discrepant to the ones performed at the time of donation (Characterisation), this must be reported via the incident submission form to the Patient Safety Team.
Results on DonorPath from the time of donation must not be changed, unless advised to do so following incident investigation.

Management Hepatitis A and Parvovirus B19 Results – SNBTS

4.12 All Organ and Tissue donors in Scotland, and pancreas sent to Edinburgh for islet isolation from anywhere in the UK, will have NAT bloods tested for Hepatitis A and parvovirus B19. The testing will be based on PCR testing and not serology i.e. it will pick up current active infection and not historical infection

- No additional sample or FRM is required to be sent by the SN.
- Please follow the flowchart on page 31 to action ALL Hepatitis A and Parvovirus B19 results.
- A confirmed negative result will be available within 24-48 hour's (excluding weekend). SNBTS will send a **negative** result to the DFCS who will upload the result and will alert POC.
- An **initial reactive positive** result will be emailed/phoned through to Hub Operations who will then page/email the SN team, the POC/SN will be required to upload this onto Donor Path and action as per page 2.
- A confirmed positive Hepatitis A and Parvovirus B19 result will take up to 10 working days.
- As Hepatitis A is a notifiable infection, our colleagues in SNBTS report to the appropriate public health organisation. SNODs can refer to **INF958** (England & Wales) **INF961** (Northern Ireland) and **INF960** (Scotland) notifiable diseases for information and support advice to the donor family under the guidance of the clinical microbiologist. Positive cases should be escalated to the LN/ OM on call for advice if required.

Please see next page for interpretation of all lab results for Hepatitis A and Parvovirus B19

Management of Hepatitis A and Parvovirus B19 Results from SNBTS

New or confirmed **NEGATIVE** Hepatitis A / Parvovirus B19 result post donation. attached to DonorPath by DFCS as per **SOP5049** and regional SN PoC informed that it is available for checking.

New or confirmed **POSITIVE** result Hepatitis A / Parvovirus B19 result post donation. HUB will page and email result. SN to attach to DonorPath and action as below.

Check 3x PID against donor record and laboratory report. Check each individual result and document result within the Investigations section using the infections box

New **Negative** Result

- Update result in the Investigations section in DonorPath using the infection 'free text' box.
- Check Organ Outcome Summary for receiving centres.
- Email RCPoCs/Research centres/NRC centres (**DAT2792**) *do not attach result to email*

Subject: ORGAN DONOR NEW INFORMATION Hepatitis A and Parvovirus B19 Report (mark as High Priority) FINAL REPORT
Body of email*: 'Dear….. please refer to TransplantPath for final microbiology - NEW INFORMATION Donor ODT, DOB and Donating Hospital'*
Please kindly acknowledge receipt of this communication and do not hesitate to contact us as required.
SN name and contact details

Confirmed **POSITIVE** Hepatitis A / Parvovirus B19 Final Result

*If an interim result has already been actioned, the RCPoC must still be emailed and telephoned to be informed that the final report is available on TransplantPath.

- The SN must escalate to LN for awareness.
- Check Organ Outcome Summary for receiving centres.
- **Telephone** RCPoCs/Research centres/NRC to inform them that an Interim or confirmed positive/indeterminate result is on TransplantPath
- SN to facilitate discussion between microbiologist and transplanting surgeon if required.
- Email centres (use as per **DAT2792**) mark as High Priority *do not attach result to email*

Subject: ORGAN DONOR NEW INFORMATION **Hepatitis A / Parvovirus B19** final antibody result
Body of email: - Donor ODT number, DOB, Date of Donation, Donating Hospital, Transplant Centre, Organ donated.
*Dear……,***Hepatitis A / Parvovirus B19** *was **DETECTED** in the above donor's blood. please refer to TransplantPath for final microbiology report -*

Please kindly acknowledge receipt of this communication and do not hesitate to contact us as required.
SN name and contact details.

Document on DonorPath under attachment in the comments. State which 3x PID has been checked and actions taken

RCPoC /Research centres/NRC to check new results on TransplantPath

4.13 **Interpretation of all lab results for Hepatitis A and Parvovirus B19**
Routine report (see mock result image below)

Results for Hepatitis A (HAV) and parvovirus B19 will be reported by:

- on the one report there will be **other samples tested in the same batch.**
- SNBTS staff will **underline** the relevant result and **apply a label** to the report.
- This label will display donor ID, full name, and DOB. These 3 points of ID are to be used so the result can be linked to the donor files.
- If there is no 3 PIDs, the report needs to be sent back to DFCS/SNBTS
- Ignore the "SAMPLE ID" on the label this does not correlate
- Donor ID might be placed on other parts of the form and not the actual label

Mock Result - Routine result (donor ID will be added on)

TEST RESULT TCS/TT2
Sample ID #: G170424 191 198 T
Sample date: 05NOV2024
Donor Surname: xxxxx
Donor Forename: yyy
Donor DOB/Chi: 01.01.1900/0101000000
Hospital: RIE
Category: ~~Bone/Stem~~/Organ/Other:
Reconciled by: AN Date: 07NOV2024.
2nd Check: fm Date: 07 NOV 2024

Sample Details

Database 'Production'

MOCK RESULT, TRAINING

Printed only selected data

Reported On: 11/5/2024 12:00:39 PM

Sample ID	Lysate ID	Assay/Analyte	Conclusion	S/CO	Reported B19 Conc	B19 Cutoff	Date	Worklist ID	Apprd?	Exp'd
=G17042419120096		Parvo	bc		< 500	5000	11/5/2024 11:58:52 AM	000590-20241105-02	☑	☑
=G17042419120096		HAV	NonReactive	0.13			11/5/2024 11:58:52 AM	000590-20241105-02	☑	☑
=G17042419119987		Parvo	bc		< 500	5000	11/5/2024 11:58:52 AM	000590-20241105-02	☑	☑
=G17042419119987		HAV	NonReactive	0.13			11/5/2024 11:58:52 AM	000590-20241105-02	☑	☑
=G17042419119889		HAV	NonReactive	0.13			11/5/2024 11:58:52 AM	000590-20241105-02	☑	☑
=G17042419119889		Parvo	bc		< 500	5000	11/5/2024 11:58:52 AM	000590-20241105-02	☑	☑

4.14 **Interpretation of all lab results for Hepatitis A and Parvovirus B19**

Hepatitis A (HAV)

- HAV is reported as a qualitative result - either **Reactive (positive)** or **NonReactive (negative)**

Parvovirus B19

- Parvovirus B19 is reported as a quantitative result - either **bc** or **cec**
- bc - below cut off (also interpreted as Negative/Non-Reactive)
- cec - concentration exceeds cut off (also interpreted as Positive/Reactive)

B19 cut off is 5000, as shown on report, and the reported B19 concentration will be shown as either <500 or a number such as 708 if above concentration of 500.

Reactive/Positive results

- If a **Reactive** or **cec** result is reported, you will not receive the result in the format of a routine result.
- SNBTS staff sharon.zahra@nhs.scot and/or Salma will be in touch in the first instance to discuss the result. Meanwhile, another testing department (NMRU) will perform confirmatory testing to confirm the original result.

See next page for Mock Result - positive result after confirmatory testing has been performed.

Mock Result - positive result after confirmatory testing has been performed.

TEST RESULT ~~TQS~~/TT2
Sample ID #: G170 424 000 000 x TO NATS QAD 081) **MOCK POSITIVE REPORT FOR TCAT TRAINING**
Sample date: 07 NOV 2024
Donor Surname: XXXX
Donor Forename: YYY
Donor DOB/Chi: 01.01.1900
Hospital: GJ NH
Category: ~~Bone/Stem~~/Organ/~~Other~~
Reconciled by: AN Date: 07 NOV 2024
2nd Check: AN Date: 07 NOV 2024

NATF 2345 03
s to SOP No. NATS NMRU 107 & NATS NMRU 174)
WNV / HAV / B19
Confirmatory Testing Report Form

NHS National Services Scotland

Originating Site:	TCAT MOCK RESULT TRAINING

Donation Number:	G170 424 000 000 X	NMRU Reference Numbers	Serum	T200302
			Plasma (PPT)	T200303
Donor ID:	N/A		Plasma (EDTA)	T200304
Date of Withdrawal:	07 Nov 2024		Plasma (Pack)	T200411

REFERRING SITE RESULTS	
NAT RESULT	B19 PCR Positive

NMRU RESULTS

NMRU Reference Number	WNV PCR	HAV PCR	B19 PCR
T200303	N/A	N/A	Positive
N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A

Comment:	**Confirmed PCR Positive for human parvovirus B19 DNA Evidence of active Infection**		
Signed:	Signed	Date:	07 NOV 2024

NMRU RESULT ADDED TO LIMS: N/A

LIMS used:	N/A		
First Entry by:	N/A	Date:	N/A
Second Entry by:	N/A	Date:	N/A

5 - Communicating with NOK/Donor Family (including communication of positive Clinical Microbiology)

Actions related to the NOK/Donor family in case of positive Clinical Microbiology findings (see flow chart p29)

SN and TES CSNT must use their professional judgement and knowledge of the donor and family's circumstances, to decide on the most appropriate course of action.

Unless there are exceptional circumstances, there is no urgency to notify the family, and it is important to await completion of tests and receipt of final laboratory report. Full understanding of the final reports is necessary.

Decision making regarding the need to inform family members or close contacts of the donor, must be made by the SN. In more complex cases to this is to be discussed with the OLN / OM On Call.
An individual risk assessment must be carried out by the SN on the known information to decide if there is a potential risk to anyone. Identified risk, would mean informing them will be to their benefit. Document decision and rationale in SoE on DonorPath.

High-Risk associated behaviours for potential transmission to be considered include but not limited to:

a) Household contacts, bed sharing, shared bath water, towel sharing, toothbrush etc.
b) Sexual contacts.
c) Recreational drug use – sharing of needles / inhalation drugs etc.
d) Anyone with caring responsibilities that may pose a risk.

At the time of donation for Organ Donors

5.1 If donation does not proceed: the SN should inform the NOK/donor family that donation will not go ahead and that investigations will be completed at the earliest opportunity and the NOK/donor family will be contacted as soon as definitive information is available. Clinical Microbiology test results in isolation are rarely the primary reason for the donation not to proceed; other factors usually contribute to the decline of organs. It is therefore appropriate to refer to unsuitability / no suitable matches without disclosing yet unconfirmed screening results.
5.2 If the donation proceeds: no further action needs to be taken until investigation of the initial results have been completed.

Post Donation for Organ Donors

5.3 Unless there are exceptional circumstances, there is no urgency to notify the family, and it is important to await completion of tests and receipt of final laboratory report.

5.4 Full understanding of the final results is necessary. The SN should also inform the Intensive Care Unit (ICU) Consultant caring for the donor. It may be appropriate for the SN to talk to the family after appropriate discussion with the OLN/ OM On Call. **FRM5037** can be used to provide the relevant information if needed.

5.5 As family circumstances vary, the SN involved with the family is best placed to judge the best way of informing them, which will more than likely be by phone or video call. In exceptional circumstances this may be in person, however this may be discussed, approved and risk assessed by the OLN. This must then be followed up in writing using **LET428.**

5.6 The SN should arrange an appropriate time to discuss the results with the family. The conversation does not need to be face-to-face. Usually there is an opportunity to tell them around 2 weeks after the donation, when the SN would ordinarily be communicating with the family.

5.7 The family should be informed of the results and advised to contact their own GP. The SN is not responsible to go into detail about any associated risk.

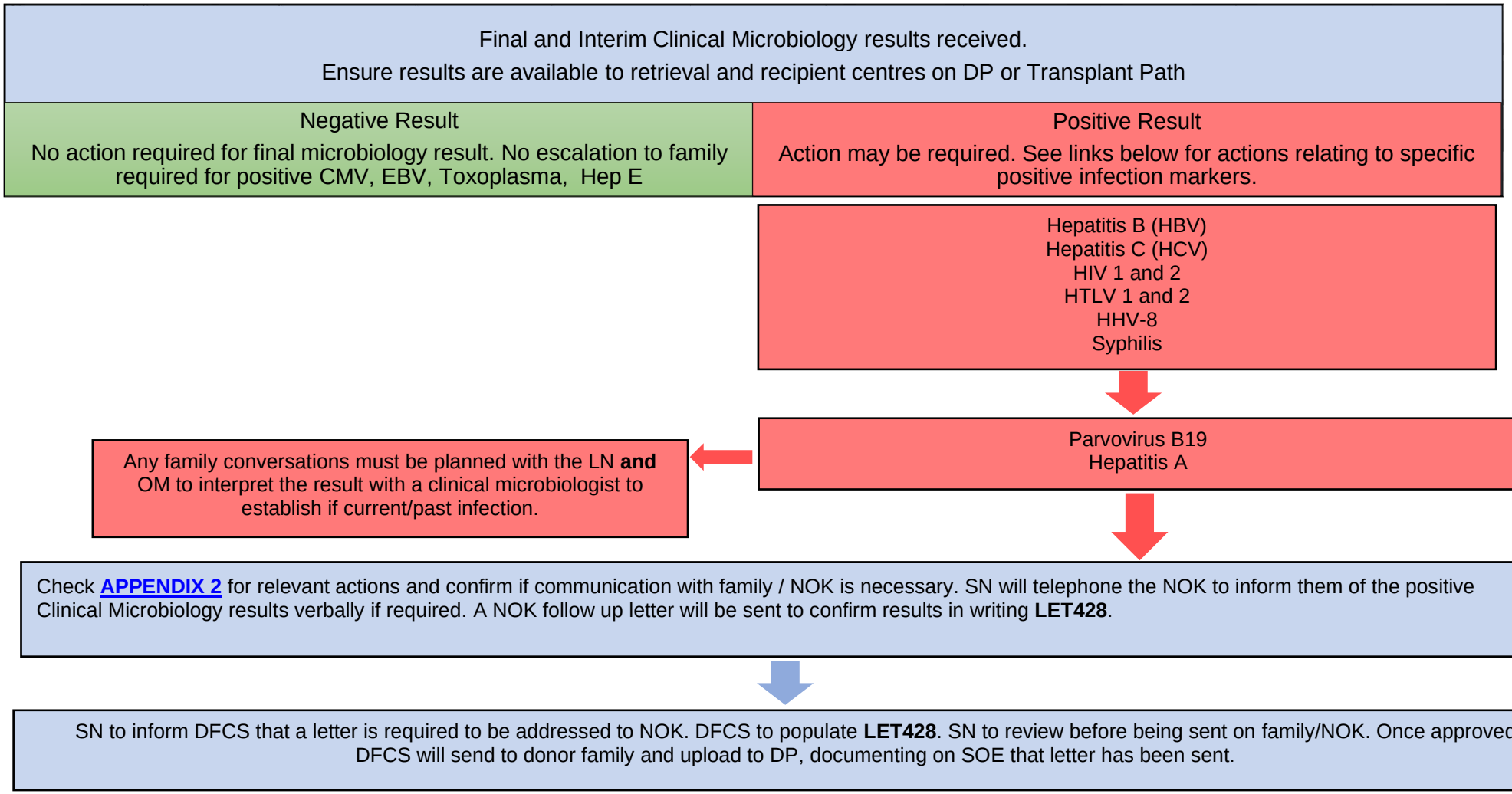
5.8 The family must be advised that their GP is best placed to discuss risk and impact with the relevant individuals. The SN will be responsible to ensure a letter **LET428** is sent to the family for them to take to their GP.

5.9 This letter must be sent by the Donor Family Care Service, and this must be double checked by the SN prior to sending for accuracy. All communications with the NOK/Donor family need to be clearly documented within the donor file and all correspondence must be uploaded to DonorPath.

Eye and / or Tissue only Donors

TES CSNT must understand the rationale and importance of microbiological screening. It is NOT the role of the CSNT to interpret these tests and it is NOT the role of the CSNT to give advice to the clinical implications of the results. If CSNT receive communication from an individual following receipt of a letter; they can seek further support from TES Medical Consultant or Consultant Virologist for further advice. For family communications see Appendix 2.

Role of the specialist Nurse Organ Donation/Clinical Support Nurse Team in Communicating positive Clinical Microbiology with Donor Families/Next of Kin



Additional Resources and Useful Links

JPAC – Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee:
https://www.transfusionguidelines.org

SABTO- Advisory Committee on Blood, Tissues and Organs - Microbiology Safety Guidelines:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/876161/SaBTO-microbiological-safety-guidelines.pdf

NHS Blood and Transplant, Colindale:
ntmrl@nhsbt.nhs.uk

Hub Operations email address:
odthub.operations@nhsbt.nhs.uk

National Referral Centre email address:
National.ReferralCentre@nhsbt.nhs.uk

Donor Family Care Service email address:
odtdonor.recordsdepartment@nhsbt.nhs.uk

Appendix 1: Microbiological Screening Tables

Terminology	Examples of Terminology used in Laboratory Reports	
Positive	Reactive Positive Detected	Terms usually used interchangeably; meets pre-defined manufacturer's criteria for positivity. Check with laboratory if further tests need to be carried out.
Indeterminate	Equivocal Indeterminate Reactive awaiting results Reactive – see interpretation Further report to follow Inconclusive	These terms indicate that results cannot be interpreted confidently as being negative or positive. Further testing may be necessary. Any indeterminate results or equivocal should be inputted as INDETERMINATE onto DP and NOT as positive. It will be up to the accepting centre to interpret and await further results.
Negative	Negative Not Detected Not Reactive	Usually used interchangeably; meets pre-defined manufacturer's criteria for negativity Indicates that the analyse tested for was not detected in the specimen.

Infection Marker	Negative/Not Detected	Indeterminate	Positive
HBsAg Anti-HBcore	Follow normal procedure. No special action required.	Follow section 3 ➢ If positive Hep B Surface antigen (not anti-HBcore only) or HBV DNA has been confirmed, when contacting HUB to commence offering request that the positive microbiology/virology offering process is commenced. ➢ If offering has been commenced prior to positive microbiology/virology results being available and is on-going, contact HUB operations to inform them of changes. ➢ In event of new findings of positive microbiology/virology when centres have accepted organs, ensure results amended on DP and telephone RCPoCs at accepting centres to inform them. SN to facilitate discussion between NHSBT MSL or consultant microbiologist and transplanting surgeon if required. ➢ **FRM5037** must only be completed if requested by MSL. This form is not needed in every positive case. When considering communication of positive microbiology/virology with NOK/family refer to Appendix 2.1	

Infection Marker	Negative/Not Detected	Indeterminate	Positive
HCV Antibody (+/- Antigen)	Follow normal procedure. No special action required.	➢ Follow section 3 ➢ If antigen or antibody is positive, contact HUB Operations to request that the positive microbiology/virology offering process is commenced. ➢ If offering has been commenced prior to positive microbiology/virology results being available and is on-going, contact HUB operations to inform them of changes. ➢ In event of new findings of positive microbiology/virology when centres have accepted organs, ensure results amended on DP and telephone RCPoCs at accepting centres to inform them. SN to facilitate discussion between NHSBT MSL or consultant microbiologist and transplanting surgeon if required. ➢ **FRM5037** must only be completed if requested by MSL. This form is not needed in every positive case. When considering communication of positive microbiology/virology with Donor Families/Next of Kin please refer to Appendix 2.2	

Infection Marker	Negative/Not Detected	Indeterminate	Positive
HIV 1 and 2 (Antigen+Antibody)	Follow normal procedure. No special action required.	Follow section 3 ➢ If positive Antibody/Antigen/RNA/pro-viral DNA has been confirmed, this indicates current infection. In event of positive results, when contacting HUB Operations to commence offering request that the positive virology/microbiology offering process is commenced. ➢ If offering has been commenced prior to positive microbiology/virology results being available and is on-going, contact HUB operations to inform them of changes. ➢ In event of new findings of positive microbiology/virology when centres have accepted organs, ensure results amended on DP and telephone RCPoCs at accepting centres to inform them. SN to facilitate discussion between microbiologist and transplanting surgeon if required. ➢ **FRM5037** must only be completed if requested by MSL. This form is not needed in every positive case. When considering communication of positive microbiology/virology with Donor Families/Next of Kin please refer to Appendix 2.3

Infection Marker	Negative/Not Detected	Indeterminate	Positive
HTLV I and II Antibody	Follow normal procedure. No special action required.		

- Anything that is not negative will need further tests completed by MSL. Repeat blood sample (one EDTA) to be sent as soon as possible to MSL with **FRM5037**. Discuss case with NHSBT Consultant Microbiologist (MSL) as soon as possible in working hours.
- Please note testing only available during daytime. If out of hours complete characterisation. Pause process prior to offering.
- If positive Antibody/pro-viral DNA has been confirmed on repeat sample discuss case with NHSBT Consultant Microbiologist (MSL). In event of positive results, when contacting HUB Operations commence offering request that the positive microbiology/virology offering process is commenced. Ensure HLA is back prior to offering.

When considering communication of positive microbiology/virology with Donor Families/Next of Kin please refer to Appendix 2.5

Infection Marker	Negative/Not Detected	Indeterminate	Positive
HHV-8 Antibody	Follow normal procedure. No special action required.	➢ Positive HHV-8 antibodies indicate prior exposure to the Virus and lifetime infection. ➢ Positive or Indeterminate/Inconclusive results for HHV-8 antibodies are clinically significant. MSL are responsible for reporting results to OTDT, this will take place post donation. ➢ Normal process for positive results must be followed as per section 4 For non-proceeding organ donors, donation team to follow normal procedures, e.g., check donation of tissues and inform NRC accordingly. Tissue services has a protocol for HHV-8 positive results from deceased organ donors **MPD897** Positive or Indeterminate antibody results do not need to be discussed with the NOK/family.	

Infection Marker	Negative/Not Detected	Indeterminate	Positive
Syphilis	Follow normal procedure. No special action required.	➢ Report must contain interpretation of result. ➢ In event of new findings of positive microbiology/virology when centres have accepted organs, ensure results amended on DP and inform HUB and request update to RCPoCs at accepting centres. ➢ Final result will inform need for further action re: management of recipient When considering communication of positive virology with Donor Families/Next of Kin please refer to Appendix 2.7	

Infection Marker	Negative/Not Detected	Indeterminate	Positive
CMV	Follow normal procedure. No special action required.	➢ Any result that indicates the donor not to be negative (e.g., indeterminate/equivocal/inconclusive) should be regarded as positive until proven otherwise, as this is the safest option. ➢ In the event of positive result, offering commences as normal, no requirement to commence positive microbiology offering process. ➢ CMV antibody status is required to inform recipient management.	

Infection Marker	Negative/Not Detected	Indeterminate	Positive
EBV	Follow normal procedure. No special action required.	➢ Any result that indicates the donor not to be negative (e.g., indeterminate/equivocal/inconclusive) should be regarded as positive until proven otherwise, as this is the safest option. ➢ In the event of positive result, offering commences as normal, no requirement to commence positive microbiology offering process. ➢ EBV antibody status is required to inform recipient management.	

Infection Marker	Negative/Not Detected	Indeterminate	Positive
Toxoplasma Gondi	Follow normal procedure. No special action required.	➢ Indeterminate/equivocal/inconclusive should be regarded as positive until proven otherwise, as this is the safest option. In the event of positive result, offering commences as normal, no requirement to commence positive microbiology/virology offering process. ➢ In the event of positive result, offering commences as normal, no requirement to commence positive microbiology offering process. ➢ Toxoplasma Gondi antibody status is required to inform recipient management.	

Infection Marker	Negative/Not Detected	Indeterminate	Positive
West Nile Virus	Follow normal procedure. No special action required.		

- Verify interpretation of laboratory report; if unclear, contact NHSBT Consultant Microbiologist (MSL) to clarify.
- Positive result for WNV RNA is clinically significant. Donation team should hear from NHSBT Consultant Microbiologist (MSL) to accompany result.
- Transplant centre clinicians need to be informed. SN to inform transplanting centres.
- NHSBT Consultant Microbiologist (MSL) to advise on management plan for recipient and family member(s) (Falls outside Appendix 2). Usually, no implication to NOK as this infection is spread through mosquito bite. There may be cases where NOK might have been in the endemic area with the donor, so details required for assessment.

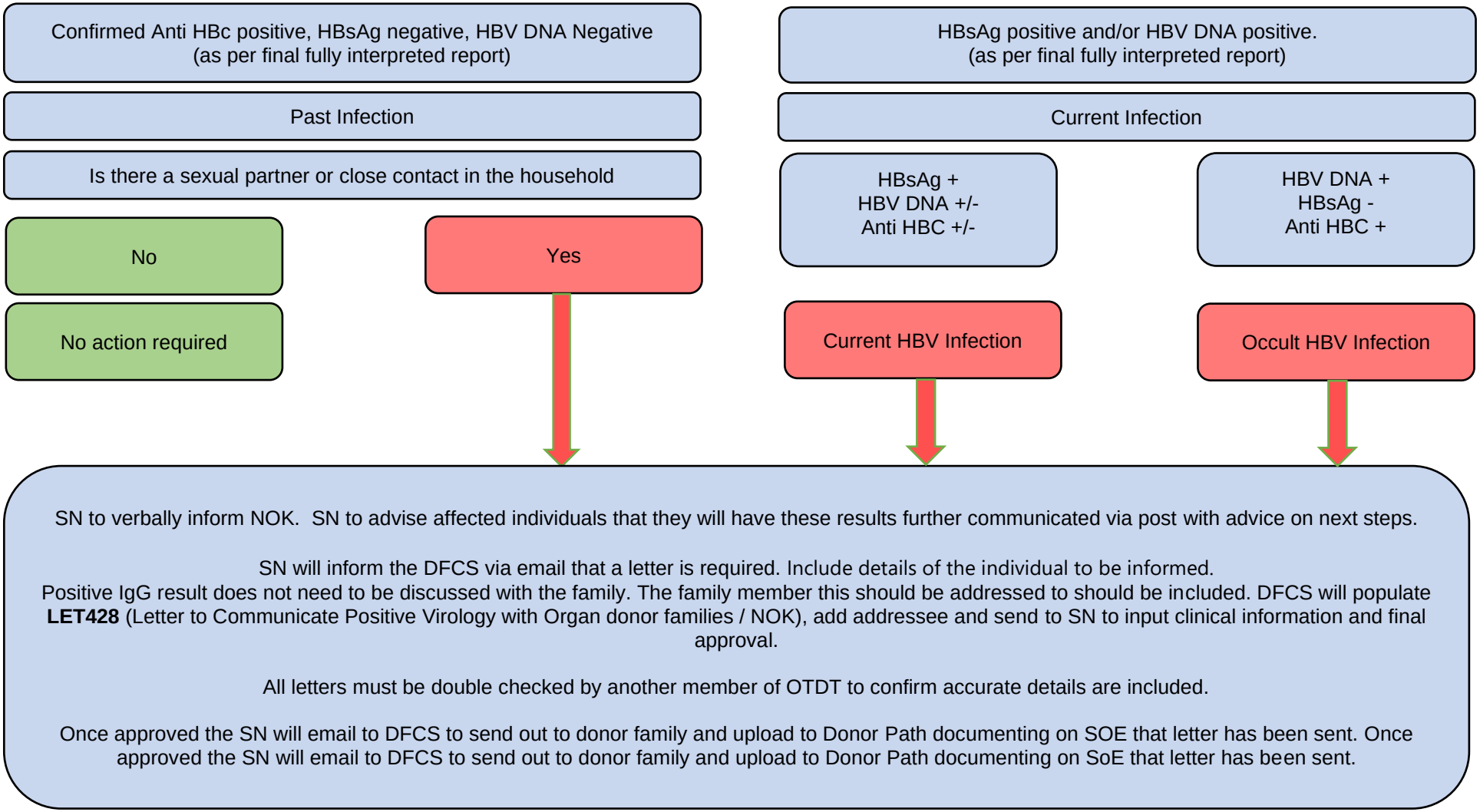
Infection Marker	Negative/Not Detected	Indeterminate	Positive
Malaria	Follow normal procedure. No special action required.	➢ Transplant centre clinicians need to be informed of positive or indeterminate results. ➢ In the case of indeterminate antibody result, a report will be issued with interpretation and advice. As a precautionary measure, transplant centres usually advised to consider including malaria in the diagnostic differential. SN's to inform transplanting centres and provide report. **For Positive results two possibilities exist:** ➢ Malaria antibody detected but Malaria DNA NOT detected. Laboratory report will contain comment advising transplant centre to consider malaria in the diagnostic differential of any episode of fever in the first 4 months' post transplantation. SN's to inform transplanting centres and provide report. ➢ Malaria antibody and Malaria DNA POSITIVE. Donation team will hear from NHSBT Consultant Microbiologist (MSL) to discuss action. Laboratory report will be issued with interpretation and advice. SN's to inform transplanting centres and provide report for immediate action. Report will include patient assessment and contact with the consultant parasitologist at the Hospital for Tropical Diseases.	

Infection Marker	Negative/Not Detected	Indeterminate	Positive
T Cruzi	Follow normal procedure. No special action required.	➢ Antibody positive result is of clinical significance. ➢ Donation team will be contacted by the NHSBT Consultant Microbiologist (MSL) to discuss actions. Report issued will contain interpretation and advice. This will be a rare occurrence and a specific set of actions will have to be triggered to mitigate harm to recipients. Consultant for Parasitology at the Hospital for Tropical Diseases will be involved ➢ SN's to inform transplanting centres and provide report. for immediate action. NHSBT Consultant Microbiologist (MSL) to advise on management plan for recipient and family member(s) (Falls outside Appendix 2)	

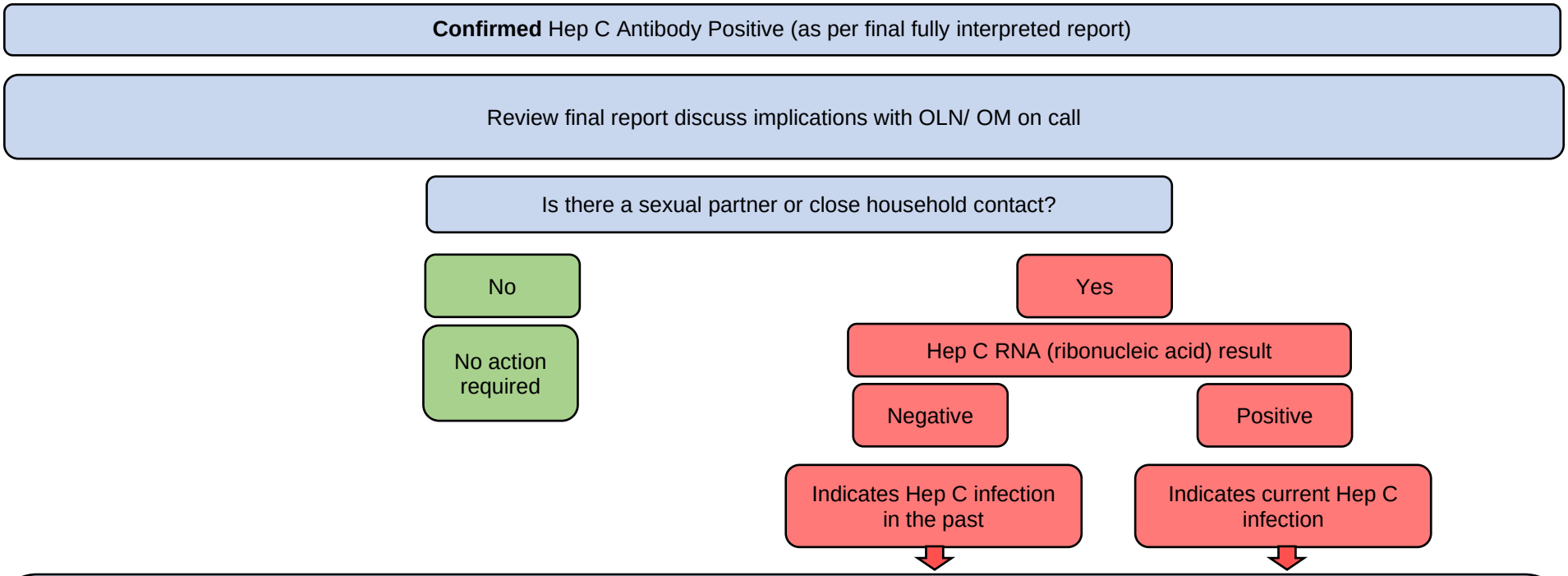
Infection Marker	Negative/Not Detected	Indeterminate	Positive
HEV	Follow normal procedure. No special action required.	➢ Obtained Laboratory report will have interpretation and advice for Transplanting centres. SN's to inform transplanting centres and provide report for immediate action. ➢ Likely recommendation will be transplanting centres are encouraged to check the HEV status of the recipient as a precautionary measure to exclude infection.	➢ HEV RNA positive result of clinical significance ➢ Laboratory report will have interpretation and advice for transplanting centres. SN's to inform transplanting centres and provide report for immediate action. ➢ Likely recommendation that recipients must be tested for HEV at intermittent time points to exclude infection.

Post donation management of NOK/Family
No action required as HEV is a food-borne infection.

Appendix 2.1 - Flow Chart for communicating Hep B Past/Current/Occult infection with Tissue and Organ Donor Families



Appendix 2.2 - Flow Chart for communicating confirmed Hepatitis C Antibody Results with Tissue & Organ Donor Families



Appendix 2.3 - Flow Chart for communicating confirmed HIV positive Results with Tissue & Organ Donor Families

Confirmed HIV positive (as per final fully interpreted report)

Review lab interpretation/comments discuss implications OLN/ OM
Following discussion if further interpretation or clarity consult NHSBT Consultant Microbiologist (MSL).

Is there a sexual partner or close household contact?

No action required

No

Yes

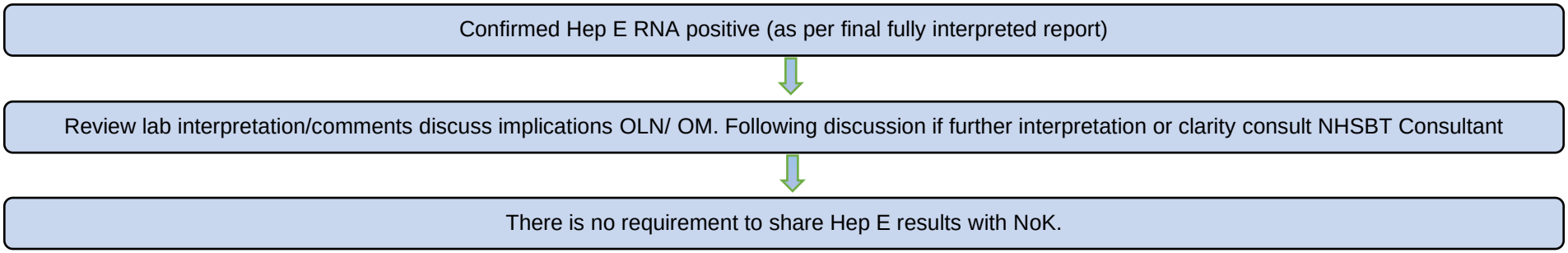
SN to verbally inform NOK. SN to advise affected individuals that they will have these results further communicated via post with advice on next steps

SN will inform the DFCS via email that a letter is required. Family member this should be addressed to should be included. DFCS will populate **LET428** (Letter to Communicate Positive Virology with Organ donor families / NOK), add addressee and send to SN to input clinical information and final approval.

All letters must be double checked by another member of OTDT to confirm accurate details are included.

Once approved the SN will email to DFCS to send out to donor family and upload to Donor Path documenting on SOE that letter has been sent.

Appendix 2.4 - Flow Chart for communicating confirmed HEV positive Results with Tissue & Organ Donor Families



Appendix 2.5 - Flow Chart for communicating confirmed HTLV positive Results with Tissue & Organ Donor Families

Confirmed HTLV positive (as per final fully interpreted report)

Review lab interpretation/comments discuss implications OLN/ OM. Following discussion consult NHSBT Consultant Microbiologist (MSL).

Is there a sexual partner or close household contact?

No

No action required

Yes

SN to verbally inform NOK. SN to advise affected individuals that they will have these results further communicated via post with advice on next steps

SN will inform the DFCS via email that a letter is required. Family member this should be addressed to should be included. DFCS will populate **LET428** (Letter to Communicate Positive Virology with Organ donor families / NOK), add addressee and send to SN to input clinical information and final approval.

All letters must be double checked by another member of OTDT to confirm accurate details are included.

Once approved the SN will email to DFCS to send out to donor family and upload to Donor Path documenting on SOE that letter has been sent.

Appendix 2.6 - Flow Chart for communicating confirmed Human Herpesvirus (HHV-8) aka Kaposi Sarcoma Herpesvirus (KSHV) positive Results with Tissue & Organ Donor Families

Confirmed Positive HHV-8 antibodies (as per final fully interpreted report)

↓

The NHSBT Consultant Microbiologist (MSL) will be aware of all positive / inconclusive results before they leave the laboratory

↓

There is no requirement to share HHV-8 results with NoK.

Appendix 2.7 - Flow Chart for communicating confirmed Syphilis Antibody positive Results with Tissue & Organ Donor Families

Confirmed Antibody positive (as per final fully interpreted report)

Review lab interpretation/comments discuss implications OLN/ OM. Following discussion if further interpretation or clarity consult NHSBT Consultant Microbiologist (MSL)

Is there a sexual partner?

No

No action required

Yes

SN to verbally inform NOK. SN to advise affected individuals that they will have these results further communicated via post with advice on next steps

SN will inform the DFCS via email that a letter is required. Family member this should be addressed to should be included. DFCS will populate **LET428** (Letter to Communicate Positive Virology with Organ donor families / NOK), add addressee and send to SN to input clinical information and final approval.

All letters must be double checked by another member of ODT/TES to confirm accurate details are included.

Once approved the SN will email to DFCS to send out to donor family and upload to Donor Path documenting on SOE that letter has been sent.

Appendix 2.8 - Flow Chart for communicating confirmed CMV, EBV, Toxoplasma Results with Tissue & Organ Donor Families

Confirmed CMV, EBV, Toxoplasma, Malaria (as per final fully interpreted report)

There is no requirement to share positive results with NOK

Appendix 3: Infection Markers: Additional Information

Hepatitis B (HBV) – Additional Information

Transmitted by blood or bodily secretions.

Can be acquired perinatally, this is the commonest route of infection in countries where the infection is prevalent.

Other possible routes of transmission include breast milk, genital secretions through sexual exposure or by sharing contaminated needles.

In most cases where HBV is acquired in adulthood, the infection is apparent and resolves. However, immunocompromised individuals and those acquiring HBV at birth/early years can chronic infection with a longstanding asymptomatic course.

Infection can be controlled effectively with oral medication, decreasing chances of long-term complications.

Hepatitis C (HCV) – Additional Information

Transmitted mainly by blood and less efficiently by heterosexual contact and through the vertical route.

Acute symptomatic infection is uncommon and most develop chronic disease which is often asymptomatic until organ (usually liver) failure.

New treatments mean cure is possible in a high proportion of cases.

Human Immunodeficiency type 1 and 2 (HIV-1 and HIV-2) – Additional Information

Affects specific cells within the immune system and is transmitted by blood or bodily secretions.

Can be acquired perinatally, this is the commonest route of infection in countries where the infection is prevalent.

Other possible routes of transmission include breast milk, genital secretions through sexual exposure or by sharing contaminated needles.

Two types of HIV have been characterized: HIV-1 and HIV-2.

Epstein Barr Virus (EBV) – Additional Information

EBV is found all over the world. Most People get infected with EBV at some point in their lives.

It Spreads most commonly through bodily fluids, primarily saliva.

EBV can cause infectious mononucleosis, also called mono, and other illnesses

Cytomegalovirus (CMV) – Additional Information

CMV is a common virus that infects people of all ages. Almost half of adults have been infected by the age of 40.

Most infected people show no signs or symptoms of CMV

Human T-Lymphotropic Virus (HTLV 1 + 2) – Additional information

The virus can cause a type of cancer called adult T-cell leukaemia/lymphoma (ATL)

HTLV is transmitted primarily through infected bodily fluids, including blood, breast milk and semen

Risk factors include possible transmission through genital secretions from sexual exposure, sharing contaminated needles and transplantation of tissue, blood, and blood products

Toxoplasma – Additional information

Infection caused by a single cell parasite. This parasite can persist for long periods in the bodies of humans and animals.

Risk factors include eating undercooked or contaminated meat or shellfish, accidental ingestion during food preparation, eating with contaminated kitchen utensils, drinking contaminated water and through close contact with cat faeces that may contain the parasite.

Though most people infected with the toxoplasma parasite may not display symptoms, care must be taken in those individuals who may be pregnant or have a weakened immune system.

Syphilis Treponema pallidum – Additional Information

Infection is transmitted through sexual contact with an in infected individual.

Without treatment, syphilis scan spread to the brain and nervous system (neurosyphilis), the eye (ocular syphilis) or the ear (ostosyphilis)

Hepatitis E Virus (HEV) – Additional Information

A virus that infects the liver and can cause Hepatitis

4 Genotypes. Genotype 1&2 transmitted via the Oro-faecal route by ingestion of contaminated water and food, mainly countries where HEV is endemic (Southeast Asia)

Infection similar to Hep-A and usually leads to acute, self-limiting illness except in pregnant women, who can develop severe hepatitis.

Genotype 3 is commonest In the UK and usually as result of ingestion of undercooked pork meat; This usually causes mild illness but in the immunocompromised chronic liver disease can develop if left untreated.

HEV can be treated with the anti-viral Ribavirin

Herpes Virus Type 8 (HHV-8) – Additional Information

Belongs to the family of DNA viruses Herpesviridae.

Causes sarcoma (a vascular malignancy) + B cell lymphoproliferative diseases such as primary effusion lymphoma (PEL) and multicentric Castleman disease (MCD)

The likelihood of HHV-8 associated malignancies is significantly higher amongst individuals living with HIV or under immunosuppression such as organ transplant recipients.

Donors who are infected with the virus can sometimes infect recipients of their organs. This doesn't happen 100% of the time + even if transmission does occur not all recipients will develop an illness.

When a donor derived transmission leads to disease, this tends to manifest within the first-year post-transplant, usually within 6 months. This can be severe in the form of a systemic illness OR Kaposi sarcoma OR other forms of disease can manifest post-transplantation if the organ recipient was already infected before receiving the transplant due to reactivation of the virus.

When a post-donation test is positive, we will inform the transplant centres so that recipients can be followed up. If the result is inconclusive, we will also inform them as a precautionary measure.

Malaria – Additional information

Mosquito-borne disease caused by a parasite.

Malaria can be a deadly disease if not diagnosed and treated quickly.

Treatment of Malaria depends on type of Malaria, geographical location where a person may have been infected and how sick they are when treatment commences.

T Cruzi – Additional information

T Cruzi, also known as Chagas disease, is caused by the parasite Trypanosoma Cruzi, it is transmitted to animals and people by insect vectors.

It is only found in the Americas (mainly, in rural areas of Latin America in areas of poverty.

Transmission can also be congenital, via blood transfusions, transplantation, consumption of food contaminated with faeces from infected triatomine bugs.

West Nile Virus (WNV) – Additional information

WNV is commonly spread to people by infected Mosquitos.

Mosquitos become infected when they feed on infected birds. In a small number of cases, West Nile Virus can be spread through congenitally or through breast feeding.

Caution should be taken in individuals who may have weakened immune systems and in pregnancy.

Yellow Fever Virus – Additional information

Yellow Fever Virus is commonly spread to people by day flying mosquito species found in tropical and subtropical regions.

Yellow Fever symptoms include high temperature, headache, nausea and vomiting, muscle pains and backache. One in four individuals may suffer from Jaundice and bleeding from the GI tract and other sites

In the event a patient has returned from a Tropical Virus Risk endemic area in the past 4 weeks or if there is evidence of previous Yellow Fever Virus infection in the past 6 months additional testing should be sent.

Zika Virus – Additional information

Zika Virus is commonly spread to people by day flying mosquito species found in tropical and subtropical regions.

Zika virus can be spread through sexual transmission. Infection is usually asymptomatic or presents as a mild self-limiting febrile illness BUT IN SOME CASES more severe disease and hospitalisation MAY OCCUR.

Infection during pregnancy carries a high risk of congenital abnormalities in the baby. Zika often can be misdiagnosed for Chikungunya or Dengue infections as these viruses often co-circulate.

In the event a patient has returned from a Tropical Virus Risk endemic area in the past 4 weeks or if there is evidence of previous Zika Virus infection in the past 6 months additional testing should be REQUESTED

Chikungunya Virus – Additional information

Chikungunya Virus is commonly spread to people by day flying mosquito species found in tropical and subtropical regions.

Chikungunya Virus is an alpha virus can cause a spectrum of disease. This may range from no or minimal symptoms to death. Most commonly it causes arthritis, high fever and a maculopapular rash.

In the event a patient has returned from a Tropical Virus Risk endemic area in the past 4 weeks or if there is evidence of previous Chikungunya Virus infection in the past 6 months additional testing should be sent.

Dengue Virus – Additional information

Dengue Virus is commonly spread to people by day flying mosquito species found in tropical and subtropical regions.

Dengue Virus gives rise to abrupt high fever with accompanying symptoms. Severe disease can progress to Dengue Haemorrhagic Fever.

In the event a patient has returned from a Tropical Virus Risk endemic area in the past 4 weeks or if there is evidence of previous Dengue Virus infection in the past 6 months additional testing should be sent.

Training Plan:

	Trainee new to the process	Trainee trained to the previous revision.
Recommended Training Method	If not trained to v6 then training to full document will be required	trained onto version 6 watch video, familiarise with changes
Assessment	• FRM511	• FRM511
Cascade Plan	Author trains department managers or key trainers, who then cascade training to their department.	Author trains department managers or key trainers, who then cascade training to their department.

Training Score – Training Plan Risk Matrix (Collapsible – Click ▸ icon to open/close)

Use the *Training Plan Risk Matrix* to identify the training method and assessment required.

The *Process Criticality Score* is determined by the potential impact on donor/patient safety and/or product quality using the table below for guidance:

	Impact on Donor, Patient safety or product quality
1. Negligible	A process whose failure, in full or in part, **cannot** impact product quality, patient/donor safety or the ability to supply products/services.
2. Minor	A process whose failure, in full or in part, **may**: (i) impact other processes thereby indirectly impacting product quality, patient/donor safety (e.g. harm only results where multiple failures in multiple processes align) (ii) result in the discard of a small number of replaceable products and/or (iii) result in an inconvenient delay to the supply of products/services (e.g. delay of 1-3hrs of non-urgent product/service).
3. Moderate	A process whose failure, in full or in part, **may**: (i) indirectly impact product quality, patient/donor safety (e.g. harm only results where failures in more than 1 process align) (ii) result in the discard of a medium number of replaceable products and/or (iii) result in a temporary delay to the supply of products/services (e.g. delay of 4-12hours of non-urgent products/services).
4. High	A process whose failure, in full or in part, is **likely** to: (i) directly impact product quality, patient/donor safety (ii) result in the discard of a large number of replaceable products (iii) result in the discard of an irreplaceable product and/or (iv) result in a delay to patient treatment.
5. Very High	A process whose failure, in full or in part, is **certain** to: (i) directly impact product quality, patient/donor safety (ii) result in the discard of a large number of replaceable products (iii) result in the discard of an irreplaceable product and/or (iv) result in a delay to patient treatment.

Process Criticality Score	4

The *Criticality of Change Score* is determined by assessing the nature of change(s) and complexity of the process using the table below for guidance.

	Change to Trainee(s)
1. Negligible	An existing process to which no material changes are made. E.g. format changes, minor clarifications of existing practice, fixing typos.
2. Minor	An existing process to which new information is added but where changes to existing knowledge and practices are minimal. E.g. clarifications that tighten existing practices
3. Moderate	An existing process of low complexity with material changes requiring different people to take action and/or people to change the tasks they perform. E.g. new roles/responsibilities, changes to the order of existing tasks, new tasks
4. High	A new process of moderate complexity, OR An existing process of moderate complexity with material changes requiring different people to take action and/or changes to the way tasks are performed. E.g. New roles and responsibilities, changes to tasks and/or the order in which tasks are performed, changes in equipment/materials, changes to values, measures or settings.
5. Very High	A new process of high complexity, OR An existing process of high complexity with material changes requiring different people to take action and/or changes to the way tasks are performed. E.g. New roles and responsibilities, changes to tasks and/or the order in which tasks are performed, changes in equipment/materials, changes to values, measures or settings.
Criticality of Change Score	2

Training Plan Risk Matrix:

Criticality of Change ↓	Process Criticality → 1. Negligible	2. Minor	3. Moderate	4. High	5. Very High
1. Low	1	2	3	4	5
2. Moderately Low	2	4	6	8	10
3. Moderate	3	6	9	12	15
4. High	4	8	12	16	20
5. Very High	5	10	15	20	25

	Trainee new to the process	Trainee trained to the previous revision.
Process Criticality Score	4	
Criticality of Change Score	2	2
Training Score	8	8

Recommended Training Method and Assessment:

Training Score	Level of Risk	Examples of Training Methods	Examples of Assessment
1 - 3	Low	Read only	Record on FRM511 only
4 - 8	Manageable	Email, team brief, word brief	Knowledge/Observation Check & FRM511
9 - 14	Medium/Significant	Formal training package	Knowledge/Observation Check & FRM511 or FRM5076
15 - 25	High	Practical	FRM5076 or equivalent