



COVID-19 IgG / IgM Test Kits

SARS-CoV2 Screening Kit

15 MINUTES DETECTION TIME

Certification Completion:



Marketed by:

SANSUI Electronics Pvt. Ltd.

Humasis Co. Ltd., South Korea | Copyright

Global Corona Virus Testing in Progress

everyone needs a rapid test
for nCoV antibodies in world

**currently one test kit at
very reasonable price.**



**World Health
Organization**

WHO urges world to 'test, test, test' for COVID-19

15 MINUTES DETECTION TIME

- Rapid test for nCoV antibodies in 15 minutes.
- Available for whole blood, serum or plasma.
- No additional equipment needed.
- RT-PCR & ICG method to detect the presence of the coronavirus

**very cost-effective solution for
SARS-CoV2 testing**

Approved Certifications:



US Food and Drug Administration



European CE certified



GMP –Korea Food & Drug Administration



ISO by TÜV Rheinland



Indian Council of Medical Research



Drugs Controller General of India



Screening method



Concerned
Citizens



Screening with
Humasis Kit



IgG / IgM Test
conducted



Results in
15 Minutes

RT-PCR & ICG method to detect
the presence of the corona virus

CE certified

FDA approved

Detection Period

15 MINUTES

- No special equipment required.
- Works with whole blood, serum, and plasma
- Tests for 2 antibodies IgM and IgG simultaneously
- Instant field screening

92% + ACCURACY

Step.1
Drop of whole blood, plasma, serum



Step.1
Immediately or in 10 sec. drops of buffer



Step.1
Wait for only 15 minutes and read result



NEGATIVE
Indicating not infected



POSTIIVE
Indicating infected



INVALID
Test did not work





authorized
for exports
of COVID-19
test kits.

Approval
from



Drugs
Controller
General of
India

(Important!!!!) COVID-19 test kits currently authorized for exports (Contact List)

2020-03-31

COVID-19 test kits currently authorized for exports (As of 30 March 2020)

NO	Company Name	Test Name	Test Type	Contact No.
20	Gencurix	GenePro COVID-19 Detection TEST	RT-PCR	070-7443-9523
21	GenBody	GenBody COVID-19 IgM/IgG	Immunoglobulin	<u>041-523-8990</u>
22	Humasis	Humasis COVID-19 IgG/IgM Test	Immunoglobulin	<u>031-478-8556</u>
23	DowGene	Dow QuickFinder™ 2019-nCoV Real time PCR	RT-PCR	1566-3313

List

SARS-CoV-2 diagnostic X + v

https://www.finddx.org/covid-19/pip

FIND Because diagnosis matters

COVID-19 WHO WE ARE WHAT WE DO NEWSROOM PARTNERS & DONORS CALL 5 FOR PARTNERS

- [Guangzhou Wondfo Biotech Co., Ltd](#) Wondfo SARS-CoV-2 Nucleic Acid Detection Kit (RUO) [Contact](#)
- [Hangzhou AllTest Biotech Co., Ltd](#) 2019-nCoV IgG/IgM Rapid Test Cassette (CE-IVD) [Contact](#)
- [Hangzhou Bigfish Bio-tech Co., Ltd](#) The golden standard of SARS-CoV-2 viral nucleic acid detection (in development) [Contact](#)
- [Hangzhou Bigfish Bio-tech Co., Ltd](#) LAMP kit for qualitative detection of SARS-CoV-2 (in development) [Contact](#)
- [Hangzhou Biotest Biotech Co., Ltd](#) COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) (CE-IVD) [Contact](#)
- [Hangzhou Clongene Biotech Co., Ltd](#) 2019-nCoV IgG/IgM Rapid Test (CE-IVD) [Contact](#)
- [Hangzhou Dan Wei Biotechnology Co.Ltd](#) 2019-nCoV Direct RT-qPCR Kit (in development) [Contact](#)
- [Hangzhou Laihe Biotech Co., Ltd](#) LYHER Novel Coronavirus(2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) (Australia TGA - CE-IVD) [Contact](#)
- [Hangzhou Matrix Biotechnology Co., Ltd](#) 2019-nCov Rapid Test Kit (RUO) [Contact](#)
- [Hangzhou Matrix Biotechnology Co., Ltd](#) 2019-nCov Rapid Test Kit (RUO) [Contact](#)
- [Hangzhou Really Tech Co., Ltd](#) 2019-nCoV LgG/LgM Rapid Test Device (CE-IVD) [Contact](#)
- [Hangzhou Testsea Biotechnology Co., Ltd](#) New Coronavirus COVID-19 Nucleic Acid Detection Kit (Fluorescent PCR Method) (RUO) [Contact](#)
- [Hecin Scientific, Inc.](#) COVID-19 IgM Antibody Rapid Test Kit (China FDA - CE-IVD) [Contact](#)
- [Hibergene](#) Hibergene (lab-based or near-POC) (In development)
- [Hologic Panther Fusion SARS-CoV-2 assay](#) (US FDA-EUA)
- [Humasis](#) Humasis COVID-19 IgG/IgM Test (Korea MFDS - CE-IVD) [Contact](#)
- [Hunan Lituo Biotechnology Co., Ltd](#) COVID-19 IgG/IgM Detection Kit (Colloidal Gold) (CE-IVD) [Contact](#)
- [Hunan Yonghe-Sun Biotechnology Co., Ltd](#) SARS-COV-2 specific antibody test kit (Immunochromatography) (RUO) [Contact](#)
- [Huwei Lifesciences Pvt. Ltd.](#) Quantipius CORONA Virus (2019nCoV) detection kit (in development) [Contact](#)
- [ICBFM](#) LAMP kit for qualitative detection of SARS-CoV-2 (RUO) [Contact](#)
- [InBios International, Inc.](#) InBios International Smart Detect SARS-CoV-2 rRT-PCR Kit (RUO) [Contact](#)
- [InDevR Inc.](#) COVID Serology Kit: Multiplexed Immunoassay (in development) [Contact](#)
- [Innovita \(Tangshan\) Biological Technology Co., Ltd](#) Novel Coronavirus (2019-nCoV) Nucleic Acid Test Kit (Multiple Fluorescence PCR) (RUO) [Contact](#)
- [Innovita Biological Technology Co. Ltd](#) 2019-nCoV Ab Test (Colloidal Gold) (IgM/IgG Whole Blood/Serum/Plasma Combo) (CE-IVD) [Contact](#)
- [Intavis Peptide Services GmbH & Co. KG](#) Covid19-hullB CelluSpot™ Array (RUO) [Contact](#)
- [Intavis Peptide Services GmbH & Co. KG](#) Covid19-hullS CelluSpot™ Array (RUO) [Contact](#)
- [InTec Products, Inc.](#) Rapid SARS-CoV-2 Antibody (IgM/IgG) (CE-IVD) [Contact 1](#) [Contact 2](#)
- [InTec Products, Inc.](#) Rapid SARS-CoV-2 Antibody Test (CE-IVD) [Contact 1](#) [Contact 2](#)
- [Intrasense SA](#) Myrian Covid-19 (China FDA-EUA - US FDA-EUA - CE-IVD) [PDF 2pg flyer](#) [Contact](#)

Humasis

Authorized & EU approved and listed on Finddx.org under WHO commercial production section

Approved from



Indian Council of Medical Research

Clinical Report Summary

Humasis COVID-19 IgG/IgM vs RT-PCR

- The left side table is comparison of testing method on the same subject 81 patients.
- Positive = 49 and Negative = 32
- The left table - method of confirmation is RT-PCR and Lung CT
- The right table - using Humasis COVID-19 test kit.
- It shows that Humasis give the same result with using RT-PCR and Lung CT.
- IgM is antibody which will release after infected with COVID-19 after 4th day.
- IgG is antibody which will release after 1 week and more as the day passed by.
- High clinical sensitivity over 90% on average for positive time more than 4 days is calculation from test positive of IgG from more than 4 days = $(13 + 9) / 24 = 91.66\%$
- 13 = test positive on 4-7 days
9 = test positive > 8 days
24 = total positive patient of both period
- 100% for Negative patient, 32/32

Confirmatory Method (RT-PCR + Lung CT)	Positive	Positive Time (Day)	No. of Specimen	Test Result			
				IgM		IgG	
				+ve	-ve	+ve	-ve
		1~3	25	4	21	4	21
		4~7	14	12	2	13	1
		>8	10	9	1	9	1
	Negative		32	0	32	0	32

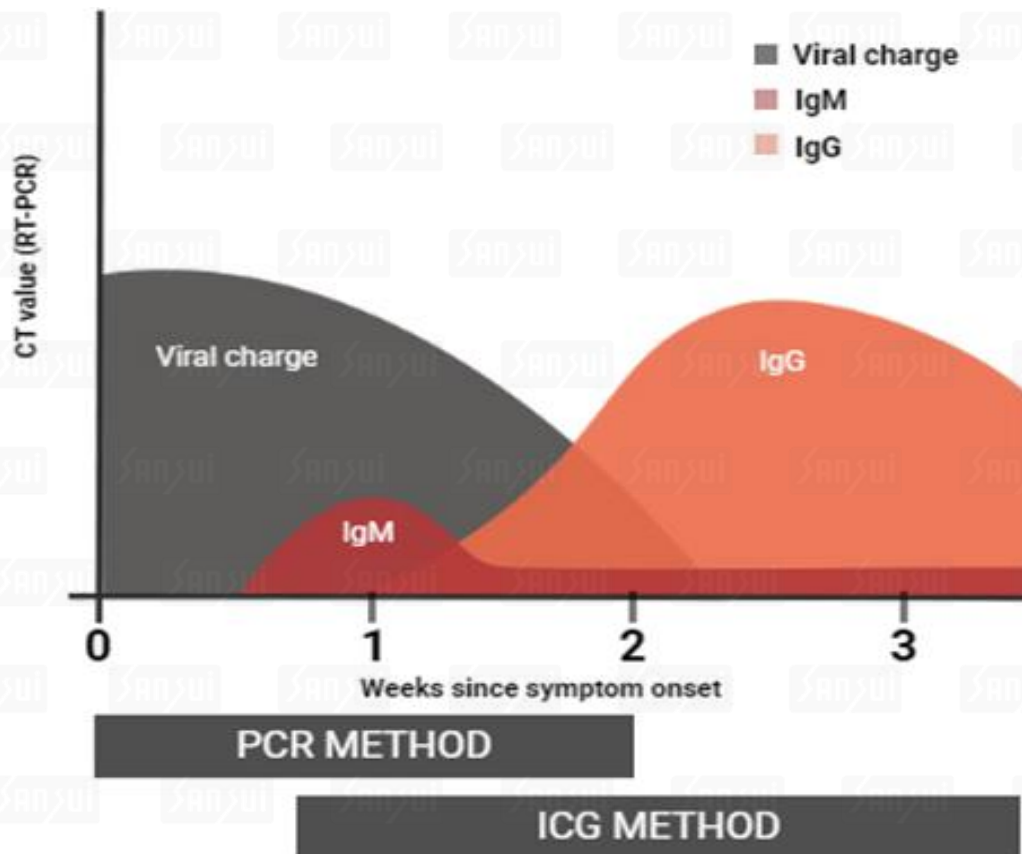
Clinical sensitivity	Positive Time (Day)	IgM	IgG
	1~3	16% (4/25) 95% CI 0.06 - 0.347	16% (4/25) 95% CI 0.06 - 0.34
	4~7	85.7% (12/14) 95% CI 0.06 - 0.96	92.8% (13/14) 95% CI 0.68 - 0.98
	>8	90% (9/10) 95% CI 0.59 - 0.98	90% (9/10) 95% CI 0.59 - 0.98
Clinical Specificity		100% (32/32) 95% CI 0.89 - 1.00	100% (32/32) 95% CI 0.89 - 1.00

- Positive specimen : Collected from COVID-19 positive patients confirmed by Rt-PCR and lung-CT.
- Negative specimen : Collected from COVID-19 negative patients confirmed by RT-PCR
- Total subjects : 81 (49 positive subjects, 32 negative subjects)

Result:

- Humasis COVID-19 IgG/IgM Test showed high clinical sensitivity over 90% on average for positive time than more 4 days.
- Clinical specificity showed 100% for negative patients.

It is widely accepted that IgM provides the first line of defence during viral infections, followed by the generation of adaptive, high affinity IgG responses for long term immunity and immunological memory. Therefore, testing of COVID-19 IgM and IgG antibodies is an effective method for the rapid diagnosis of COVID-19 infection. Furthermore, detection of COVID-19 IgM antibodies tends to indicate a recent exposure to COVID-19, whereas detection of COVID-19 IgG antibodies indicates a later stage of infection. Thus, this combined antibody test could also provide information on the stage of infection.



Diagnostic Analysis

Humasis COVID-19 IgG / IgM Test was evaluated in a clinical study carried out at the Sun Yat-Sen University Hospital for the validation of sensitivity and specificity. The test showed high clinical sensitivity above 90% on average, for a positive time for more than 4 days. Clinical specificity showed 100% for negative patients.

Humasis COVID-19 IgM/IgG Diagnostic Testing Comparison with Other Brand

	Humasis COVID-19 IgM/IgG Test	OTHER COVID-19 IgM/IgG Test
Method	Immunochromatographic Assay	Immunochromatographic Assay
Test Type	Cassette	Cassette
Sample Type	Whole blood, Serum or Plasma	Whole blood, Serum or Plasma
Sample Size	10 uL	5 uL
Test Time	15 min	10 min
Storage	2 –30 C	2 –30 C
Shelf-Life	6 months (shelf-life will be extended soon)	--
Kit Components	Test Device, Diluent buffer 10 uL of capillary tube, Instruction manual	--
Sensitivity	Day 4 –7: IgM 85.7%, IgG 92.8% After Day 8: IgM 90% , IgG 90%	Day 3 after symptom: IgM 30%, IgG 0% After day 7: IgM 80%, IgG >95%
Specificity	IgM 100% (32/32) IgG 100% (32/32)	IgM 98% (118/120) IgG 99% (119/120)
No of Tests Per Box	25 Tests	20 Tests

TECHNICAL COMPARISON

2019-nCoV
IVD Solution

Kit Details

Brand

Humasis Production Capacity

750,000 Kits per day

CE & FDA Certified Facility

Composition

- Test Diluent
- Instruction for use
- Capillary tube 10 μ l

Content

- Gross weight : 23kg / carton
- Dimension : (620 x 540 x 480) mm
- Validity : 6 months

Pricing

Per Kit Costs

Price on request.

One Kit + GST@12%

100% Advance Payment.

MOQ

Min. 10,000 kits

1 Box = 25 tests kits

1 Carton = 102 Box

ETA

15 days **Approximate
time excluding clearance
delays if any*

About

Humasis



➤ Humasis Co. Ltd, is authorized by WHO since last 20 years.



➤ EU certification for influenza, SARS-COV-1, Malaria & recent SARS-COV-2.



➤ Listed under WHO on Finddx.org in commercial production section.



➤ Approved under Food and Drug Administration of the United States.



➤ Register under GMP – Korea Food & Drug Administration.



➤ ISO certified company by TÜV Rheinland.



➤ Authorized for exports of COVID-19 test kits in approx. 23+ countries.



➤ Certified under guideline of ICMR - Indian Council of Medical Research.



➤ Approval from DCGI - Drugs Controller General of India.

Marketed by:

Sansui Electronics Pvt. Ltd.

CONTACT US

+91-7767-900-040

management@Sansui.co.in

www.SansuiScales.com



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