



**FAST  
LABORATORY  
DIAGNOSTICS**

**OaCP**

# SARS-COV-2 ANTIGEN FAST TEST KIT

**CE-IVD; BFARM/PEI**

## MANAGEMENT TEAM

**CEO | Enrico Di Oto** - Bs, MD, PhD, +17 years in cancer diagnosis

**CTO | Simone Di Giacomo** - PhD, +15 years in R&D

**CMO | Andrea Faviere** - MBA, +10 years in marketing and sales

**CIO | Matteo Allegro** - +10 years in IT

## NETWORK

- ◆ **SOSV - The Accelerator VC**
- ◆ **Alma Mater Studiorum** - Università di Bologna
- ◆ **Fondazione Golinelli**
- ◆ **Policlinico S.Orsola-Malpighi** di Bologna
- ◆ **ITA** - Italian Trade Agency
- ◆ **EIT Health** - European Institute of Innovation & Technology
- ◆ **Enterprise Ireland**
- ◆ **Shangai Technology Innovation Center**

## WHO WE ARE

- ◆ Years of experience in advanced diagnosis
- ◆ Innovation-driven company
- ◆ Patients oriented solutions
- ◆ CE-IVD marked and patented products



**OaCP**

## CONTACTS

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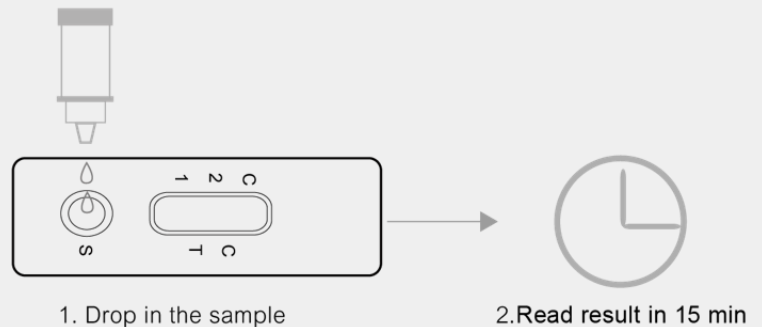
## INTENDED USE

For qualitative detection of the nucleocapsid protein antigen of SARS-CoV-2 in nasopharyngeal and nasal swab, and saliva specimens from individuals and is aid in rapid diagnosis of patients with suspected SARS-CoV-2 infection

## FEATURES

- ◆ Carefully selected special monoclonal antibody to the nucleocapsid protein antigen from SARS-CoV-2.
- ◆ Various applicable specimen: Nasopharyngeal swab, Nasal swab and Saliva.
- ◆ Easy to use, easy results interpretation by naked eyes.
- ◆ Test result available within 15 minutes.

## SIMPLE TEST PROCEDURE



## RESULTS INTERPRETATION



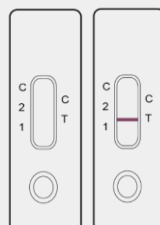
**POSITIVE:** A red line appears on the test line (T) and the control line (C).

*NOTE: A positive result does not rule out co-infections with other pathogens.*



**NEGATIVE:** Only the control line (C) appears, and no red line appears on the test line (T).

*NOTE: A negative result does not exclude infection.*



**INVALID:** There is no red line at the position of the control line (C).

*Regardless of whether the TEST line (T) is displayed, it is an invalid result and the sample should be tested again.*



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## CLINICAL PERFORMANCE

SARS-CoV-2 Antigen Test Kit	Comparator Method (NTA)		
	Positive	Negative	Total
Positive	97	0	97
Negative	3	100	103
Total	100	100	200
Positive Agreement (95% CI): 97/100 97% (83.3% - 99.9%)			
Negative Agreement (95% CI): 100/100 100.0% (95.5% - 100%)			

- LoD: 1.5×10<sup>2</sup> TCID<sub>50</sub> for virus lysate, 10pg/mL for recombinant Nucleocapsid protein antigen.
- Compared with NAT method, the specimens with the Ct range between 30-35 will be detectable.
- No cross-reactions with various bacteria, viruses and fungi normally available in respiratory track.
- Positive Agreement (95% CI): 97/100, 97% (83.3% - 99.9%)
- Negative Agreement (95% CI): 100/100, 100.0% (95.5% - 100%).

**[Product Name]:** SARS-CoV-2 Antigen Test

**[Product Code]:** Cat# FP-318

**[Sample Type]:** Nasopharyngeal swab / Nasal swab /Saliva

**[Detection Method]:** Colloidal Gold

**[Reaction Time]:** Within 15min

**[Packing Size]:** 1T x 20 cassettes + Sample buffer 20 vials x 0.5mL + 20 samples collection swab x1.

**[Storage Condition]:** 2oC ~30oC

**[Shelf Life]:** 12/18 months

**[CE Mark Registration No.]:** RPS/499/2021.

## DISTRIBUTED BY

**Crosstrak LTD**

Mail to: [giorgio@crosstrak.co.uk](mailto:giorgio@crosstrak.co.uk)



## IN PARTNERSHIP WITH



## CONTACTS

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