

# CerTest SARS-CoV-2 card test

Test for antigen detection

Now  
available!

## Rapid mass diagnosis

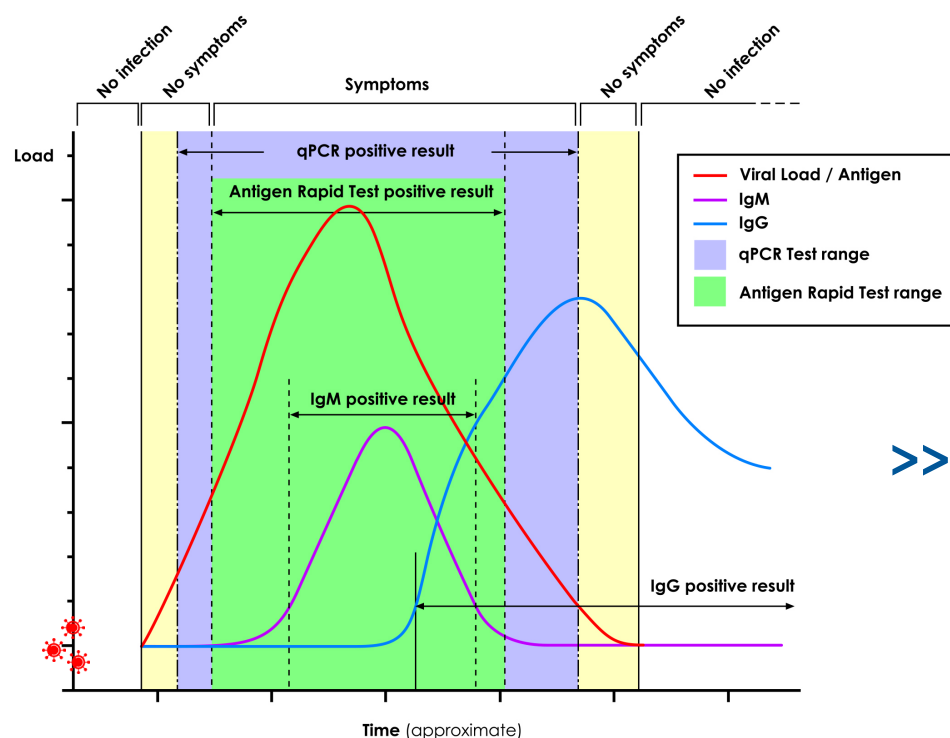
The **One Step SARS-CoV-2 Antigen Test Device** is a rapid chromatographic immunoassay for the **qualitative detection of Coronavirus (SARS-CoV-2) antigens** in human nasopharyngeal swab specimens to aid in the diagnosis of Coronavirus (SARS-CoV-2) respiratory infection.

**This rapid test represents a valuable alternative in the context of a global shortage of diagnostic tests and allows to obtain results quickly and reliably, in a wide population group.**

Clinically, patients with SARS-CoV-2 infection tend to suffer symptoms such as olfactory and gustatory dysfunction, fever, dry cough, anosmia, fatigue, dyspnoea, headache, diarrhoea and sore throat, followed by vascular and systemic complications. COVID-19 commonly results in pneumonia, which can evolve into acute respiratory distress syndrome, leading to respiratory or multiorgan failure.

**On March 11, 2020, the WHO declared the disease a pandemic, due to the high number of infected people and the rapidity of its spread worldwide.**

The following graph shows the evolution of disease:



- Non-invasive diagnosis.**  
Nasopharyngeal swab sample.
- No need for additional equipment.**  
All components included in the kit.
- Low cost throughout the process,**  
reaching less developed populations.
- Immediate results.**  
Result in 10 minutes
- Very simple use and interpretation.**  
More amount of analysis in the same time.

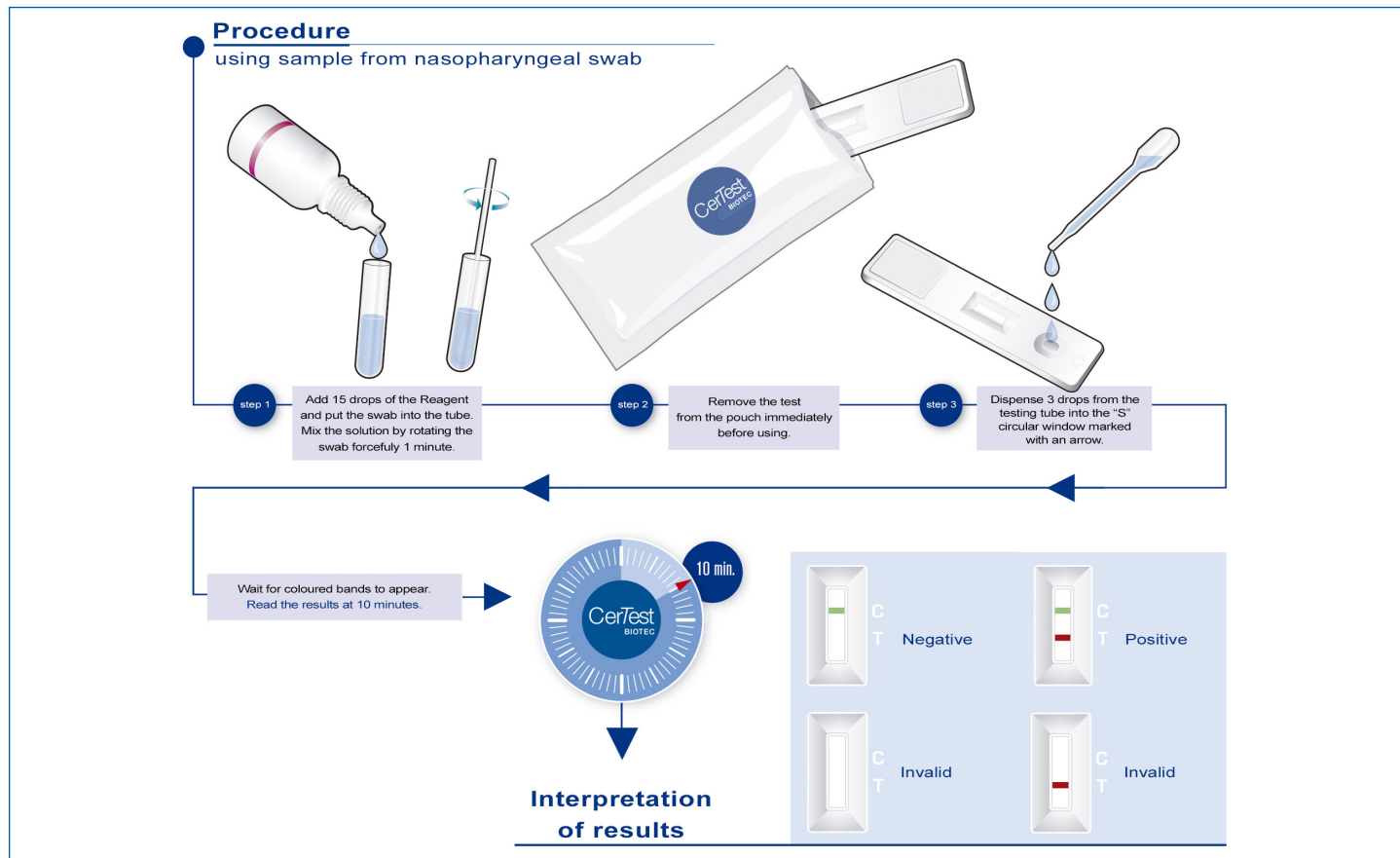
**>> Comparing antigen detection with antibody detection, detection period is longer for antigens, and the diagnosis is earlier.**

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## Procedure.



Although it is a very simple test to use, the handling of the samples is considered potentially dangerous, so they must be treated in the same way as an infectious agent, and by trained and qualified personnel.



### Sensitivity:

- For PCR positive samples with  $Ct \leq 25$ : **96,0%**  
(Confidence interval 76,6 - 99,9%)
- For PCR positive samples with  $Ct \leq 30$ : **90,0%**  
(Confidence interval 73,5 - 97,9%)
- Full evaluation result: **72,4%**  
(Confidence interval 64,5 - 79,3%)

### Specificity:

**98,4%**  
(Confidence interval 91,3 - 100%)



Detection of the viral antigen implies the presence of the virus, **so a positive test result is indicative of current SARS-CoV-2 infection**. High specificity implies high reliability of the positive result. On the other hand, **at the discretion of the prescriber, a negative result may require confirmation by another technique**.

**CerTest**  
BIOTEC

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For more information and procedure for use, read the instructions for use included in this product.



RapidTest/SARS-CoV-2/0920EN

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