

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



TROD sore throat Streptatest®
EAN : 353 267 922 660 5 RÉF. : 100 25



TROD influenza Influenzatop® BSS
EAN : 353 267 858 890 2 RÉF. : SW40002



TROD COVID-19 COVID-19 BSS (IgG/IgM)
EAN : 353 267 859 073 8 RÉF. : SW40005A



TROD urinary infection Urinotop®
8 PARAMETERS:
EAN : 353 267 942 691 3 RÉF. : 58

COVID-19 Ag BSS
EAN : 353 267 859 113 1 RÉF. : SW40006

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, SW40006, 859081, 859082: Biosynex Swiss SA



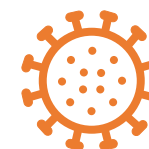
Biosynex designs, manufactures and distributes **Rapid Diagnostic Tests (RDTs)** in France and internationally. The RDTs, in their professional version, allow a better medical management of the patients thanks to the speed of their result and their simplicity of use. In their **self-test** version, they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



Self-test COVID-19

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

TEST YOURSELF!



Result in 10 minutes



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



FLY_859081_859082_EN_V01202009R04

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

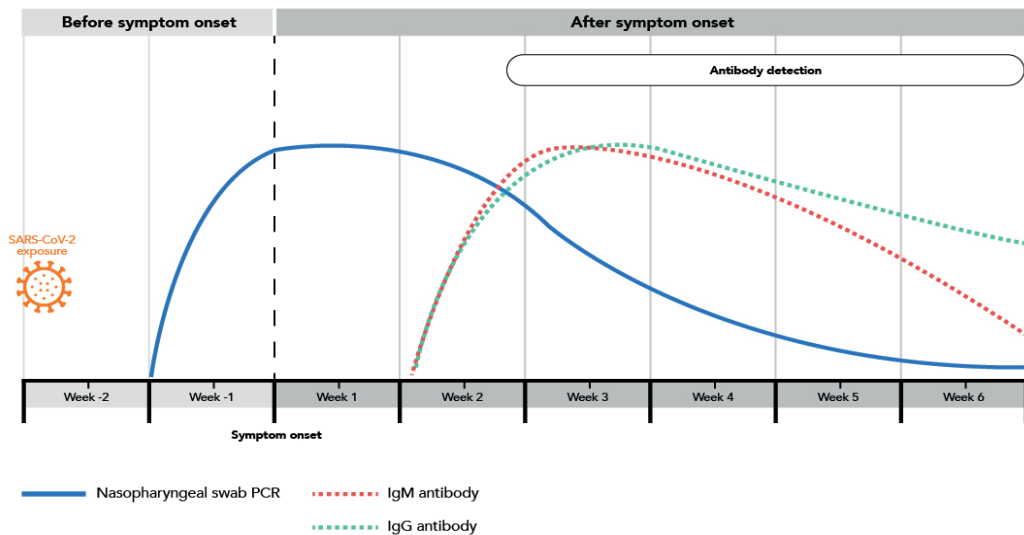
- TDR, TROD or ELISA (Enzyme-Linked Immuno Assay)
- Detects antibodies against the virus (IgG and IgM)
- Blood sampling



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

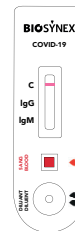


Instructions for use

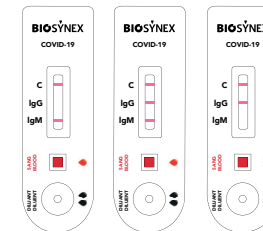
- Disinfect the fingertip.
- Wipe off traces of alcohol with the compress.
- Place the lancet against your fingertip and press down firmly to trigger the device.
- Form a large drop of blood at the tip.
- Collect the drop of blood **without pressing the bulb** of the pipette.
- Empty the contents of 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%