

The undersigned (*) _____, born in _____,
on _____, fiscal code _____

Identified with (mandatory field):

ID Card number _____ Passport number _____

Fill data if it's not possible to complete informatic database:

Current address in Italy _____

City _____

Nationality _____ Phone number: _____

DECLARE

to have received and understood the informative material and therefore accept to

GIVE MY CONSENT DO NOT GIVE MY CONSENT

for the execution of the molecular RT-PCR test for Sars-CoV

Please confirm if you are (to be reported in the clinical database):

- coming from an endemic area
- coming from an outbreak area
- previously being positive
- vaccinated
- nothing to declare

I ask for test results also in english

I agree with sharing the test results with the Public Health Authority for epidemiological purpose according to the Italian Privacy Law.

General practitioner (Data required in case it is not possible to complete the informatic database):

name and surname _____ phone number _____

Date _____ Sign _____

.....
* NOTE: SECTION TO BE COMPLETED ONLY IF THE PERSON WHO FILL OUT THIS FORM IS THE PARENT/GUARDIAN OF A MINOR / PERSON WITH LEGAL GUARDIANSHIP *

The undersigned declare to have provided personal data relating to the person indicated above and to sign this form on behalf of this person as:

PARENT GUARDIAN OF THE PERSON

name and surname _____, born in _____,

on _____, fiscal code _____

Date _____ Sign _____

INFORMATIVE MATERIAL Coronavirus – SARS-CoV-2 diagnostic tests

Nucleic acid extraction is performed starting from sample in order to detect SARS-CoV-2 RNA through Real-Time Polymerase Chain Reaction (rRT-PCR).

Starting with an RNA template, a double-stranded DNA (cDNA) is obtained through a retro-transcription step and it is followed by an amplification process by PCR. More in details, the COVID19 molecular test is based on a “one-step” rRT-PCR, by which the retro-transcription and amplification steps are sequentially performed in the same reaction tube. This kind of diagnostic test has a high specificity based on primers and probes designed to target viral genome sequences. At each thermal cycle (Ct) during the amplification, a fluorescence signal is generated and detected.

Our lab employs World Health Organization (WHO) suggested diagnostic protocols (<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance>) and CE-IVD certified kits.

| REPORT RESULTS SARS-CoV-2 molecular test | WHAT DOES IT MEAN? | WHAT I HAVE TO DO? |
|--|---|---|
| Negative | No SARS-CoV-2 RNA detected. | <p>If you had a negative result after a positive serological test it means that you have been infected by SARS-CoV-2 but you are currently cured of the infection.</p> <p>If you went through an sample sampling because you have fever, it could be that either you are currently facing a disease not caused by SARS-CoV-2 or that the viral load is below the limit of detection of the assay.</p> <p>If the sample was tested for other reasons, the instrument did not detect SARS-CoV-2 viral RNA.</p> <p>In any case, please contact your medical doctor and share the results in order to critically analyze the outcome.</p> |
| Positive | SARS-CoV-2 RNA detected. The result is positive and you are subjected to 14 days of home quarantine. Contact your Medical Doctor or the local Health Authority | Contact as soon as possible your Medical Doctor or the local Health Authority. You have to stay confined until otherwise stated by your Medical Doctor or the local Public Health Authority. Stay away from other family members, if possible, in a well-ventilated single room and should not receive visitors. |
| Low Positive | SARS-CoV-2 RNA detected albeit at low levels. You are subjected to 14 days of home quarantine. Contact your Medical Doctor or the local Health Authority. | Contact as soon as possible your Medical Doctor or the local Health Authority. You have to stay confined until otherwise stated by your Medical Doctor or the local Public Health Authority. Stay away from other family members, if possible, in a well-ventilated single room and should not receive visitors. |
| Redraw requested | It was not possible to perform the analysis due to an inadequate sampling or due to the presence of inhibitory substances that damaged or degraded viral RNA. A new sample is needed. | You have to repeat the test. |