BioSpeedia
A spin-off from Institut Pasteur

END-TO-END SOLUTIONS for the screening of SARS-CoV-2 (COVID-19)

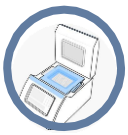
BioSpeedia is a spin-off from Institut Pasteur, the premier non-profit foundation that was founded in 1887 and has since originated 10 Nobel Prizes.

Launched in 2011, the company specializes in rapid tests across various infectious diseases.

BioSpeedia Overview

BioSpeedia is a French company headquartered at the innovation campus at St Etienne and has privileged access to **CHU of St Etienne, GIMAP and Ecole des Mines** and has a license **from the Institut Pasteur granting access to major reagents.**

BioSpeedia provides **both Antigen and Antibody** rapid testing kits that are **fast, accurate, and totally secured.**



BioSpeedia provides **an extraction kit as well as a Multiplex, RT –qPCR Kit.**

5

BioSpeedia can provide up to **5 million test kits per month for each test** through our existing manufacturing facilities.

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Rapid tests for COVID-19

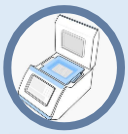
Why are antibody tests important

How to use the tests

BioSpeedia Product Covid-19 Portfolio

Rapid antigen test – 5 to 15 minutes – for the qualitative detection of specific SARS-CoV-2 antigen in human nasopharyngeal swab specimen. **Saliva and Sputum antigen test under development.**

Rapid antibody test – 5 to 10 minutes – for the qualitative detection of specific IgM and IgG antibodies against SARS-CoV-2, in human whole blood, serum or plasma.



Real-time PCR testing kit for the detection of 2019-nCoV genome; in this one-step real-time RT-PCR, reverse transcription of viral RNA is combined with the qPCR step in a single tube reaction.

Difference between an antibody test and an antigen test

COVID 19

Antigen test

Antigen tests use nasal or throat swabs to detect **active COVID-19 infection**.

Antigen tests detect specific proteins on the surface of the virus. Antigen tests are similar to PCR tests but are **quicker and less expensive** than a PCR test with also a **high sensitivity/specificity.**

Antibody test

Serology (blood-based) antibody tests detect presence of antibodies for **an active or past COVID-19 infection.**

Antibody tests show that you **might still be infected (IgM) or were previously infected (IgG) by the virus**, even if you never showed any signs or symptoms (asymptomatic).

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BioSpeedia Rapid Antigen Test

IVD

Description: This is an immunochromatographic assay designed for the qualitative detection of specific SARS-CoV-2 antigen in human nasopharyngeal swab specimen. It is intended to be used by the professionals as a screening test and as an aid in the early diagnosis of SARS-CoV-2 infection.

Features	
Platform	Immunochromatographic Assay
Format	Cassette
Detection	Specific SAR-CoV-2 antigen
Specimen	Nasopharyngeal swabs
Assay time	5-15 minutes
Shelf life	18 months

Clinical performance: A study of 324 patients shows a sensitivity of 97.4%* and a specificity of 99%. The study was done in 2 French hospitals and also shows higher cut-off versus similar tests.

Results	PCR Positive	Test Negative	Total	Sensitivity (PPA, Positive Percent Agreement)	Specificity (NPA, Negative Percent Agreement)
Positive	107	3	110	94.7% (107/113)*	99% (208/211)
Negative	6	208	214		
Total	113	211	324	* Sensitivity = 97.4% for CT < 32	

COVID 19

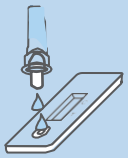
Procedures (Simplified Version)

1. 
Add 200 µl (~ 8 drops) extraction buffer to the tube

2. 
Immerse the swab head and mix vigorously at least 10 times

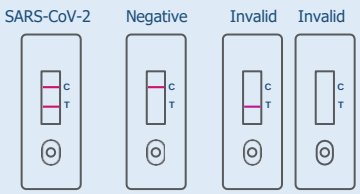
3. 
Squeeze liquid from swab and discard the swab head

4. 
Cover the dripper head and mix thoroughly

5. 
Add 50 µL (2 drops) to the sample well. Read result in 10-15 minutes

Result interpretation

C : Control Line
T : Test Line



BioSpeedia Rapid Antibody Test

CE IVD

Definition: This is an immunochromatographic assay designed for the qualitative detection of specific IgM and IgG antibodies against SARS-CoV-2, in human whole blood, serum or plasma. It is intended to be used by the professionals as a screening test and as an aid in the early diagnosis of SARS-CoV-2 infection.

Features

Platform	Immunochromatographic Assay
Format	Cassette
Detection	Specific IgM and IgG antibodies against SARS-CoV-2
Specimen	Whole blood, serum or plasma
Specimen volume	20 µl
Assay time	5-10 minutes
Shelf life	18 months

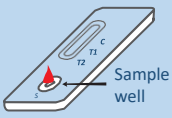
Clinical performance: COVID-19 Rapid IgG/IgM Test has been validated by 5 hospitals located in 3 European countries (Italy, France, Germany). A total of 564 patients, all confirmed positive for SARS-CoV-2 RNA by RT-PCR, including 549 symptomatic and 15 asymptomatic patients, were included for the sensitivity analysis. Results below:

Results (IgM+IgG)	PCR Positive	Test Negative	Total	Sensitivity (PPA, Positive Percent Agreement)	Specificity (NPA, Negative Percent Agreement)
Positive	392	4	396	92.2% (392/425)	98.1% (211/215)
Negative	33	211	244		
Total	425	215	640		

COVID 19

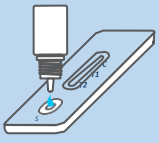
Procedures (Simplified Version)

1



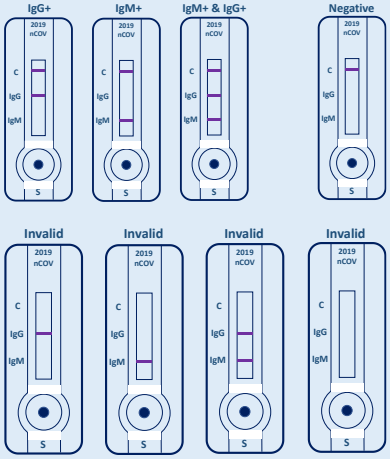
Add 20 µL of whole blood, serum or plasma to the sample well. Make sure there is no air bubble.

2



Add 1 drop of buffer to the same sample well. Read result within 15 minutes.

Result Interpretation



Why use antibody testing?

Conduct epidemiological studies; plan for social distancing	Find good candidates for convalescent plasma therapy	Identify children with MIS
Reassess medication for immune compromised patients	Identify *first-in-line* candidates for vaccination	Identify high-risk patients among asymptomatic populations

Why antibody testing is important

In communities with lower prevalence (5 – 25%), infection risk is very high. **Antibody tests** allow governments and organizations to remain alert on that potential risk and adjust measures and resources to **prevent** significant **loss of lives and businesses**.

Around 25% (approx. 1.8 billion people) of the world's population has **underlying medical conditions** including old-age, obesity, severe cardiac, liver, lung, asthma, diabetes, kidney. Antibody tests allow **high-risk asymptomatic** patients to know if they've been previously infected by COVID-19 and whether their underlying conditions have been adversely impacted and/or if any change is required in their prescription medications.

Periodic anti-body testing allows organizations to address their exposure to COVID-19 and assess whether additional distancing measures should be taken.

Combo 2019-nCoV Viral Extraction and Real-time RT-qPCR Kit

A combination of:

- GF-1 Viral Nucleic Acid Extraction Kit and 2019-nCoV Multiplex RT-qPCR Kit
- A-Z COVID-19 testing solution from COVID-19 RNA extraction till RT-qPCR

Easy and convenient: Able to complete the entire process from nucleic acid purification to RT-qPCR assay within 3.5 hours

Nucleic Acid Extraction

GF-1 Viral Nucleic Acid Extraction Kit (Mini-Prep Kit)

- Rapid and efficient purification of viral DNA/RNA from samples such as serum, plasma, body fluid, supernatant of virus-infected cell culture or supernatant of virus-infected swabs and/or nasopharyngeal swab
- Efficient recovery of highly pure DNA or RNA
- Purified DNA/RNA is suitable for downstream reactions, such as RT-qPCR and library prep for next generation sequencing
- Eliminates the need of toxic or organic-based extraction

One Step RT-qPCR Master Mix

One Step AtTaq RT-qPCR Master Mix

- Formulation optimized with Hot Start Taq, M-MULV enzyme and enhancers
- ROX dye is supplied separately
- Compatible with most of the real-time PCR platform
- Multiplex up to 3 targets

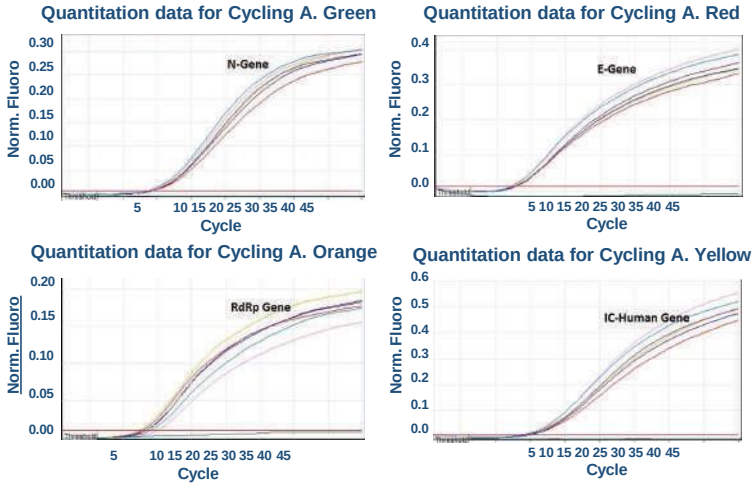
Description	Pack Size
Combo 2019-nCoV Viral Extraction and Real-time RT-qPCR Kit	100 preps
GF-1 Viral Nucleic Acid Extraction Kit (Proteinase K & Carrier RNA included)	100 preps
2019-nCoV Multiplex RT-qPCR Kit	100 preps
One Step AtTaq RT-qPCR Master Mix	100 preps

Combo 2019-nCoV Viral Extraction and Real-time RT-qPCR Kit

Multiplex RT-qPCR Assay

2019-nCoV Multiplex RT-qPCR Kit

- Multiplex detection in a single tube: N gene, RdRp gene and E gene
- Ready-to-use solution with all necessary components (primer, probe and master mix) in a single tube
- Internal control (IC): human gene is included
- Minimize technical error
- Enable immediate reaction set up with short processing time



	Ct Value			
Well/Sample	FAM	CY5	Texas Red	Hex
Pos Control 1	14.36	12.43	12.87	15.01
Pos Control 2	13.94	12.39	12.45	14.07
Pos Control 3	14.43	12.68	13.42	15.11
Pos Control 4	14.24	12.5	13.36	14.56
Pos Control 5	14.41	12.1	15.01	14.11
Pos Control 6	13.62	12.01	14.06	14.18
NTC	No Ct	No Ct	No Ct	No Ct

The graphs show the consistency of the kit performance for different genes in 2019-nCoV Multiplex RT-qPCR Kit. The kit was tested for stability from week one until week six for ready-to-use One Step RT-qPCR pre-mixed with four different genes of primers and probes in the real-time master mixes. The graphs and Ct values show that the kit has stable and consistent performance.

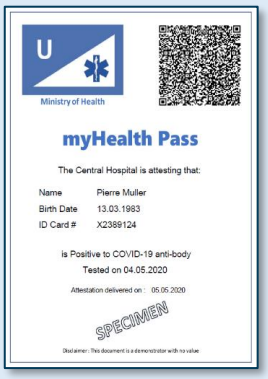
COVID Certified myHealth Pass

A Biospeedia SICPA® Solution

Biospeedia is partnering with SICPA® in developing a **secured and certified health pass** featuring COVID-tests results to allow secured traveling.

SICPA® is a trusted global provider of security inks as well as a leader in secured identification, traceability and authentication solutions.

CERTUS™ myHealth Pass provides guaranteed and secured proof of test status in both digital and material form. It protects against fraud thanks to a cutting edge blockchain-secured digital seal, based on the Guardtime KSI® Blockchain.



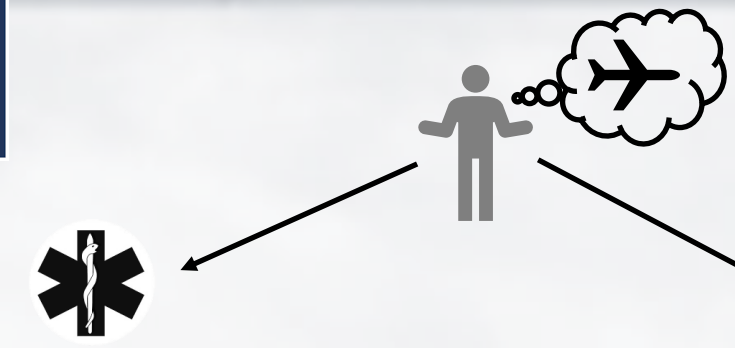
Biospeedia Test status data is revocable and thus always up-to-date. It respects personal privacy concerns while providing incontrovertible assurances of health status to the aviation and border authorities.

The credential is authenticated by scanning a tamper-proof QR-code with a smartphone or a computer. The verification is independent of the document issuer. No personal or sensitive information is stored, either directly or encrypted, in any data base or on the blockchain and no extra-infrastructure is required.

COVID Certified myHealth Pass

A Biospeedia SICPA® Solution

SICPA



Passengers can take a test prior to the flight (**72-24 hours**) at a clinic or hospital by healthcare professionals (doctors, pharmacists, certified nurses)

Passengers can take a test prior to the flight (**<4 hours**) at the airport done by onsite certified professionals

Results in 15 minutes are saved in "myHealth Pass"

Results in 15 minutes are saved in "myHealth Pass"

Positive Result: quarantine and re-test. Can't board flight

Negative Result: authorities can access "myHealth Pass" and allow passengers to board the flight

Positive Result: quarantine and re-test. Can't board flight

COVID 19

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ORDERING INFORMATION

BioSpeedia Rapid Antigen Test

CE IVD

Cat. No	Product Description	Test Specimen	Product Format	Intended Use	Storage Temp	Packing Size
BSD_0503-25	COVID19Speed-Antigen (with Nasopharyngeal Swab)	Nasopharyngeal swab sample	Cassette	Coronavirus disease	4-30°C	25 T/ Kit
BSD_0503-10	COVID19Speed-Antigen (with Nasopharyngeal Swab)	Nasopharyngeal swab sample	Cassette	Coronavirus disease	4-30°C	10 T/ Kit

BioSpeedia Rapid Antibody Test

CE IVD

Cat. No	Product Description	Test Specimen	Product Format	Intended Use	Storage Temp	Packing Size
BSD_0501	COVID19SEROSpeed-IgM-IgG (with disposable dropper, alcohol swab, lancet)	Whole blood, serum or plasma	Cassette	Coronavirus disease	4-30°C	25 T/ Kit

BioSpeedia Viral Nucleic Extraction Kit

CE IVD

Cat. No	Product Description	Test Specimen	Intended Use	Storage Temp	Packing Size
BSD_0510	Viral Nucleic Acid Extraction Kit	Serum, plasma, body fluid, virus-infected cell culture supernatant, VTM buffers consists of virus infected swabs	Isolation and purification of Viral nucleic Acid (DNA/RNA)	4-30°C	100 Preps

BioSpeedia 2019-nCoV Multiplex RT–qPCR Kit

CE IVD

Cat. No	Product Description	Test Specimen	Intended Use	Storage Temp	Packing Size
BSD_0511	2019-nCoV Multiplex RT-qPCR Kit	Extracted RNA from nasopharyngeal & oropharyngeal swab	Detection of SARS-CoV-2's RNA from nasopharyngeal and oropharyngeal swabs	-20°C	100 Preps

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