Biosynex COVID-19 antigen (Ag) test

- a brief description

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Introduction

- The publicly listed biotech company Biosynex SA, France has developed a rapid antigen test named Biosynex COVID-19 Ag BSS to detect SARS-CoV-2 without the need for machinery, laboratory facilities and specially trained staff.
- Biosynex COVID-19 Ag can be read in 15 minutes and is equivalent to a validated RT-PCR metode.

Key product facts

- BIOSYNEX COVID-19 antigen test is an immunochromatographic assay for the detection of the so-called important nucleocapsid protein antigen from SARS-CoV-2.
- The tests use highly specific monoclonal antibodies to detect the nucleocapsid protein from SARS-CoV-2.
- The test contains colloidal-gold conjugated particles with monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2 - the latter being the antigen from the pathogenic virus.
- The test is capable of detecting both degraded and intact SARS-CoV-2.
- For the best performance of the test, nasopharyngeal swabs should be tested after collection and the results of the test can be read after 15 minutes.
- Clinical data regarding Biosynex COVID-19 Ag was originally based on samples obtained from 203 patients with PCR proven SARS-CoV-2, thus:
    - *sensitivity* = 97.3% (95% confidence intervals: 93.6 - 98.4%)
    - *specificity* = 100% (95% confidence intervals: 100 - 100%)
    - *accuracy* = 98% (95% confidence intervals: 96,5 - 99.6%)
- Presently, validated scientific data regarding Biosynex COVID-19 Ag includes a total of 1078 samples from four European university centers.
- Likewise, the sensitivity of the Biosynex COVID-19 Ag test has been calculated based on the Ct-values of the positive clinical specimens showing *sensitivity data* as follows:
    - $0 \leq Ct \leq 20$ = 96%
    - $21 \leq Ct \leq 30$ = 98%
    - $31 \leq Ct \leq 35$ = 94%
- *Therefore, Biosynex COVID-19 Ag is the optimal rapid test for the detection of COVID-19 in asymptomatic patients or in patients with mild symptoms with an accuracy rivalling the most expensive, laborious and costly PCR tests.*