biotech MC

COVid

Molecular diagnostic test for the identification of SARS-CoV-2 RNA from saliva

CE IVD

Patents: EP1275715; EP2253717; EP1327679; EP2031058

MC Biotech

A SPIN-OFF OF MEDICAL CENTER

Medical Center is a private health clinic that offers a wide range of healthcare services, including a state-of-the-art medical analysis laboratory, a renowned multi-specialist medical center, a unit of Medicine and Job Safety and a diagnostic imaging department. With a strong commitment in raising quality standards, daily at the service of Patients, Specialists and Companies, Medical Center has invested considerable resources and efforts in R&D of innovative diagnostic solutions, which recently led to the birth of the start-up MC BioTech.

MISSION AND VISION

MC BioTech's mission is to design, develop and commercialize smart diagnostic solutions for different clinical areas, ranging from *in vitro* molecular tests for the diagnosis of pathogenic microorganism and virus infections, to susceptibility and genetic predisposition tests, immune-nutritional methodologies (oxidative stress, intolerances, hypersensitivity) and gastrointestinal analyses (microbiome, dysbiosis).

Taking advantage of the inter-disciplinary skills that converge in MC BioTech, the proposed solutions focus on the use of non-invasive biological samples (such as saliva), rapid methods with high sensitivity and specificity, Point-of-Care platforms, and advanced nanobiotechnologies.

The vision of MC BioTech is to propose a high-performance diagnostics concept, with personalized solutions at the service of the Patient, and as reliable support for the medical Specialist, in continuous evolution and updating, and attention towards the new market needs and technology advancement.

www.mcbiotech.it

The international context

On December 31st, 2019, the Chinese Health Authorities notified the World Health Organization (WHO) of the first cases of a pneumonia with unknown etiology, detected in the Wuhan City. On March 11th, 2020, the WHO classified the infection caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the COVID-19, as a pandemic.

In this time-critical framework, the timely diagnosis of COVID-19 appears crucial to counteract and contain the global emergency. Therefore, beyond the high sensitivity and specificity, the availability of rapid and accessible diagnostic solutions, able to allow early preliminary rating and massive screening, facilitates a rationale and sustainable infection surveillance activity, with a decisive impact on the widespread outbreak transmission and on the healthcare systems stretched beyond their capacities.

COV^id

Molecular diagnostic test for the identification of SARS-CoV-2 infection

The COV^id molecular test allows the diagnosis of COVID-19 infection starting from a simple saliva sample. The test operates the rapid qualitative detection of 2 specific genes of the SARS-CoV-2 viral genomic RNA, by means of a molecular isothermal amplification analysis.

Non-invasive sampling (saliva)

1-step extraction free

80 patients/kit

Sensivity up to 6 virus copies/µl saliva

CE-IVD Test

Specificity 100 %

COVid

Molecular identification of SARS-COV-2 RNA in saliva

Time saving

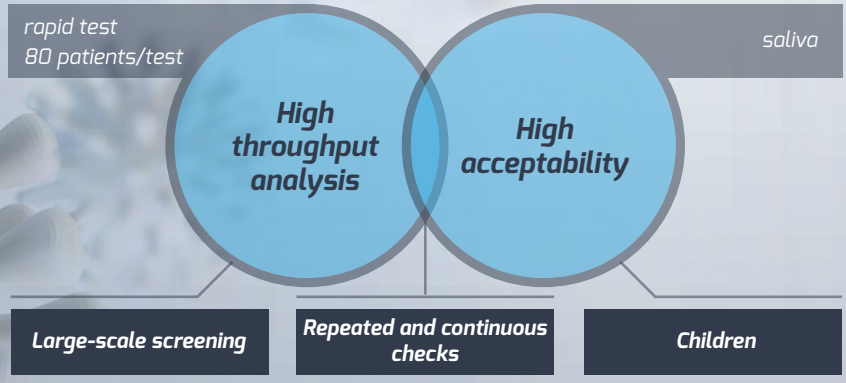
Saliva self-collection	Dilution No extraction No purification	Viral RNA identification < 30 mins

COVid

Molecular diagnostic test for the identification of SARS-CoV-2 infection

The COVid test key-points, i.e. the saliva sampling and the high throughput, enable an effective surveillance through repeated and frequent massive screening, making the daily infection tracking possible.

COVid is a strategic tool, for instance, to screen suspected or high-risk COVID-19 clusters in community contexts, as well as in routine checks in schools, professional sport, and company settings, or for social-health workers with high exposure risk, and in case of contact tracing or link with epidemiological risk areas. Moreover, the use of saliva is the most attractive choice for less-cooperative patients and for children, or when a serial sampling is required.



COV^{id}: how it works

The entire procedure is easy and non-invasive. The saliva sample is treated at room temperature with a fluidifying buffer, and then added directly to the reaction solution. At the reaction temperature, the viral particles in the saliva sample are lysed, and the viral RNA is released, retro-transcribed and finally amplified in isothermal conditions. The SARS-CoV-2 detection occurs in real-time by standard fluorescence readers (i.e., real-time PCR equipment). High/medium viral loads are detected as fast as in 7-15 minutes.

Step 1

Saliva sampling

Step 2

Saliva treatment

Room temperature
30 minutes

Step 3

Viral RNA extraction

Isothermal dual-gene amplification

Real-time fluorescence detection

1-STEP
7-30 minutes

Saliva sampling

NON INVASIVE, EASY, AND TOLERABLE

Considering the pivotal role of the respiratory secretions in human-to-human transmission of the SARS-CoV-2 virus, several effective diagnostic methods based on saliva sampling have been proposed and developed. Recent scientific publications have shown the high concordance rate of viral load in saliva and nasopharyngeal swabs during the first week after symptoms onset, with values ranging approximately between 10^3 and 10^8 copies/mL. For both biological matrices, temporal monitoring of the viral load reported maximum peak values within the first week.

The use of saliva specimen allows quicker and easier sampling procedure, which is completely non-invasive and user-friendly to the patient. Sampling could be carried out both in decentralized settings and in specialized laboratories, by patient self-collection under the supervision of qualified personnel.

Compared to rhino-pharyngeal swab sampling, saliva sampling:

1) **improves the patient's test compliance, eliminating the great discomfort commonly experienced with the traditional swab specimen. The non-invasive sampling facilitates continuous and routine testing, crucial for rapid infection tracking, and it is more acceptable for children;**
2) **does not require qualified personnel to directly carry out the collection of the sample;**
3) **could reduce the risk of false negatives due to technical errors in the correct swab execution;**
4) **does not require specific sampling devices, avoiding the risk of an insufficient supply for test equipment.**

1-STEP

All-in-one extraction-free test: overcoming the standard methods

The COV^{id} is a single-step test, where the viral RNA extraction-amplification-detection occur one-pot at the same time. The test does not include any viral RNA extraction/isolation step, making the overall experimental procedure straightforward. The 1-step procedure thus bypasses the complex bottleneck step of standard molecular tests, ensuring ease and speed of processing comparable to those of rapid antigen tests, but with the high performance, accuracy, and specificity of a molecular diagnostic test based on RNA identification.

DUAL-GENE

Multiplex identification of 2 specific genes of SARS-CoV-2 virus

COV^{id} works with a double-gene detection: the viral RNA is retro-transcribed and isothermally amplified through a multiple reaction on the N gene and the ORF1ab region of the SARS-CoV-2 virus.

HIGH THROUGHPUT TEST

Time saving – high diagnostic capability

The fast test execution and the short turnaround time, thanks to the single-step strategy and the fast viral RNA amplification (between 7 and 30 minutes), and the analysis up to 80 patients in a single round of testing, remarkably increase the diagnostic effectiveness and capability, enabling the testing of a high number of patients in a short time slot.

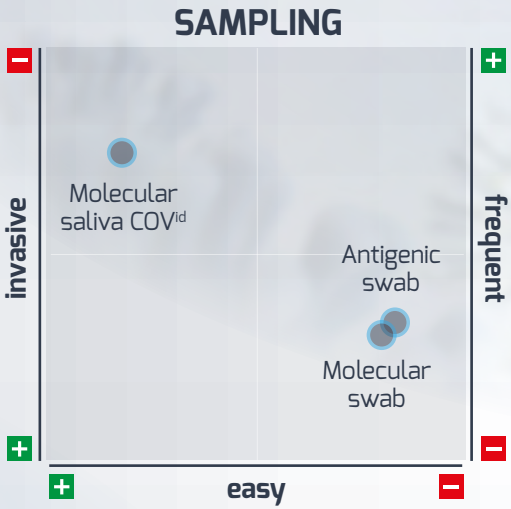
TEST SENSITIVITY

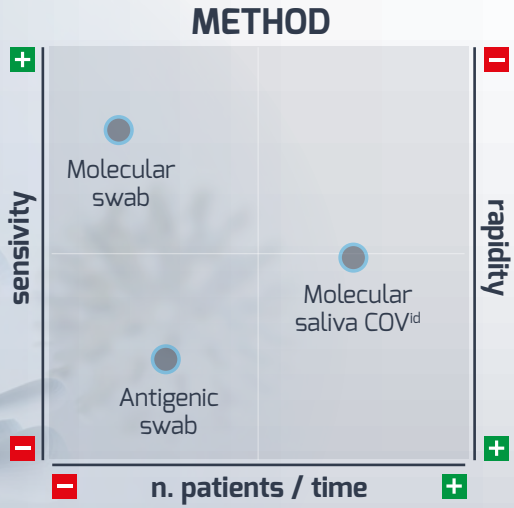
The COV^{id} sensitivity is up to 6 copies of SARS-CoV-2 per µl of saliva sample.

CLINICAL CONCORDANCE

In the clinical validation, COV^{id} performances on saliva samples were compared with a RT-PCR gold standard method performed on nasopharyngeal swabs, showing excellent agreement in the detection of high and medium viral load with Ct<35, and 100% specificity, confirming the in silico cross-reactivity analysis.

COV^{id} technical advantages





This technology is patent protected: EP1275715, EP2253717, EP1327679, EP2031058.

CE-IVD validated diagnostic kit

COVid

Molecular diagnostic test
for the identification
of SARS-CoV-2 RNA from saliva

biotech MC

powered by **Medical Center**

MC BioTech srl
Via IV Novembre, 1
CAP 21018 - Sesto Calende (VA)
PEC: **mcbiotech@legalmail.it**

Numero REA VA - 379379
Piva: 03792560124
Tel: +39 0331 958 095
Mail: **amministrazione@mcbiotech.it**