CerTest BIOTEC

CerTest Rapid Test

CerTest *SARS-CoV-2* card test

Test for antigen detection

Now available!

Rapid mass diagnosis

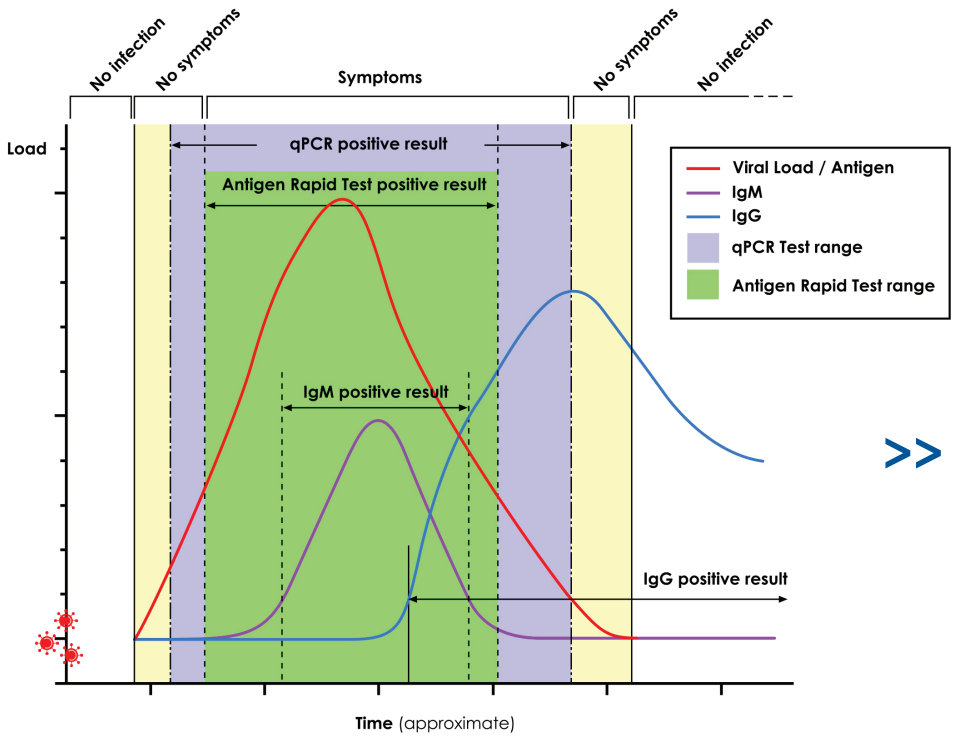
The ***One Step* SARS-CoV-2 *Antigen Test Device*** is a rapid chromatographic immunoassay for the **qualitative detection of Coronavirus (SARS-CoV-2) antigens** in human nasopharyngeal swab specimens to aid in the diagnosis of Coronavirus (SARS-CoV-2) respiratory infection.

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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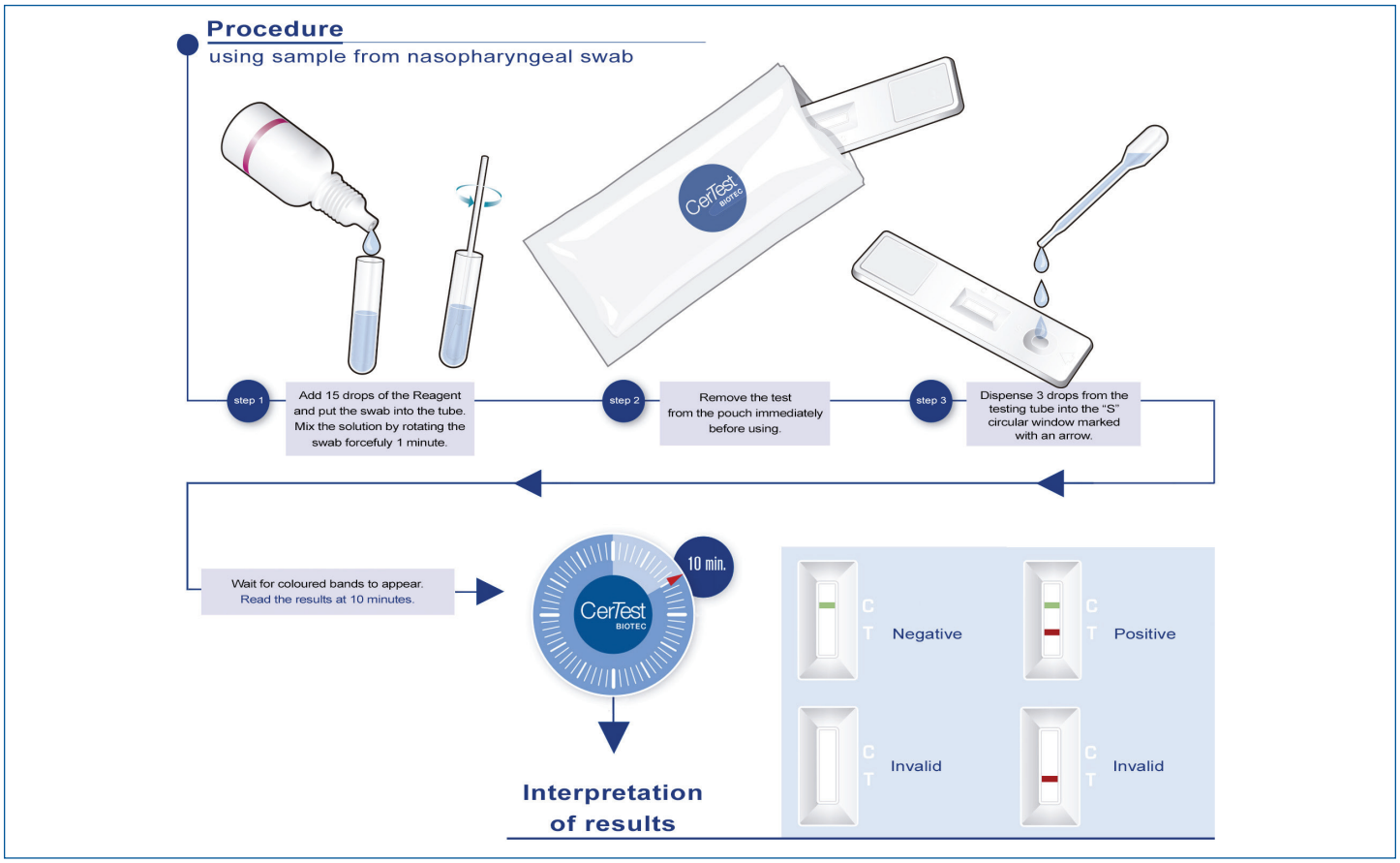
Procedure.

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 & Specificity

CerTest SARS-CoV-2 vs. qPCR Technique		
	Mean Value	**95% Confidence interval**
Sensitivity (*)	92.9%	76.5 - 99.1%
Specificity	99.6%	97.6 - 100.0%
PPV	96.3%	81.0 - 99.9%
NPV	99.1%	97.0 - 99.9%

(*) Taking into account the recommendations for *Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays (11 September 2020)* from the WHO, the sensitivity of the test was calculated with nasopharyngeal samples with high viral load (high viral loads is expected in early symptomatic phases of the illness (with the first 5-7 days of illness) in the range of Ag-RDT test detection).

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.**

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

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