

# EDIFICE - Observational study on the diagnostic evaluation of the intestinal microbiota of French people infected with the Coronavirus

Head :MARTI Guy

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## General

### Identification

Detailed name                      Observational study on the diagnostic evaluation of the intestinal microbiota of French people infected with the Coronavirus

Sign or acronym                      EDIFICE

CNIL registration number,  
number and date of CPP  
agreement, AFSSAPS (French  
Health Products Safety Agency)  
authorisation                      20.04.14.68238

### General Aspects

Medical area                      Gastroenterology et hepatology  
Immunology  
Infectious diseases  
Internal medicine

Study in connection with Covid-19                      Yes

Health determinants                      Others (specify)

Others (details)                      Microbiota

Keywords                      intestinal microbiota

### Scientific investigator(s) (Contact)

Name of the director                      MARTI

Surname                      Guy

Email                      guy.marti@doctocare.com

Organization                      Clinique St Jean de l'Hermitage

### Collaborations

Funding	
Governance of the database	
Sponsor(s) or organisation(s) responsible	LUXIA SCIENTIFIC
Organisation status	Private
Presence of scientific or steering committees	Yes
Additional contact	
Name of the contact	CERVINO
Surname	Alessandra
Address	HCenter, 11 Rue Benjamin Franklin 77000 La Rochette
Email	acervino@luxia-scientific.com
Organization	Luxia Scientific
Main features	
Type of database	
Type of database	Others
Specify	CRF
Database recruitment is carried out by an intermediary	A selection of health institutions and services
Database recruitment is carried out as part of an interventional study	No
Database objective	
Main objective	Validate the hypothesis for a relationship between the loss of diversity of the intestinal microbiota and screening positive for COVID-19, by comparing hospitalised COVID-19 positive patients with an exposed French population represented by hospital medical and paramedical personnel
Inclusion criteria	COVID-19 positive patients: hospitalised patients diagnosed with COVID-19 in one of the two investigating sites, and able to provide a stool

sample  
Exposed subjects: Medical and paramedical personnel working at one of the two investigating sites, having been in direct contact with the patients.  
Aged between 18 and 85 years  
Subjects able to read the French-language study information leaflet  
Patients with social cover

## Population type

Age  
Adulthood (19 to 24 years)  
Adulthood (25 to 44 years)  
Adulthood (45 to 64 years)  
Elderly (65 to 79 years)  
Great age (80 years and more)

Population covered  
General population

## Pathology

Gender  
Male  
Woman

Geography area  
National

Detail of the geography area  
Ile de France and Loire Atlantique

## Data collection

### Dates

### Size of the database

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

Details of the number of individuals  
160

## Data

Type of data collected  
Clinical data  
Biological data

Clinical data (detail)  
Direct physical measures

Biological data (detail)  
Analyses of the intestinal microbiota by 16s

Presence of a biobank  
No

Health parameters studied

Health event/mortality

## Procedures

Data collection method

Paper CRF

Quality procedure(s) used

ISO13485

Participant monitoring

No

Followed pathology

Links to administrative sources

No

## Promotion and access

Promotion

Access