

# ONCOVID-21 - Evaluation of a ddPCR technology for the SARS-CoV-2 detection based on different types of samples in cancer patients with suspicion of COVID-19 (symptomatic)

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## General

### Identification

Detailed name Evaluation of a ddPCR technology for the SARS-CoV-2 detection based on different types of samples in cancer patients with suspicion of COVID-19 (symptomatic)

Sign or acronym ONCOVID-21

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CPP - Ile de France 8 - 20 06 32

### General Aspects

Medical area Cancer research  
Infectious diseases

Study in connection with Covid-19 Yes

Pathology (details) SARS-CoV-2 detection in cancer patients

Keywords SARSCOV2, CANCER, ddPCR, RT-qPCR, SEROLOGICAL ASSAYS

### Scientific investigator(s) (Contact)

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Unit Medical Oncology Department

Organization CENTRE LEON BERARD

## Collaborations

## Funding

## Governance of the database

Sponsor(s) or organisation(s) responsible CENTRE LEON BERARD

Organisation status Private

## Additional contact

## Main features

## Type of database

Type of database Study databases

## Database objective

Main objective To determine the ddPCR ability to detect the SARS-CoV-2 in nasopharyngeal samples of symptomatic patients with suspected COVID-19 infection using an IgG serological assay (EUROIMMUN Anti-SARS-Cov2 ELISA IgG) as gold/reference standard (FDA validated commercial serologic test).  
The primary endpoint will be the sensibility of the ddPCR assay for SARS-CoV-2 detection based on nasopharyngeal samples.

Inclusion criteria

1. Age ? 18 years on the day of signing informed consent.
2. Confirmed diagnosis of any type of solid or hematologic tumor.
3. Ongoing anticancer treatment at the time of inclusion or within the last 3 months prior to inclusion (last treatment administration or last loco regional procedure)
4. Suspicion of COVID-19 infection. Patients must not have underwent diagnostic test and/or chest imaging before inclusion.  
\* At least one of the following clinical symptoms: fever (>38°C), dry cough, fatigue, pulmonary involvement (febrile respiratory infection or respiratory difficulties), pharyngalgia, headaches, myalgia, gastrointestinal symptoms including abdominal pain and diarrhea, anosmia and ageusia, radiological signs of pneumonia as described by Shi et al.
5. Covered by a medical/health insurance.
6. Signed and dated informed consent form.

## Population type

Population covered Sick population

Pathology II - Neoplasms

Geography area Local

## Data collection

### Dates

Date of first collection (YYYY or MM/YYYY) 2020

Date of last collection (YYYY or MM/YYYY) 2021

### Size of the database

Size of the database (number of individuals) < 500 individuals

### Data

Type of data collected Clinical data  
Biological data

Details of collected clinical data MEDICAL HISTORY, CANCER HISTORY, CLINICAL EXAMINATION, ANTI-CANCER TREATMENTS, SYMPTOMS, RESULTS OF ddPCR, RT-qPCR AND SEROLOGY

Biological data (detail) HEMATOLOGY, BLOOD CHEMISTRY

### Procedures

Followed pathology

## Promotion and access

### Promotion

### Access