

EASE your burden of
COVID-19 diagnosis



immtek

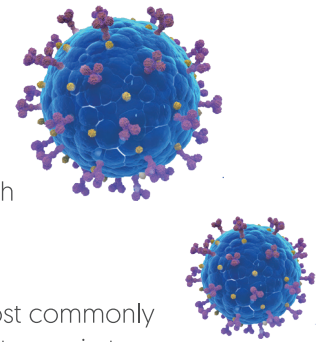
COVID-19
Antigen Rapid Test

METAS
BIOMEDICAL INC.



What's COVID-19

COVID-19 is a respiratory illness caused by the novel coronavirus named "Severe Acute Respiratory Syndrome Coronavirus 2 [SARS-CoV-2]" that was discovered in Wuhan, China 2019, and it is currently a World Health Organization [WHO] declared pandemic. People with SARS-CoV-2 infection may be asymptomatic but still could transmit it through respiratory droplets from coughs and sneezes.¹

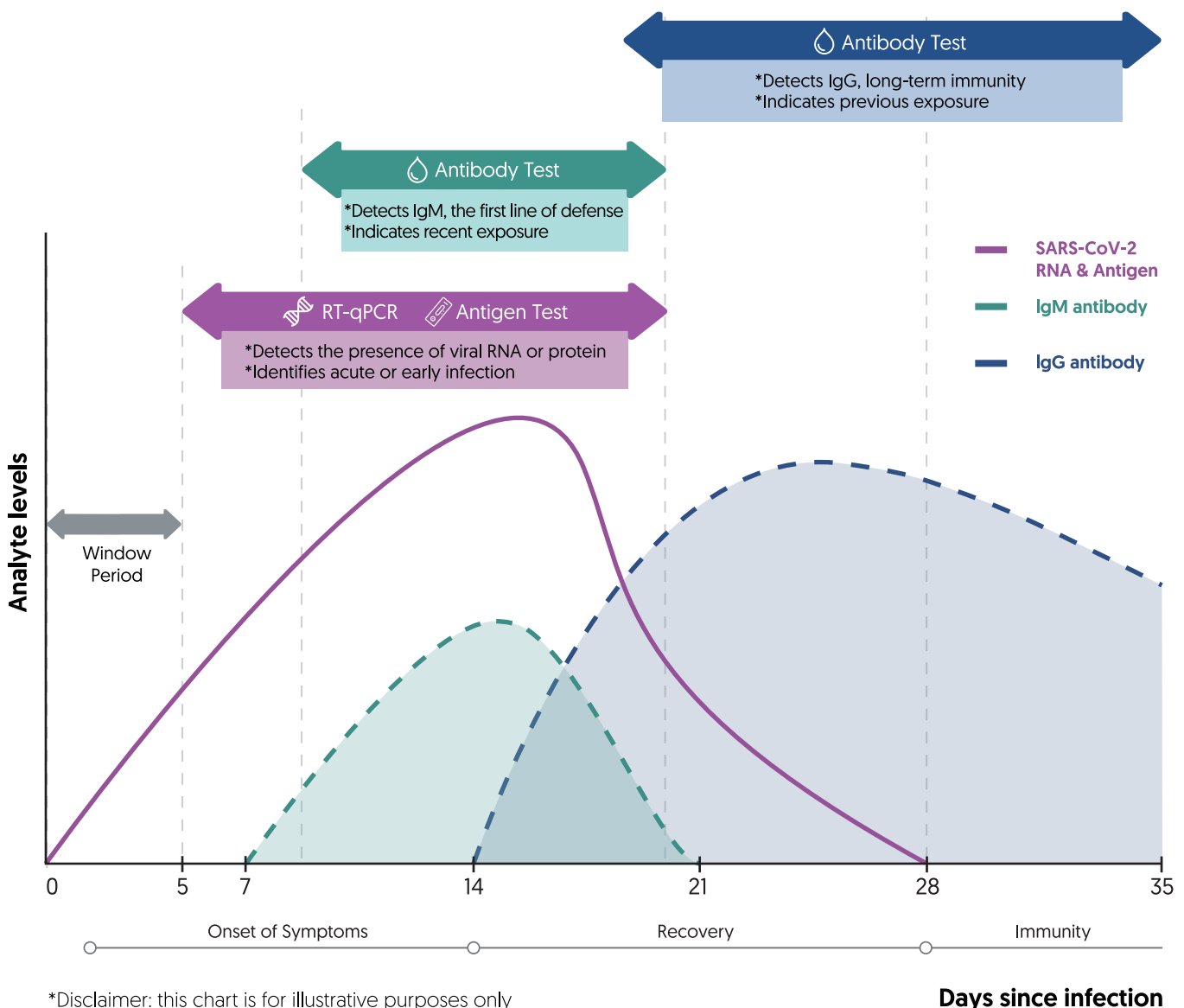


Symptoms and signs of COVID-19 are non-specific, however in symptomatic individuals most commonly include fever, cough, fatigue, and shortness of breath. Severe patients may progress to acute respiratory distress syndrome [ARDS], septic shock, diffuse alveolar damage [DAD], and death.²

In addition to maintaining good personal hygiene, the rapid diagnosis of COVID-19 is critical for prevention and control of this pandemic.

Diagnostic Solutions

The ImmTek™ COVID-19 product line aims to ease the burden of diagnosis on health facilities. We hope each product category can play a critical and complementary role in response to COVID-19 pandemic from early-stage detection to epidemiological surveillance, and assist health facilities to efficiently improve patient management, public health decisions, and ensure timely treatment of patients.



EASE *Your Burden of COVID-19 Diagnosis*



Expedited results

Visible and reliable result appears in 10 minutes.

Accurate interpretation

No cross-reactivity to MERS and other common human coronaviruses.

Simple procedure

One step, no equipment required.

Efficient POCT

Minimizes specimen degradation or contamination during transportation and storage.



Intended Use

ImmTek™ COVID-19 Antigen Rapid Test is an in vitro immunochromatographic assay intended for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigen in nasal or nasopharyngeal swab specimens from individuals with suspected symptoms within 5 days, as an aid to the initial diagnosis of SARS-CoV-2 infection. Test results should be interpreted by medical professionals in conjunction with clinical history and symptoms.



Health Facility



Airport



Station



Hotel



School



Mass Screening

Specification

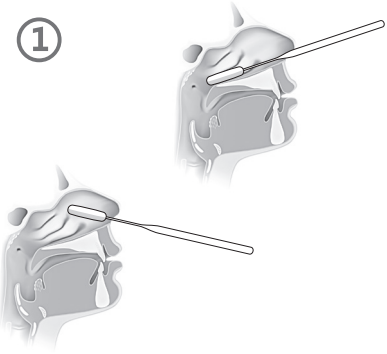
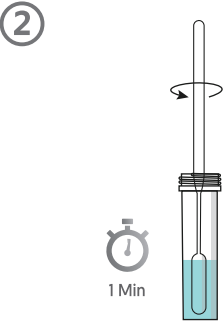
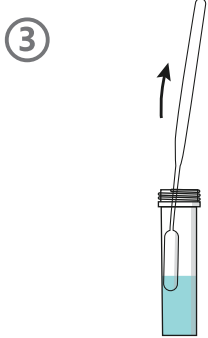
Test Principle	Lateral Flow Immunochromatographic Assay
Target Antigen	SARS-CoV-2 Nucleocapsid Protein
Specimen Type	Fresh Nasal or Nasopharyngeal Swab Specimen
Reaction Time	10 Minutes
Interpretation	Clear and accurate reading of dual colored C line and T line.
Limit of Detection	3.13×10^2 TCID ₅₀ /ml
Cross Reactivity	No cross reactivity with other viruses and bacteria tested.
Interference	Not affected by the interfering substances tested.
Sensitivity	93.48% [95%CI: 82.10%-98.63%]
Specificity	99.14% [95%CI: 95.29%-99.98%]
Storage	Room Temperature 15-30°C [59-86°F]

Order Information



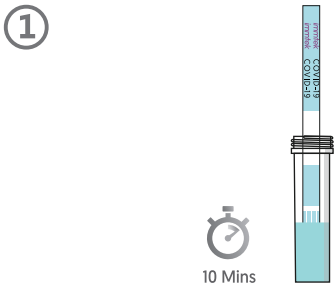
Catalogue No.	Product Name	Product Type	Package
INFCOV1925C	ImmTek™ COVID-19 Antigen Rapid Test	Cassette	25 Tests/Box
INFCOV1950S		Strip	50 Tests/Box

Specimen Collection

		
<p>Carefully insert the Sterile Swab into the nostril to collect nasal swab specimens or nasopharyngeal swab specimens.</p>	<p>Immediately place the swab with specimen into the Extraction Buffer Tube. Rotate the swab 5 times and let stand for 1 minute.</p>	<p>Squeeze as much liquid as possible from the swab by pressing the tip against the side of the tube.</p>

Test Procedure Strip

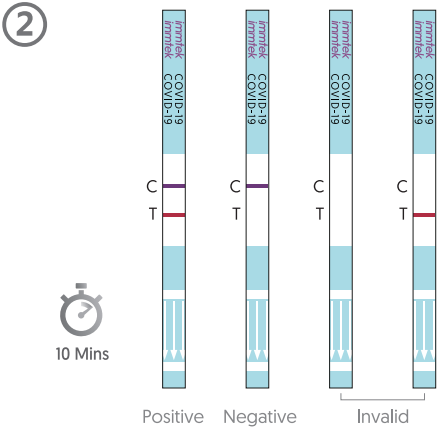
1



10 Mins

Keep **Test Strip** (with arrow pointing down) in the tube for 10 minutes.

2



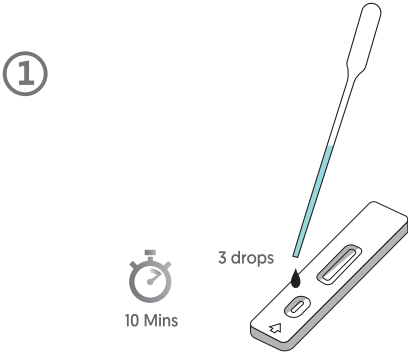
10 Mins

Positive Negative Invalid

Read result at 10 minutes. Some positive results may appear sooner. Results measured after 10 minutes are invalid.

Test Procedure Cassette

1

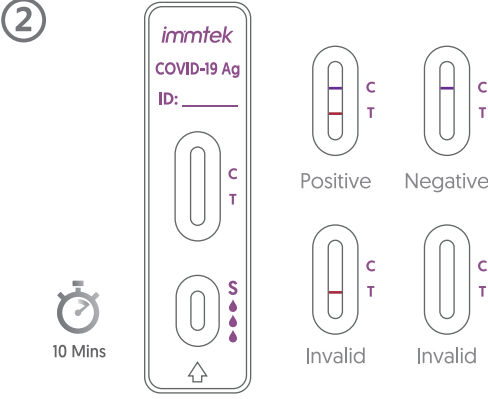


3 drops

10 Mins

Use **Dropper** to dispense 3 drops of extracted specimen into the sample well of **Test Cassette**.

2



10 Mins

Positive Negative Invalid Invalid

Read result at 10 minutes. Some positive results may appear sooner. Results measured after 10 minutes are invalid.

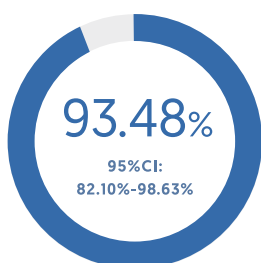
Performance

High Sensitivity and Specificity compared to RT-PCR

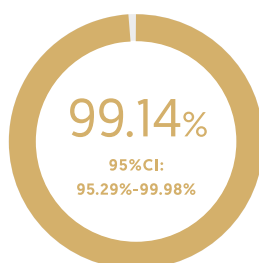
A total of 162 nasopharyngeal swab specimens collected from 148 symptomatic patients were tested using Immtek™ COVID-19 Antigen Rapid Test. The clinical performance was compared to a FDA EUA molecular assay [RT-PCR].

N=162		RT-PCR	
		Positive	Negative
ImmTek™ COVID-19 Antigen Rapid Test	Positive	43	1
	Negative	3	115

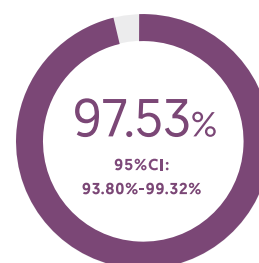
Sensitivity



Specificity



Accuracy



Low Limit of Detection (LoD)

The study was performed by testing a 2 fold dilution series of 3 replicates per concentration, and then the final LoD was determined to be the lowest detectable concentration at which at least 95% replicates are positive.

No.	Type	Strain	Limit of Detection	Result
1	Inactivated SARS-CoV-2 gamma-irradiated	USA-WA1/2020	3.13x10 ² TCID ₅₀ /ml	Positive 20/20
2	SARS-CoV-2 recombinant nucleocapsid protein		30 ng/ml	Positive 20/20

No Cross-reactivity

There was no cross-reactivity with the following bacteria and viruses tested.

Bacteria panel		Virus panel	
<i>Bordetella pertussis</i>	<i>Mycoplasma pneumoniae</i>	Adeno virus type 7	Human parainfluenza virus (HPIV)
<i>Candida albicans</i>	<i>Pseudomonas aeruginosa</i>	Adeno virus type 41	Influenza A-H1N1
<i>Chlamydia pneumoniae</i>	<i>Staphylococcus aureus</i>	Enterovirus type 68	Influenza A-H3N2
<i>Escherichia coli</i>	<i>Staphylococcus epidermidis</i>	Enterovirus type 71	Influenza B-Vic
<i>Haemophilus influenzae</i>	<i>Streptococcus pneumoniae</i>	Human coronavirus 229E	Influenza B-Yam
<i>Legionella pneumophilla</i>	<i>Streptococcus pyogenes</i>	Human coronavirus NL63	Respiratory syncytial virus
		Human coronavirus OC43	Rhinovirus
		hMPV 3 type B1	

Not Affected by Interfering Substances

There was no interference from Endogenous/Exogenous interfering substances listed below.

Interference substances	Concentration
Afrin [Oxymetazoline]	15% v/v
Aspirin	20 mg/ml
Chloraseptic [Menthol/Benzocaine]	1.5 mg/ml
CVS Nasal Drops [Phenylephrine]	15% v/v
CVS Saline Nasal Spray	15% v/v
Dextromethorphan	10 mg/ml
Diphenhydramine HCl	5 mg/ml
Fisherman's Friend	1.5 mg/ml
Hemoglobin	20 mg/ml
Homeopathic [Alkalol]	1:10 dilution
Hosoon Troches [ROOT]	20 mg/ml
Ibuprofen	20 mg/ml
Mucin	0.50%
Mupirocin	10 mg/ml
Nasal Ointment	10%

Interference substances	Concentration
Nasal Washing Salt	20 mg/ml
Naso GEL [NeilMed]	5% v/v
Nasal Gel [Oxymetazoline]	10% v/v
NASONEX Aqueous Nasal Spray	10%
Oxymetazoline HCl	10 mg/ml
Phenylephrine HCl	100 mg/ml
Ponstan	20 mg/ml
Ricola [Menthol]	1.5 mg/ml
Sore Throat Phenol Spray	15% v/v
Swinin nasal sprays	10%
Tamiflu [Oseltamivir Phosphate]	5 mg/ml
Tobramycin	4 µg/ml
Whole Blood	4%
Zicam	5% v/v

Reference:

1. Z. Hu, C. Song, C. Xu, et al. Clinical characteristics of 24 asymptomatic infections with COVID-19 screened among close contacts in Nanjing, China. *Sci China Life Sci.* 2020; 63(5): 706-711.
2. How to Protect Yourself & Others. Centers for Disease Control and Prevention [CDC]. 8 April 2020. Archived from the original on 26 February 2020. Retrieved 9 April 2020.
3. L. Liu, W. Liu, Y. Zheng, et al. A preliminary study on serological assay for severe acute 2 respiratory syndrome coronavirus 2 [SARS-CoV-2] in 238 admitted hospital patients. *Microbes and Infection.* 8 March 2020.
4. B. Aylward, W. Liang, et al. Report of the WHO-China Joint Mission on Coronavirus Disease 2019 [COVID-19]. 16-24 February 2020.

For more information and assistance, please contact us
or your local sales representative.
We are with you to combat COVID-19 together
in these challenging times!



No Cross

There was no c

Bacteria panel

- Bordetella pertussis*
- Candida albicans*
- Chlamydia pneumoniae*
- Escherichia coli*
- Haemophilus influenzae*
- Legionella pneumophila*

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