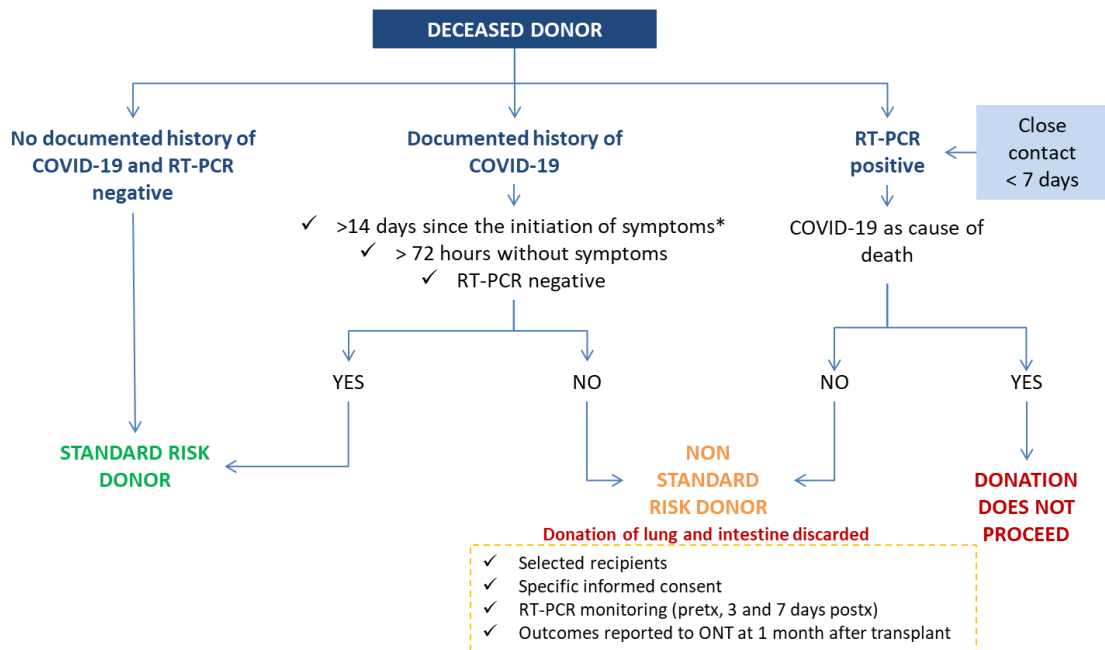




SPANISH RECOMMENDATIONS FOR THE EVALUATION AND SELECTION OF DONORS AND RECIPIENTS REGARDING COVID-19 (EXTRACT FROM THE BIOVIGILANCE ALERT REFERENCE BV-ES-20200122 LAST UPDATE 4 APRIL 2022)

DECEASED ORGAN DONATION

Universal screening for SARS-CoV-2 is indicated in all potential deceased organ donors.



*This period will be extended to 21 days if absence of symptoms cannot be evaluated and in case of lung or intestine donation.

Late complications of COVID-19 (e.g. thrombotic phenomena) not included. These sequelae are not considered absolute contraindications to organ donation and will be considered carefully on an individual basis.

- Potential donors with no documented history of COVID-19 and negative RT-PCR for SARS-CoV-2, donation of all organs can proceed (standard risk donor).
- Potential donors with a documented history of COVID-19 (microbiologically confirmed or based on a high clinical suspicion), donation of all organs can proceed (standard risk donor) if all the following criteria are met:
 - a. more than 14 days since the initiation of symptoms or since the microbiological diagnosis in asymptomatic cases;
 - b. more than 72 hours asymptomatic;
 - c. negative RT-PCR for SARS-CoV-2 in a sample of the respiratory tract obtained within 24 hours prior to organ recovery.

Time since the start of symptoms (criteria a) will be extended to 21 days in case of lung or intestine donation or if the absence of symptoms (criteria b) cannot be evaluated.

- Potential donors with positive RT-PCR for SARS-CoV-2 (in the context of a previous diagnosis of COVID-19 or when the diagnosis has been established at the time of donation), donation of organs can proceed (nonstandard risk donor), except for lung and intestine and as long as the



donor has not died as a result of COVID-19. Organs from these donors will be preferentially allocated into:

- ✓ Recipients in an urgent or critical condition at risk of imminent death and/or
- ✓ Recipients that, regardless of their clinical condition on the waiting list, exhibit a positive serology for SARS-CoV-2 **OR** have received a complete vaccination scheme (three or more doses) **OR** have been diagnosed with COVID-19 during the previous year.

Specific informed consent must be obtained (Annex 2) and the recipient will be monitored by RT-PCR for SARS-CoV-2 in samples of the respiratory tract (before, and at days 3 and 7 after transplantation). Outcomes will be reported to ONT at one month after transplantation (Annex 3).

- **Potential donors who have been in close contact with a confirmed COVID-19 case in the previous seven days and with negative RT-PCR for SARS-CoV-2, donation of organs (nonstandard risk donor) will proceed as specified in the previous point.**

LIVING ORGAN DONATION

Universal screening for SARS-CoV-2 is indicated in all potential organ donors prior to surgery. It is recommended to **defer donation** if the potential donor is a **confirmed case of COVID-19, there is a high clinical suspicion of COVID-19 or screening for SARS-CoV-2 is positive or inconclusive. It is recommended to defer donation until after more than 14 days since the initiation of symptoms and more than 72 hours with no symptomatology.** It is advisable that the potential donor has a negative result for SARS-CoV-2 by RT-PCR prior to donation. In case RT-PCR persists positive, donation can be considered on a case by case basis after a careful risk/benefit analysis.

SAMPLES AND TESTS FOR SCREENING OF DONORS FOR SARS-CoV-2

- Donor screening will be performed by **RT-PCR in a sample of the respiratory tract.** Currently, it is not recommended to use antigenic or serologic tests for screening.
- **Ideally, the sample for the screening of deceased organ donors should be obtained from the lower respiratory tract** (tracheal or bronchial aspirate, or bronchoalveolar lavage) **and this will be the type of sample required in case of lung or intestine donation, or if the donor has been diagnosed with pneumonia.** In the rest of potential donors, it is acceptable to use a sample from the **upper respiratory tract** (nasopharyngeal swab).
- The sample will be **obtained as close as possible to the retrieval time, ideally within the previous 24 hours.** An individualized analysis should be performed if a result is available in a sample obtained within the 72 hours prior to organ recovery. The result should be available before the recovery of organs.
- **In case of tissue donation,** should *pre mortem* samples not be available, these can be obtained within the first 24 hours following the determination of death. To make screening possible at the Tissue Establishment, the same samples that would be used for the screening of organ donors should be obtained.

TRANSPLANTATION

To ensure the protection of patients on the waiting list, it is recommended to include **in pre-transplant tests the screening for SARS-CoV-2 by RT-PCR in a sample of the respiratory tract. If the potential recipient is a confirmed case of COVID-19, it is recommended to temporarily exclude the patient from the waiting list until after more than 14 days since the initiation of symptoms and more than 7 days with no symptomatology.** It is advisable that the potential recipient has a negative result for SARS-CoV-2 by RT-PCR prior to activation on the waiting list. In case RT-PCR persists positive, activation on the waiting list can be considered on a case by case basis after a careful risk/benefit analysis.