

<b>BIOSYNEX</b>	<b>Product summary</b>		
	BIOSYNEX Covid-19 Ag self-test Ref: 859256/859257/859258 (Kit of 1 test) Ref: 859261/859262/859263 (Kit of 5 tests)		
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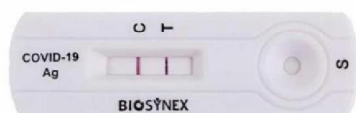
**Product:**

Kit Box with individual bag including: test cassette (in individual pouch with a desiccant), sterile swab, pre-filled buffer vial, dropper teat, red dropper stop + package insert.

**Product details:**

- **Test**

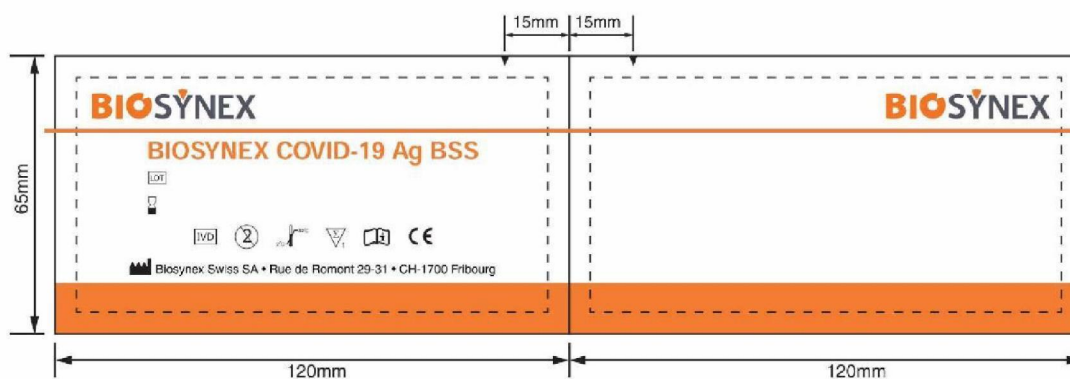
- **Mould**



Front: white cassette with black imprint "COVID-19 Ag", "C", "T", "S", "BIOSYNEX LOGO"

Back: orange cassette

- **Pouch**



Note: this is the same cassette and same pouch than the professional EC version test. This test will be re-packed in a special non CE box adapted for self-testing with a non CE IFU adapted for self-testing.

- **Desiccant**




- **Extraction buffer**

1 pre-filled vial of extraction buffer sealed with aluminium + 1 dropper teat + 1 red dropper stop

Filling volume: 360 µL



Approved by : 5.1.2e Quality Assurance & Regulatory department

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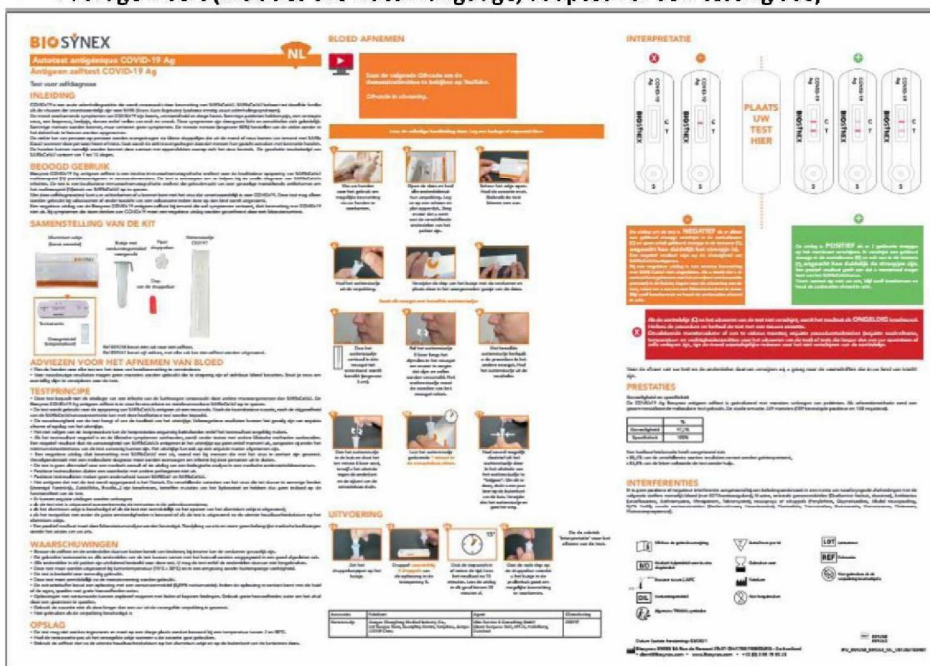
• Sterile swab (CE0197)



All the above mentioned components are packed in an individual plastic bag :



• Package insert (Includes the Dutch language, adapted for self-testing use)



**BIOSYNEX**  
Antigen sneltest COVID-19 Ag  
Antigen zelftest COVID-19 Ag

**BLOED AFNEMEN**

**INTERPRETATIE**

**PRESTATIES**

**WAARSCHUWINGEN**

**OPSLAG**

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### Packing:

- **BIOSYNEX Box, adapted for a self-testing format : includes the Dutch language.**  
 1 box Reference 859256/859257/859258 contains 1 individual package containing :
  - 1 test cassette in an aluminium pouch
  - 1 pre-filled buffer vial + 1 dropper teat + 1 dropper stop
  - 1 sterile swab

A package insert is also included in the kit

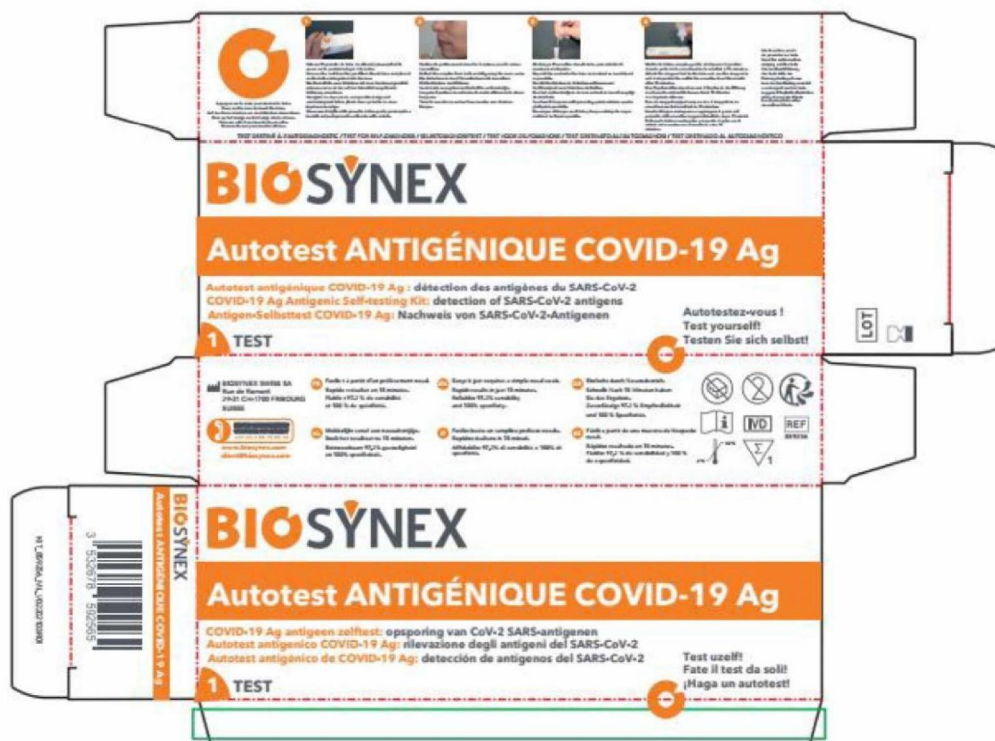
- 1 box Reference 859261/859262/859263 contains 5 individual packages containing each :
  - 1 tests cassette (each in an aluminium pouch)
  - 1 pre-filled buffer vial + 1 dropper teat + 1 dropper stop
  - 1 sterile swab

A package insert is also included in the kit

### Note :

Reference 859256/859257/859258 are the product references for the kit of 1 test

References 859261/859262/859263 are the product references for the kit of 5 tests



Note 1: since other languages will be added, the design of the above box and IFU may change

Note 2: workstation is included in the box itself as showed in the below picture

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*Note 3: BIOSYNEX is a company that is really listening the market needs. If there are special needs for a self-testing kit with a different number of tests than 1 or 5 tests, BIOSYNEX is opened to a discussion around this project.*