Humasis Co. Ltd.

COVID-19 IgG / IgM Test Kits

SARS-CoV2 Screening Kit

15 MINUTES DETECTION TIME

Certification Completion:

FDA · CE · GMP · TÜV SÜD ISO 13485:2003 · icmr INDIAN COUNCIL OF MEDICAL RESEARCH · DCGI DRUG CONTROLLER GENERAL OF INDIA

Marketed by:

Sansui Electronics Pvt. Ltd.

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

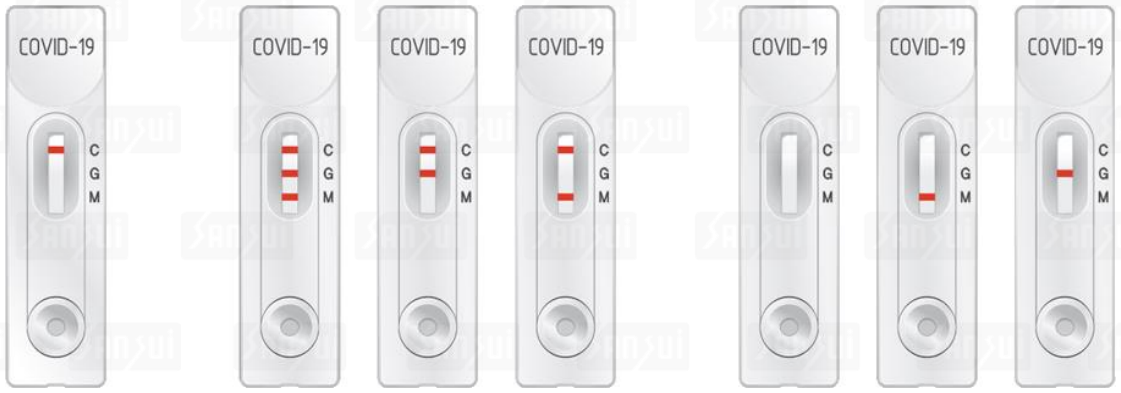
Step.1
Immediately or in 10 sec. drops of buffer

Step.1
Wait for only 15 minutes and read result

NEGATIVE
Indicating not infected

POSTIIVE
Indicating infected

INVALID
Test did not work



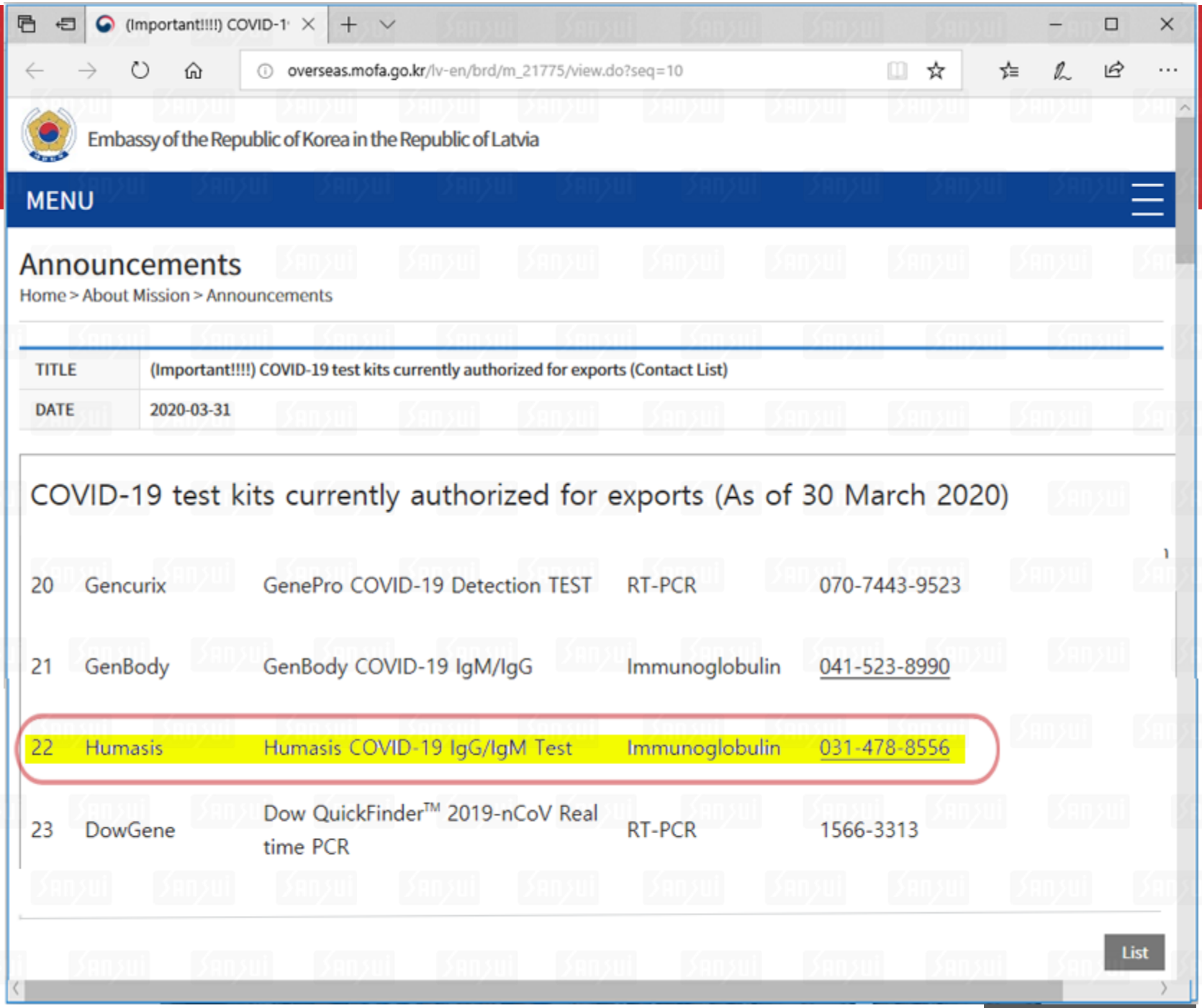
Humasis

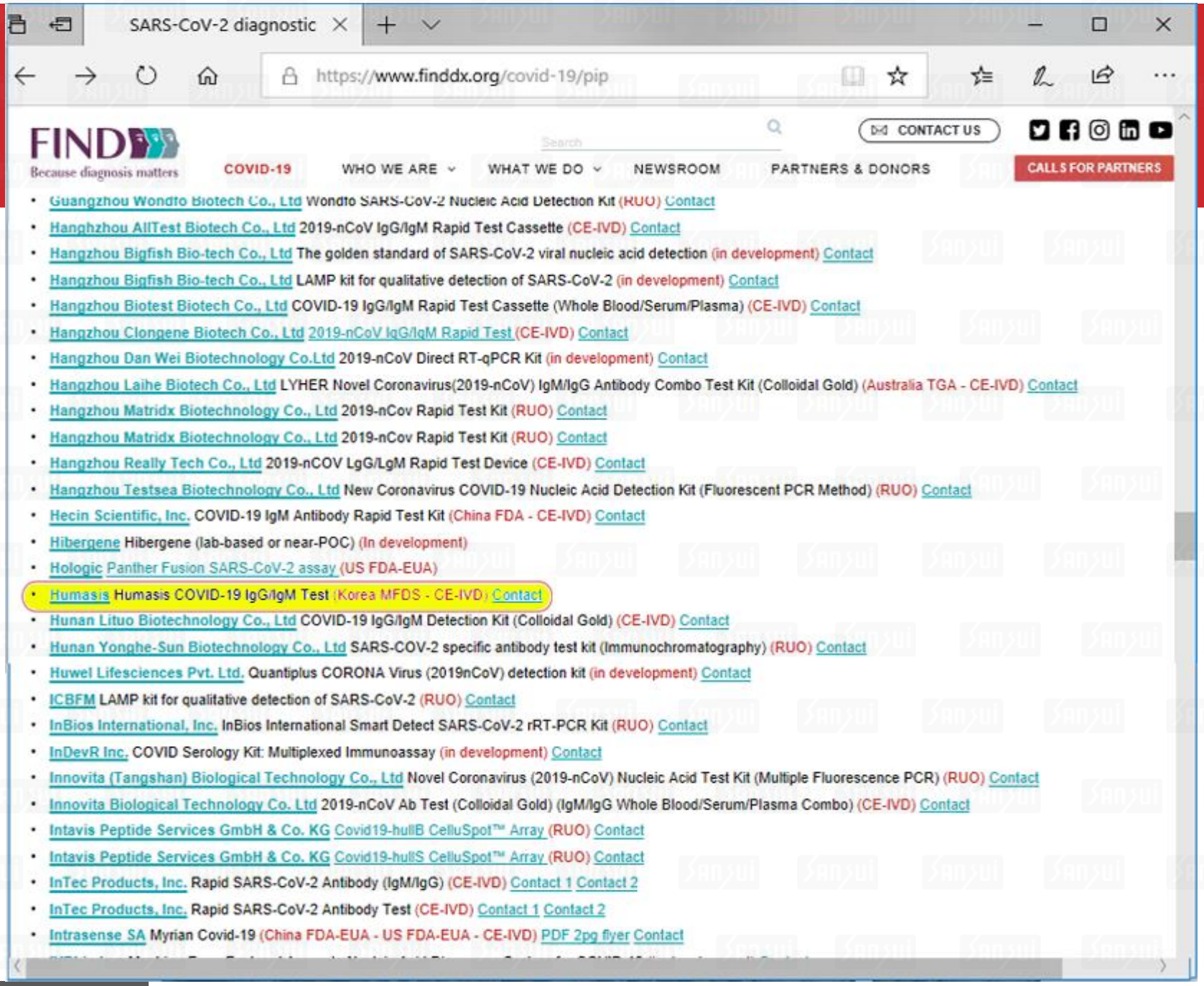
authorized for exports of COVID-19 test kits.

Approval from

DCGI
DRUG CONTROLLER GENERAL OF INDIA

Drugs Controller General of India





Humasis

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

Approved from

ICMR
INDIAN COUNCIL OF MEDICAL RESEARCH
Serving the nation since 1911

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 Time (Day)	No. of Specimen	Test Result			
				IgM		IgG	
				+ve	-ve	+ve	-ve
	Positive	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

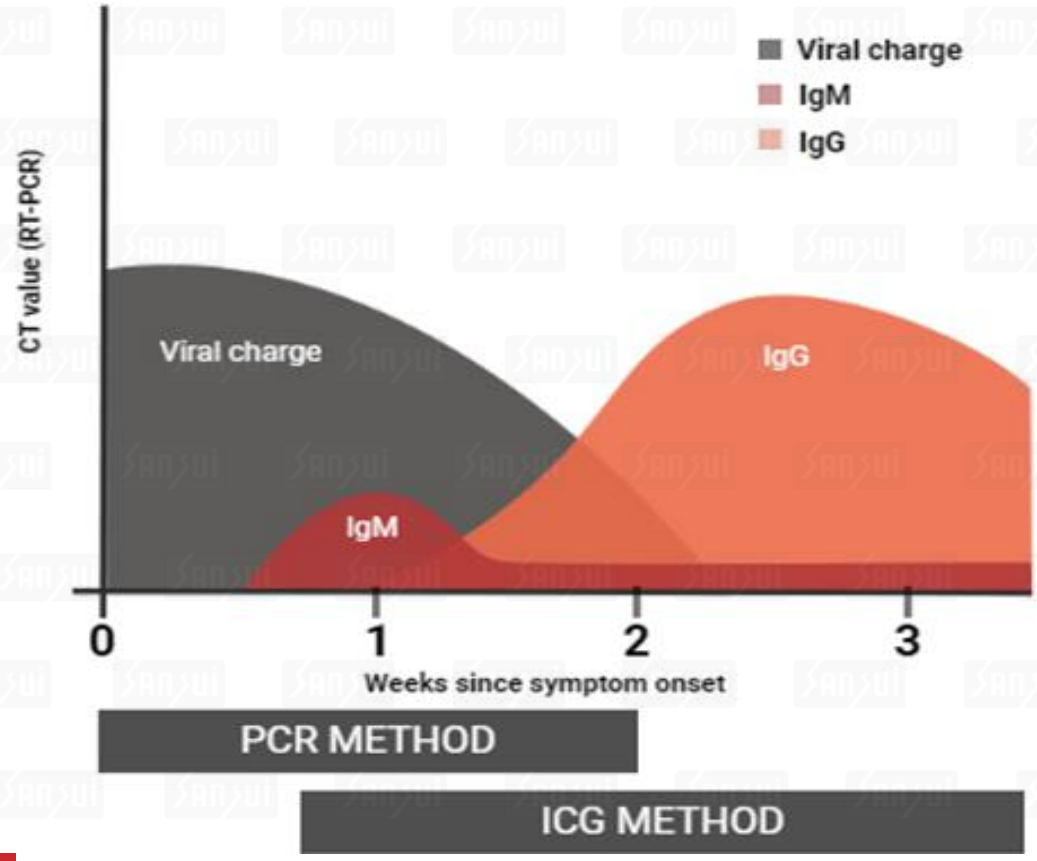
Clinical sensitivity	Positive Time (Day)	IgM	IgG
	1~3	16% (4/25) 95% CI 0.06 - 0.347	16% (4/25) 95% CI 0.06 - 0.34
	4~7	85.7% (12/14) 95% CI 0.06 - 0.96	92.8% (13/14) 95% CI 0.68 - 0.98
	>8	90% (9/10) 95% CI 0.59 - 0.98	90% (9/10) 95% CI 0.59 - 0.98
Clinical Specificity		100% (32/32) 95% CI 0.89 - 1.00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

- Positive specimen : Collected from COVI1 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

TECHNICAL COMPARISON

2019-nCOV
IVD Solution

	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

Kit Details

Brand

Humasis Production Capacity

750,000 Kits per day

CE & FDA Certified Facility

Composition

- Test Diluent
- Instruction for use
- Capillary tube 10 µl

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

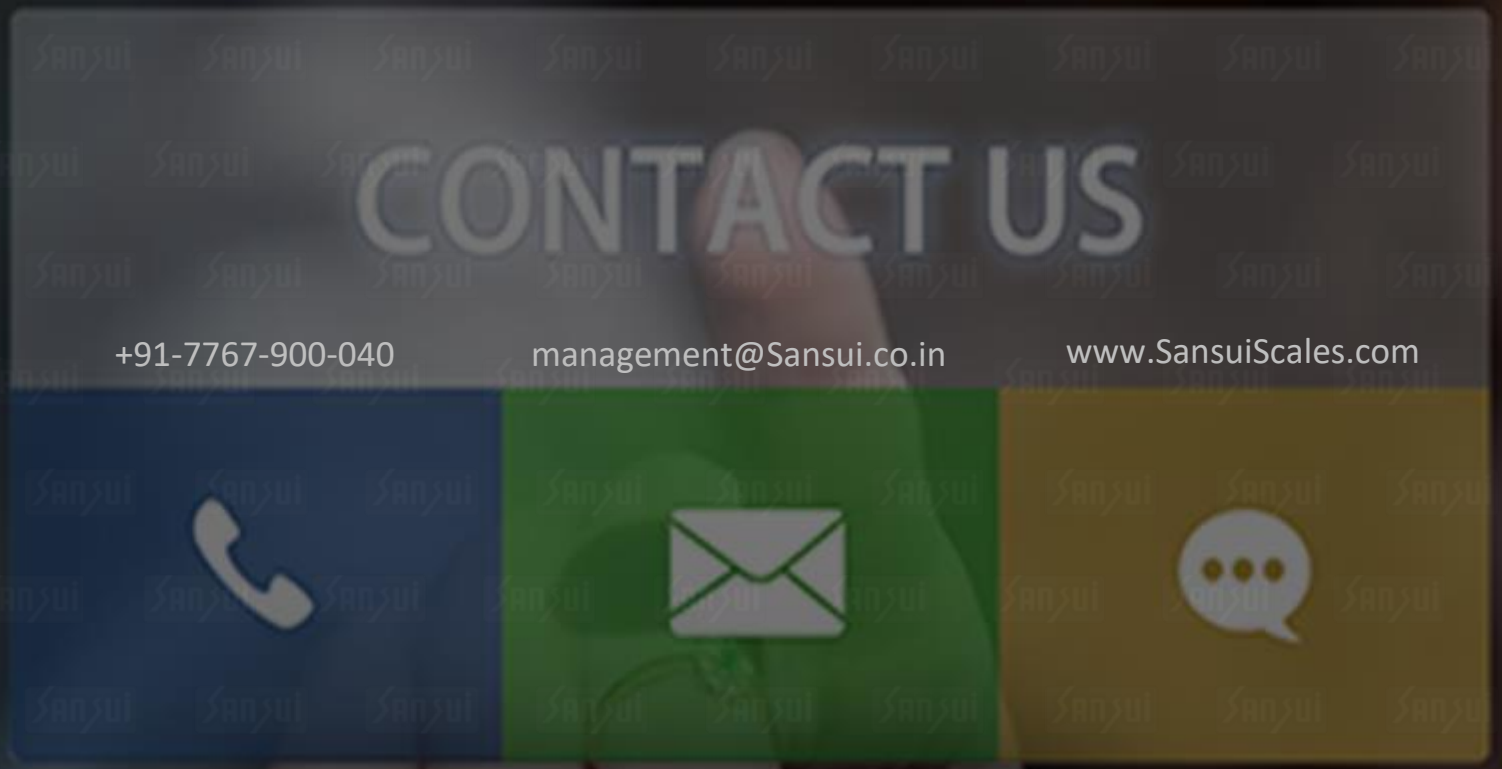
delays if any

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.



Humasis Co. Ltd.