BIOSYNEX
EASY DIAGNOSTICS FOR LIFE SWISS

Strasbourg, April 15th 2021

EXECUTIVE SUMMARY 2
Version 04: April 2021

BIOSYNEX® COVID-19 BSS, references SW40005 and SW40005A
BIOSYNEX® AUTOTEST COVID-19, references 859082 and 859081

a. Intended use

The Biosynex COVID-19 BSS test is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies against SARS-CoV-2 in human whole blood, serum, or plasma as an aid in the diagnosis of SARS-CoV-2 infections. It is for professional of self-test in vitro diagnostic use.

b. General description of test

Medical product type:	In vitro diagnostic (IVD) medical device
Test type:	Rapid visual immunoassay
Detection of:	IgG and IgM antibodies against SARS-CoV-2. **Targeted protein: Spike protein Receptor Binding Domain (RBD)**
Indication:	Aid in the diagnosis of SARS-CoV-2 infections
Detection in:	Whole Blood/Serum/Plasma
Usage by:	Professional or layman users (depending on reference)
Determinations per test:	Single use
Product name and reference :	**BIOSYNEX COVID-19 BSS – for professional use** Reference: **SW40005** (EAN code: 3 532678 590554) Variant reference **SW40005A**: with lancets **BIOSYNEX AUTOTEST COVID-19 – for layman use (self-test)** Reference: **859082** (EAN code: 3 532678 590820) Variant reference **859081** (EAN code: 3 532678 590813)

c. Short summary of test characteristics (performance data, stability ...)

Sensitivity	Grand Hôpital de l'Est Francilien, in Jossigny, France (results for positive samples **>13 days** after symptoms onset) Total sensitivity IgM+ IgG: 100% against RT-PCR
Specificity	Grand Hôpital de l'Est Francilien, in Jossigny, France 100%
Stability	>18 months

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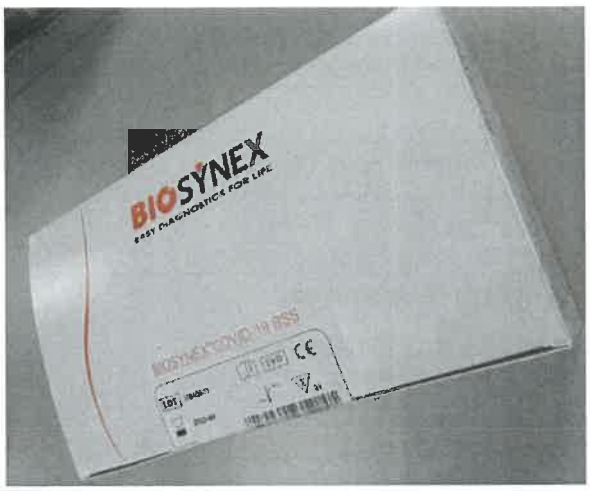
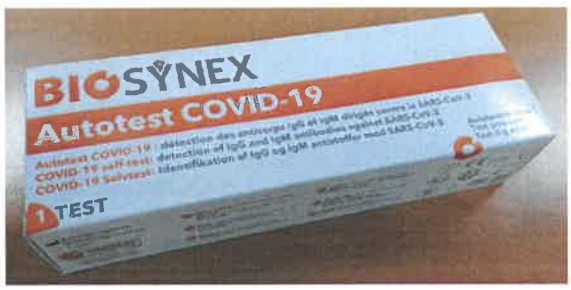
d. Regulatory information

- Product **CE marked**; classification: not listed in the IVD directive 98/79/EC
- **CE certificate** delivered by **TÜV SÜD** for self-test version
- Free Sale Certificate released by Swissmedic (Swiss Agency for Therapeutic Products)
- FDA registration on-going
- Product sold in Europe and outside Europe (Asia, Africa, Latin America)
- Listed on FIND: https://www.finddx.org/covid-19/pipeline/
- Listed on European commission: https://covid-19-diagnostics.jrc.ec.europa.eu/devices
- Listed on French MOH: https://covid-19.sante.gouv.fr/tests

e. Commercial presentations of the product

<table>
<tr>
<td>Professional version – 25 tests/kit:
- 25 tests, each is under aluminum pouch with a desiccant
- 25 droppers or capillary collectors
- 1 diluent buffer bottle
- 1 Instructions For Use
(+ 25 sterile lancets in reference SW40005A)
  </td>
<td>Self-test version – 1 test/kit:
- 1 test under aluminum pouch with a desiccant
- 1 pipette
- 1 diluent buffer bottle
- 1 sterile lancet
- 1 plaster
- 1 alcohol wipe
- 1 sterile compress
- 1 Instructions For Use
  </td>
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f. Summary of the conclusions of the external evaluations conducted on the product

- **Performance evaluation report for the detection of anti SARS-COV 2 antibodies (National Center of Reference, Institut Pasteur-FRANCE)- 119 samples tested whose 43 positive patients confirmed by RT-PCR**
  - *"The overall sensitivity for the detection of IgG / IgM in COVID-19 + subjects **reaches 100% beyond 15 days** in accordance with other studies".*

- For BIOSYNEX rapid test IgG, the sensitivity of the kit **appears slightly higher than the ELISA N total** Ig of the NRC on plasma dilutions while it is comparable or slightly lower on dilutions of sera.

- **Serologic responses to SARS-CoV-2 infection among hospital staff with mild disease in eastern France (Emergency service-Strasbourg hospital-FRANCE) Medrxiv 2020- 162 hospital staff tested, PCR confirmed**
  - **100 %** Antibodies against SARS-CoV-2 detection in hospital staff sampled **from 13 days** after the onset of COVID-19 symptoms.
  - *"This finding supports the use of serologic testing for the diagnosis of individuals who have recovered from SARS-CoV-2 infection. The neutralizing activity of the antibodies increased overtime".*

- **Report of an evaluation conducted by the Laboratory of Medical Biology of the Grand Hôpital de l'Est Francilien in Jossigny-FRANCE**
  - The overall sensitivity (IgG and/or IgM) is **100%, 13 days** after the first signs of COVID-19 infections, it is 82% between 6 and 10 days respectively, and 90% between 11 and 15 days after the first signs.

- **External practicability study for self-testing ("Capillary whole-blood IgG-IgM COVID-19 selftest as a serological screening tool for SARS-CoV-2 infection adapted to the general public") published in PLoS ONE peer-reviewed journal**
  - Over 167 participants, 98.5% achieved the correct reading and interpretation of test results, 100% found that performing the COVID-19 self-test was easy, and 98.8% found the interpretation of the self-test results easy.

Yours faithfully,

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