

## The Biosynex COVID-19 antigen test - a brief description

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Translated from Danish by Alan Jordan PhD, authorised medical translator.

### Introduction

- The EU based biotech firm Biosynex SA has developed a rapid antigen test named Biosynex COVID-19 Ag to detect SARS-CoV-2 in nasopharyngeal swabs without the need for machinery, laboratory facilities and specially trained staff.
- Biosynex SA is a publicly listed company in France.
- Biosynex COVID-19 Ag can be read in just 15 minutes and is provides a evidence based diagnosis regarding COVID-19.

### Key product features - “The 10 important facts”

1. The BIOSYNEX COVID-19 antigen test is an in vitro immunochromatographic assay for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2.
2. The tests use highly specific monoclonal antibodies to detect the nucleocapsid protein from SARS-CoV-2.
3. The test strip contains colloidal-gold conjugated particles with monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2 – the latter being the antigen in swabs containing the pathogenic virus.
4. For the best performance of the test, direct nasopharyngeal swabs should be tested as soon as possible after collection and the results of the test and can be read after 15 minutes.
5. The test is capable of detecting both degraded and intact SARS-CoV-2.
6. The clinical data regarding the Biosynex COVID-19 Ag are based on 248 samples obtained from 203 patients with PCR proven SARS-CoV-2 including 103 samples confirmed positive and 145 negative samples.
7. The sensitivity of the test = 96% (95% confidence intervals: 93.6 - 98.4%).
8. The specificity of the test = 100% (95% confidence intervals: 100 - 100%).
9. The accuracy of the test = 98% (95% confidence intervals: 96,5 - 99.6%).
10. The Biosynex COVID-19 Ag is therefore the optimal rapid test for the detection of COVID19 with an accuracy rivalling the most expensive, laborious and costly PCR tests.