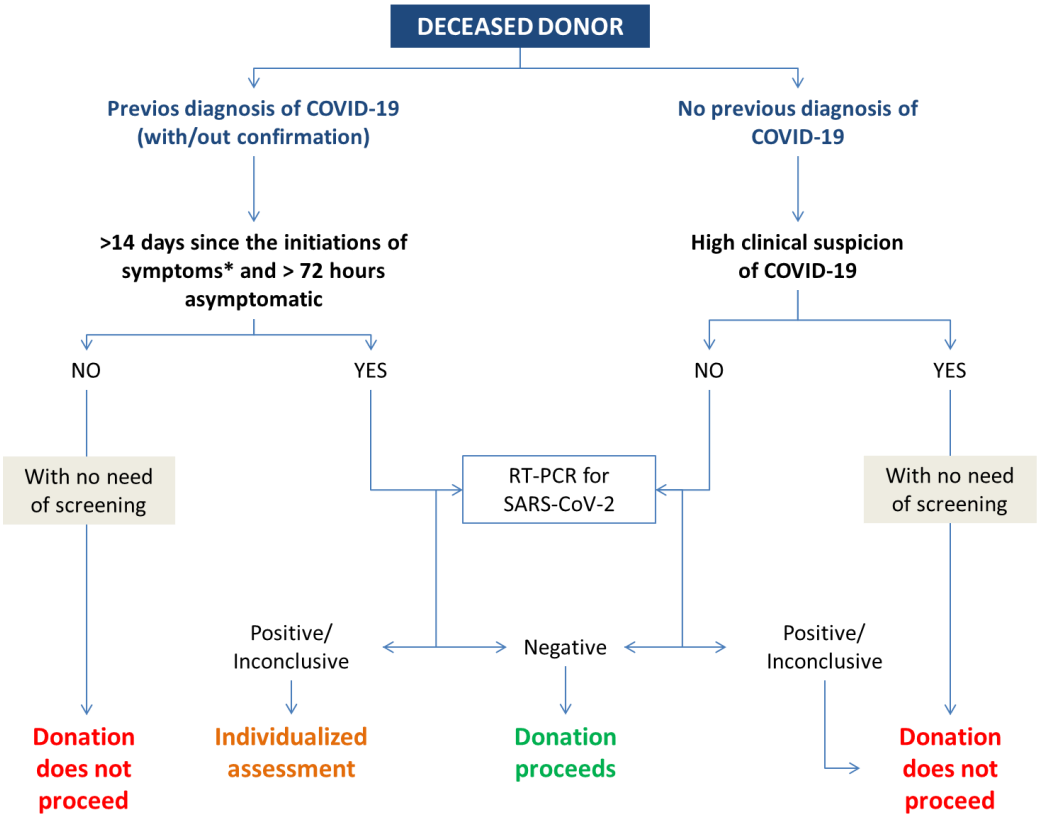
SPANISH RECOMMENDATIONS FOR THE EVALUATION AND SELECTION OF DONORS AND RECIPIENTS REGARDING COVID-19

(EXTRACT FROM THE BIOVIGILANCE ALERT REFERENCE BV-ES-20200122 LAST UPDATE 24 MARCH 2021)

DECEASED DONATION

Universal screening for SARS-CoV-2 is indicated in all potential organ and tissue 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 sequealae are not considered absolute contraindications to organ donation and will be considered carefully on an individual basis.

Donation will not proceed in the following circumstances:

1. Cases with **high clinical suspicion of COVID-19** regardless of microbiological results (including close contacts with a confirmed case in the previous 10 days).
2. Cases with a **positive or inconclusive result in the screening for SARS-CoV-2 by RT-PCR.**
3. **Confirmed cases of COVID-19.**

In cases with a previous diagnosis of COVID-19 (confirmed or suspected), donation can be considered if the following criteria are met:

a. more than 14 days since the initiation of symptoms (extensive to 21 days if the absence of symptoms cannot be evaluated and in case of lung or intestine donation);
b. more than 72 hours with no symptomatology;

c. negative result for SARS-CoV-2 by RT-PCR in a sample of the respiratory tract obtained within 24 hours prior to organ recovery.

If criteria a and b are met, but positivity for SARS-CoV-2 by RT-PCR persists, organ donation may be considered (except for lung and intestine) on a case by case basis after a careful risk/benefit analysis. To evaluate the potential risk of transmission of the infection, the following factors must be taken into account: severity of the COVID-19 episode (lower risk if hospital admission was not required and lower risk if admission to the ICU was not needed), time since the onset of symptoms (lower risk if more than one month), Ct of RT-PCR (lower risk if >30) or viral load (lower risk if <10,000 copies) and serology (lower risk if IgG positive). Specific informed consent must be obtained and careful monitoring of the recipient should be undertaken by RT-PCR in samples of the respiratory tract and by serology for SARS-CoV-2. Detailed information on the outcome of these recipients must be reported to ONT at three months after transplantation (Annex 4).

LIVING DONATION

Universal screening for SARS-CoV-2 is indicated in all potential 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, applying the criteria proposed in section 2.5.

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 neither as an alternative to RT-PCR. **However, serologic tests can be of help in the decision-making process regarding donation in case of potential donors with a previous diagnosis of COVID-19 who persist with a positive RT-PCR** (section 2.5).
- **Ideally, the sample for the screening of deceased 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 exhibits signs consistent with a respiratory infection.** 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**. Each donor coordination unit should know in advance the estimated time to have the RT-PCR result for SARS-CoV-2 available. The sample should be taken with enough time to facilitate the logistical organization of the donation process and avoid any possible delay.
- **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,** which result should be available before the transplant procedure is performed. Currently, it is not recommended to use antigenic or serologic tests as an alternative to RT-PCR. It is recommended **not to proceed with transplantation and temporarily exclude the patient from the waiting list** if the potential recipient 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**. The patient may be activated on the waiting list 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, applying the criteria proposed in section 2.5.