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 agueusia, 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	