



ODTI Guideline for the testing requirements for COVID 19 in potential deceased organ donors

1. INTRODUCTION

1.1 PURPOSE

The purpose of this guideline is to update the practices on assessment and evaluation of potential donors for COVID-19.

1.2 BACKGROUND

Informing and updating this guideline is the latest European Centre for Disease Prevention and Control (ECDC) report. This technical report published in August 2023 is entitled ‘*Coronavirus disease 2019 (COVID-19) and supply of substances of human origin in the EU/EEA – third update*’. This third update of the document incorporates further experience gained during the COVID-19 pandemic regarding the safety of substances of human origin (SoHO) and recent scientific developments in understanding the evolution of the disease and its transmissibility through different types of SoHO.

At the time of the report’s publishing, ‘with the exception of cases following lung transplantation, no transmission of COVID19 via SoHO and plasma-derived medicinal products has been reported worldwide. In the field of organ transplantation, there is evidence of non-lung organs, and even lungs being transplanted from individuals known to have tested positive for SARS-CoV-2 just prior to death, without reported transmissions.

Numerous recent studies in the field of organ donation have not demonstrated any transmission and show that use of SARS-CoV-2 NAT-positive non-lung donors resulted in similar recipient outcomes to SARS-CoV-2 NAT-negative donors in terms of the quality of organs.’ (ECDC 2023)

The report concludes that based on current knowledge the risk of COVID-19 transmission via SoHO is negligible, except for lung and potentially intestine transplantation. The report recommends mitigation measures should follow general guidelines for respiratory, Influenza-like diseases. The updated recommended testing protocol is outlined below. As cited previously, deceased donors with COVID-19 as cause of death, are not eligible for the donation of SoHO. (ECDC 2023)



1.3 OBJECTIVE

To ensure clinical staff involved in donation and transplantation activities are aware of the ECDC recommended testing strategies during the identification and characterisation of a potential organ donor.

2.0 GLOSSARY

BAL:	Broncho – Alveolar Lavage
COVID 19:	SARS-CoV-2 Virus
ET Aspirate:	Endo-Tracheal Aspirate
ECDC:	European Centre for Disease Prevention and Control
NODTAG:	National Organ Donation and Transplant Advisory Group
NOPS:	National Organ Procurement Service
NP Swab:	Nasopharyngeal Swab
ODNM:	Organ Donation Nurse Manager
ODTI:	Organ Donation Transplant Ireland
RT-PCR:	Real Time Polymerase Chain Reaction
SoHO:	Substances of Human Origin

3.0 ECDC RECOMMENDATIONS

Table 1. Recommendations for donor eligibility criteria-standard donors

Donor	Eligibility criteria for donation according to the type of SoHO ¹				
	Blood	Non-reproductive tissues and cells	Non-lungs organs	Lungs and intestine	
No history of COVID-19 and no contact with COVID-19 patients.	Standard donor selection procedures should be applied			<ul style="list-style-type: none"> Negative SARS-CoV-2 RT-PCR² test on respiratory secretions from BAL³ or deep bronchial aspirate. Test should be performed within 24 hours preferably, or max. 48 hours prior to procurement. 	
Donors with positive history of COVID-19, confirmed or unconfirmed.	<ul style="list-style-type: none"> >14 days after the complete resolution of symptoms. 	<ul style="list-style-type: none"> >7 days after clinical and virological recovery. 	<ul style="list-style-type: none"> >14 days after the onset of symptoms (or 7 days after documented virological recovery) >72 hours symptom free. 	<ul style="list-style-type: none"> >21 days after the onset of symptoms >72 hours symptom free. 	
			Deceased donors <ul style="list-style-type: none"> Negative SARS-CoV-2 RT-PCR test on respiratory secretions from BAL or deep bronchial aspirate. 		Not applicable
			Living donors <ul style="list-style-type: none"> Negative SARS-CoV-2 RT-PCR test on respiratory secretions from a nasopharyngeal swab. Tests should be performed within 24 hours preferably, or max. 48 hours prior to procurement. 		
Donors with history of close contact with COVID-19 patients.	<ul style="list-style-type: none"> Standard donor selection procedures should be applied. 	<ul style="list-style-type: none"> Standard donor selection procedures should be applied. 	Deceased donors <ul style="list-style-type: none"> >7 days since contact. Negative SARS-CoV-2 RT-PCR test on respiratory secretions from BAL or deep bronchial aspirate. 	Not applicable	
			Living donors <ul style="list-style-type: none"> >7 days since contact negative SARS-CoV-2 RT-PCR test on respiratory secretions from a nasopharyngeal swab. Tests should be performed within 24 hours preferably, or max. 48 hours prior to procurement 		
			Deceased donors <ul style="list-style-type: none"> Standard donor selection procedures should be applied. 		
Donors vaccinated with non-replicating, inactivated, or mRNA-based COVID-19 vaccine.	<ul style="list-style-type: none"> >48 hours since vaccination; without complications; this deferral period is recommended to prevent discarding and waste of resources due to the post donation notification of possible vaccine side effects [21,44]. 	Deceased donors <ul style="list-style-type: none"> Standard donor selection procedures should be applied. 	Deceased donors <ul style="list-style-type: none"> Standard donor selection procedures should be applied. 	Not applicable	
		Living donors <ul style="list-style-type: none"> Standard procedure for donor vaccination should be followed. 			

¹ Donors eligible for donation should meet all the criteria listed in the corresponding column.

² RT-PCR = real-time polymerase chain reaction

³ BAL = bronchoalveolar lavage.

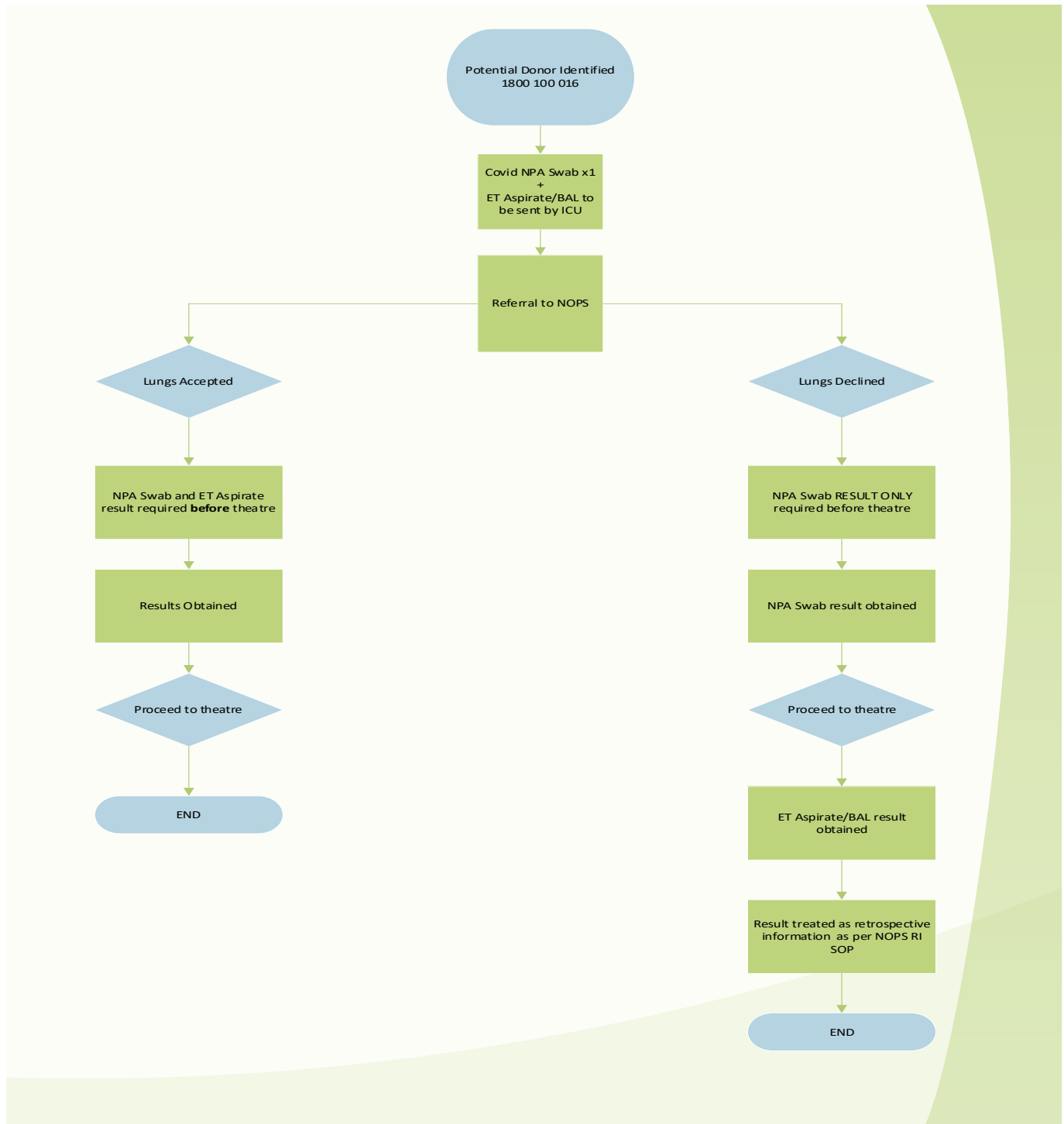
4.0 TESTING REQUIREMENTS

All potential organ donors must have COVID testing prior to donation.

Results required prior to organ procurement surgery:

- Lung donation requires ET aspirate and NP swab result within previous 24 hours to maximum 48 hours before donation.
- All other Solid Organs / tissue require NP swab result only within previous 24 hours to maximum 48 hours before donation.
- At the time of potential donor identification, ET aspirate and NP swab to be sent for urgent processing. This should not delay notifying the national organ procurement service of a potential donor. Results are not required prior to potential organ donor referral.
- Should donation surgery begin within 24 hours to (maximum 48 hours) of these tests no further COVID testing is required (unless specifically requested by the NOPS team on behalf of transplanting centres).
- Subsequent COVID testing may be requested by the NOPS coordinator if donation surgery is not scheduled within 24 hours (maximum 48 hours) of the initial testing.
- Where there is a delay in proceeding to theatre and lungs have already been declined, the NOPS coordinator may only request a repeat COVID NP swab.

5.0 PROCESS FLOW



6.0 GUIDELINE

1. On donor identification within the ICU, refer to ODTI ODTI-C-GDE-0006 Guideline for Minimum Dataset for Donor Referral.
2. Notify the National Organ Procurement Service (NOPS) on 1800 100 016 or 01 8788388.
3. Obtain x1 Nasopharyngeal Swab and Endotracheal Aspirate/Bronchoalveolar Lavage for testing, as close as possible to donation. If there are extended delays between the covid sample(s) being obtained and the patient proceeding to theatre – the testing may need to be repeated. The responsibility for requesting covid testing for samples lies with the ICU.
4. Covid Swab and ET Aspirate/BAL should be sent to the donating hospitals microbiology lab for testing. If the Aspirate/BAL cannot be processed in the donating hospital, it should be sent to the main hospital within the hospital group for processing as per AMRIC.
5. The responsibility for transporting the samples to the main hospital in the group lies with the ICU. The staff member sending the sample should record the following:
 - Taxi Company
 - Name of Driver
 - Contact Details of Driver
 - Time of Sample Pick up
6. If lungs are accepted for transplant, there is a requirement for the NPA swab AND ET Aspirate/BAL result to be obtained prior to the patient proceeding to theatre.
7. If lungs are declined for transplant, the NPA swab result only is required prior to the patient proceeding to theatre. The ET Aspirate/BAL test result (if not obtained pre operatively) will be treated as retrospective information as per NOPS-C-SOP-0005.

7.0 REFERENCE LIST

The following references were used in the development of this guideline.

- ODTI, A framework for Quality and Safety of Human Organs Intended for Transplantation
- S.I. No: 325 of 2012, European Union (Quality and Safety of Human Organs Intended For Transplantation)
- S.I. No: 198 of 2014, European Union (Quality and Safety of Human Organs Intended for Transplantation (Amendment) Regulations 2014
- Commission Directive 2010/53/EC of 7 July 2010 of the European Parliament and the Council of the European Union on standards of quality and safety of human organs intended for transplantation
- Commission Directive 2012/25/EU laying down information procedures for the exchange, between Member States, of human organs intended for transplantation
- Guide to the quality and safety of Organs for Transplantation, (2022) 8th Ed, *European Directorate for the Quality of Medicines & Healthcare (EDQM)*, France.
- European Centre for Disease Prevention and Control. Coronavirus disease 2019 (COVID-19) and supply of substances of human origin in the EU/EEA – third update. August 2023. Stockholm: ECDC; 2023.



8.0 GUIDELINE CIRCULATION

These guidelines will be disseminated to the circulation list identified below following approval.

GUIDELINE CIRCULATION
Guideline Circulation
Director ODTI
Chief Operations Officer ODTI
Director of Quality ODTI
Quality and Biovigilance Manager ODTI
Clinical Leads Organ Donation
Organ Donation Nurse Managers
Responsible Person National Organ Procurement Service
Donor Coordinators National Organ Procurement Service
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Responsible Person Cardiothoracic Transplant Centre
Quality Manager Cardiothoracic Transplant Centre
Responsible Person Renal Transplant Centre
Quality Manager Renal Transplant Centre
Responsible Person Liver and Pancreas Transplant Centre
Quality Manager Liver and Pancreas Transplant Centre
NVRL and NHISSOT
NOPs Medical Clinical on Call



9.0 DOCUMENT APPROVAL

Guidelines for the assessment of COVID19 in potential organ donors		
REFERENCE NUMBER	ODTI-C-GDE-0007	
DOCUMENT TYPE	Guideline Document	
APPROVED BY	NODTAG	
VERSION NUMBER	1	
EFFECTIVE DATE	16/12/2024	
DEVELOPMENT GROUP		
RESPONSIBILITY	NAME	POSITION
REVIEWED BY	NODTAG	National Organ Donation and Transplant Advisory Group
APPROVED BY	Dr. Brian O' Brian	On Behalf of NODTAG Director of ODTI
VERSION	DOCUMENT REVIEW HISTORY	
1	Revised Guideline	