



BIO SYNEX

Self-test COVID-19

HAVE YOU
DEVELOPED
ANTIBODIES
AGAINST THE VIRUS
RESPONSIBLE FOR
COVID-19?

TEST YOURSELF!



**Result
in 10 minutes**



CE ongoing

Biosynex Autotest COVID-19 (Internal ref 859081 & 859082) is a self-diagnosis test intended for the qualitative detection of IgG and IgM antibodies against SARS-CoV-2 for private use by laypersons. This self-test is reliable in detecting IgG and IgM antibodies directed against SARS-CoV-2 in the blood. Carefully read the instructions in the user manual and possibly seek advice from your pharmacist. If in doubt about the result obtained, consult your doctor. Manufactured by Biosynex Swiss SA.
POS_859081_859082_EN_V01202009R02 Latest revision: 09/2020

BIO SYNEX

biosynex.com

COVID-19

- COVID-19 is an acute respiratory infection caused by a new CoronaVirus (CoV), SARS-CoV-2.
- The main symptoms of COVID-19 are fever, tiredness and dry cough. Severe cases result in pneumonia, respiratory distress and even death.

RT-PCR

- Reverse Transcriptase Polymerase Chain Reaction = Reverse transcription and amplification technique of RNA (or DNA)
- Detects the virus genome (RNA)
- Nasopharyngeal swab



Check for
VIRUS
in the body

SEROLOGICAL TEST

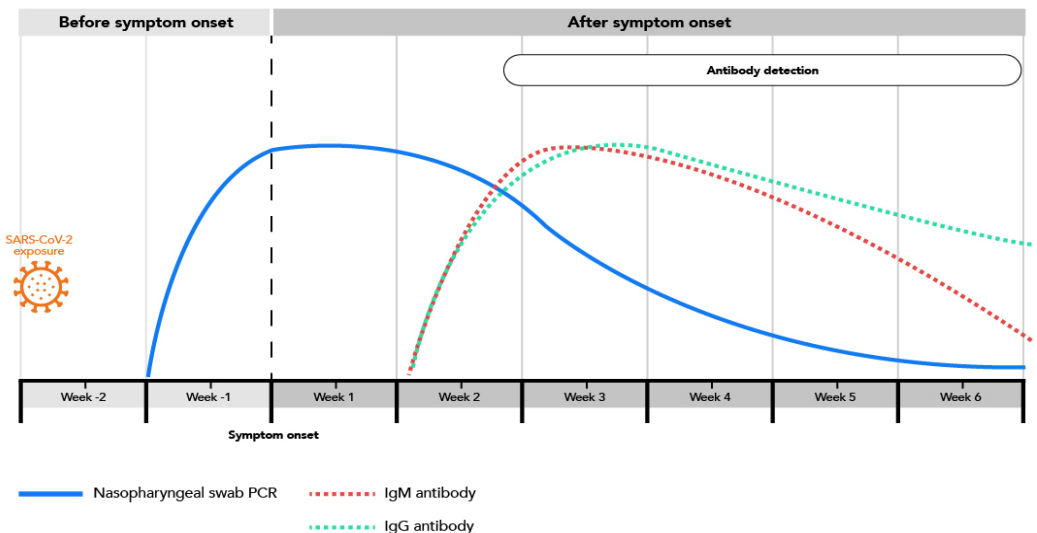
- TDR, TROD or ELISA (Enzyme-Linked Immuno Assay)
- Detects antibodies against the virus (IgG and IgM)
- Blood sampling



To find out if the organism produced
ANTIBODY
in response to a past infection.

The serological test

Tests based on antibody testing are used to check whether antibodies to SARSCoV-2 have been developed. They can identify people who were not known to be infected, either because they never developed symptoms or because they had mild symptoms.



Biosynex COVID-19 Self-test

Contains: 1 bag with

- 1 test cassette
- 1 lancet
- 3 pipettes
- 1 diluent
- 1 alcohol wipe
- 1 compress
- 1 dressing



Instructions for use



Disinfect the fingertip.



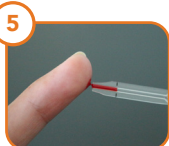
Wipe off traces of alcohol with the compress.



Place the lancet against your fingertip and press down firmly to trigger the device.



Form a large drop of blood at the tip.



Collect the drop of blood **without pressing the bulb** of the pipette.



Empty the contents of the pipette into the square «**Blood**» well.



Place 2 drops of diluent in the round «**Diluent**» well.



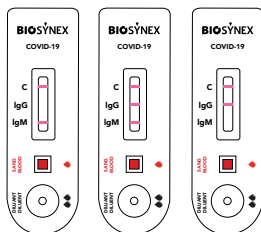
Wait 10 minutes to read the result. Do not read beyond 20 minutes.

Interpretation

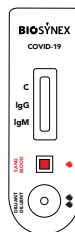
NEGATIVE



POSITIVE



INVALID



Performances

Sensitivity and specificity

Biosynex COVID-19 self-test was compared to the clinical diagnosis (confirmed). The study involved 456 samples for IgG and 466 samples for IgM.

	Sensitivity	Specificity
IgG	100%	99,5%
IgM	92,6%	99,2%

Range of Rapid diagnostic tests



Test HIV x1

EAN : 353 267 855 164 7

RÉF. : 855 164

CE 0123



Test HIV x2

EAN : 353 267 855 169 2

RÉF. : 855 169

CE 0123



Simply pregnancy test

EAN : 353 267 855 147 0

RÉF. : 855 147

EAN : 353 267 858 851 3

RÉF. : 858 851

CE 0123



Early pregnancy test

EAN : 353 267 858 931 2

RÉF. : 858 931

CE 0123



Ovulation test

EAN : 353 267 855 146 3

RÉF. : 855 146

CE 0123



Vaginal infection test

EAN : 353 267 855 163 0

RÉF. : 855 163

CE 2797



Urine infection test

EAN : 353 267 942 692 0

RÉF. : 942 692

CE 0123



Cannabis test

EAN : 353 267 858 836 0

RÉF. : 858 836



Gluten test

EAN : 353 267 858 865 0

RÉF. : 858 865

CE 0123



Streptatest®
TROD sore throat

EAN : 353 267 922 660 5

RÉF. : 100 25



Influenzatop® BSS
TROD influenza

EAN : 353 267 858 890 2

RÉF. : SW40002



COVID-19 BSS
TROD COVID-19

EAN : 353 267 859 073 8

RÉF. : SW40005A



Uritop®
TROD urinary infection

8 PARAMETERS:

EAN : 353 267 942 691 3

RÉF. : 58

10 PARAMETERS:

EAN : 353 267 942 643 2

RÉF. : 50

Sources

https://www.has-sante.fr/upload/docs/application/pdf/2020-04/cahier_des_charges_test_serologique_covid19.pdf
https://www.has-sante.fr/upload/docs/application/pdf/2020-05/rapport_tests_serologiques_rapides_covid-19_vd.pdf
<https://covid-19.sante.gouv.fr/tests>
 Sethuraman N, Jeremiah SS, Ryo A. Interpreting Diagnostic Tests for SARS-CoV-2. JAMA. 2020;323(22):2249–2251.
 doi:10.1001/jama.2020.8259

Read carefully the instructions for use of the various products.

Manufacturer of numbers 855164, 855169, 858931, 855147, 858851, 855146, 855163, 942692, 858865, 858836, 858963, 100 25, 58, 50: Biosynex SA
 Manufacturer of numbers SW40002, SW40005A, 859081, 859082: Biosynex Swiss SA

BIO SYNEX

Biosynex designs, manufactures and distributes **Rapid Diagnostic Tests (RDTs)** in France and **internationally**. The RDTs, in their professional version, allow a better medical management of the patients thanks to the speed of their result and their simplicity of use. In their **self-test** version, they allow the general public self-monitoring of various pathologies thus ensuring **better prevention** and accelerating the demand for care.