

# BIOSYNEX

## COVID-19 Ag BSS

### TRACEABILITY SHEET FOR PERFORMING NASOPHARYNGEAL ANTIGEN DIAGNOSTIC RAPID TESTS FOR THE DETECTION OF SARS-COV-2

Give a copy of this sheet to the patient and keep a copy.

Last name:		First name:	
Date of birth:		NIR:	
Postal code of place of residence:		Phone number:	
Documentation:	ID <input type="checkbox"/>	Passport <input type="checkbox"/>	Residence permit <input type="checkbox"/>
	Number:		

Pharmacists, doctors, nurses, midwives, dental surgeon and masseur-kinésithérapeutes are authorized to perform the TROD COVID - 19 Ag BSS following the order of July 10, 2020 (french law). He is responsible of informing the patient of the result of the test, specifying that **this result only constitutes diagnostic orientation**. The test must be performed in accordance with the manufacturer's recommendations described in the instructions for use, and will be eliminated with the consumables required for the test, in the DASRI sector, after use.

<b>BIOSYNEX</b> Référence : SW40006 Biosynex Swiss SA Nasopharyngeal antigen diagnostic rapid test for the detection of SARS-CoV-2		Sensibility: 96 % Specificity: 100 %
Lot:	Date:	Test time:
Test result:	Positive <input type="checkbox"/>	Negative <input type="checkbox"/>

AP-HP study (07/10/2020): among the 6 tests evaluated, the BIOSYNEX COVID-19 Ag BSS test is one of the 3 most efficient<sup>1</sup>.

Study by the Strasbourg Institute of Virology (25/09/2020): the results show an excellent performance of the Biosynex antigen test for viral loads less than or equal to 30 Ct, which varies between 93% and 100% for fresh samples.

#### If the BIOSYNEX Covid-19 Ag BSS test is positive:

The patient must isolate himself, contact his doctor for medical treatment and list the people he could have infected. Contact 15 in the event of respiratory distress.

#### If the BIOSYNEX Covid-19 Ag BSS test is negative:

For symptomatic people 65 years or older and people who have at least one risk factor for COVID-19, it is recommended to consult a doctor and confirm the result by an examination for the detection of the SARS-CoV-2 genome by RT-PCR. In all cases, continue to respect barrier gestures.

Last name / first name of healthcare professional:
Signature and stamp (obligatory):

PLACE  
THE  
TEST  
HERE

<sup>1</sup>A study carried out by the virology laboratory of the Henri Mondor hospital in Créteil (APHP) was carried out using frozen samples diluted in viral transport medium or physiological saline. The overall sensitivity versus PCR is 59.6% and 71.3% for Ct <33. The specificity is 100%. Among the 6 tests evaluated, the BIOSYNEX COVID-19 Ag BSS test is one of the 3 most efficient.