COVID-19 Antibody Test

- ☑ IgM/IgG Antibody Test
- ☑ 15 minutes Fast Testing
- ☑ Individual Home-Testing

Sensitivity: >95%

Specificity: >99%

- Data compared to RT-PCR confirmed cases results.
- Third Party University Clinical Reports.
- COVID-19 Designated Hospitals Reports.

Also available to: CE-IVD / Philippine-FDA
ANVISA / Chile ISP Listed.

WhatsApp:+86-571-87763175 | Web: reOpenTest.com

Contact: sales@reopentest.com

reOpenTest

Leading In-Vitro Diagnostic Testing.

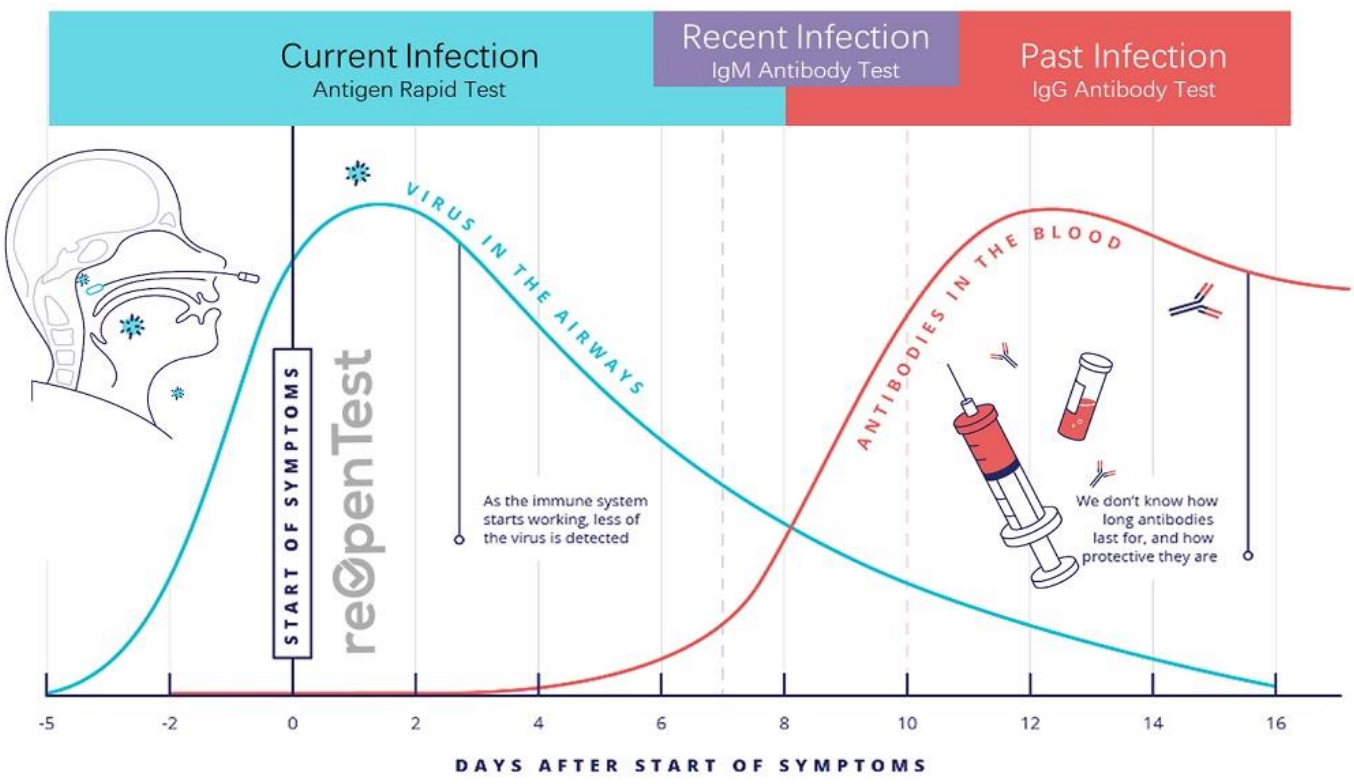
reOpenTest vs EUA Approved

SARS-CoV-2 IgM/IgG Antibody Test

reOpenTest vs EUA Approved brand

Brand	Method	Sensitivity	Specificity	Data From
Cellex (EUA)	Lateral Flow Immunofluorescent	96.8%	97.8%	IFU
Roche (EUA)	Lateral Flow Immunofluorescent	76.9%	99.8%	IFU
Healgen (EUA)	Lateral Flow Immunofluorescent	96.7%	97.0%	IFU
reOpenTest *	Lateral Flow Immunofluorescent	94.5%	99.3%	IFU/Hospital Clinic Data / China(n=453)
		95.9%	97.8%	Hospital Clinic Data / Greece(n=120)
LUNGENE (Non-EUA)	Lateral Flow Immunofluorescent	87%	98.9%	IFU

* with ANVISA, CE-IVD, Chile Whitelist.



All EUA Brands Data can be referred by FDA Referance:
https://tinyurl.com/y8utovjj
(Brands IFU included)

reOpenTest

What is the purpose of testing for COVID-19?

		Viral Test	Selorogy Test					
Group		**RT-PCR Antigen Test**	**Antibody Test**		**Person Quarantine Days**			**Risk**
			IgM	**IgG**	**Early(1-3days)**	**Middle(3-14days)**	**Later(14+days)**	
With Symptoms	reOpenTest	Postive	Postive	Postive	✕ Active Infection			High+
		Postive	Negative	Negative	✕ Active Infection			High+
		Postive	Negative	Postive	✕ Active Infection			High+
		Negative	Postive	Postive	Re-Test-Viral	✕ Active Infection	Re-Test-Viral	High-
		Negative	Negative	Postive	N/A	Current Infection / Quarantine & Re-Test-Viral!		Middle
		Negative	Negative	Negative	Quarantine & Re-Test-Viral!			Middle
Without Symptoms, But At High Risk Of Exposure		Positive	Positive	Postive	✕ Active Infection			High+
		Positive	Negative	Postive	✕ Active Infection			High+
		Negative	Negative	Postive	⚠ Past Infection / Quarantine to confirm		✔ Past Infection-Safe	Low+
		Negative	Negative	Negative	Quarantine		⚠ Safe	Middle
Surveillance		Negative	Positive	Positive	Re-Test-Viral	✕ Active Infection		High-
		Negative	Negative	Positive	N/A	✔ Past Infection - Safe		Low
		Negative	Negative	Negative	No past infection			Low

reOpenTest™

Carton Information

Professional	Home Pack / OTC
■ 25 Test / Box	■ 1 Test / Box
■ Box: 260*120*65 mm	■ Box: 135*80*20 mm
■ Carton: 64*34*55 cm	■ Carton: 42*42*42 cm
■ 1250 pcs/ctn	■ 300 pcs/ctn
■ GW:15kg	■ GW:4.5kg
■ Materials:	■ Materials:
• Cassettes x25	• Cassette x1
• Droppers x25	• Dropper x1
• Lancets x25	• Lancet x1
• Pads x25	• Pad x1
• Buffer x25	• Reagent Solution x1
• Package Insert x1	• Package Insert x1

ATTACHED LIST

- Manufacturer Declaration – Antibody Test
- CE / NQA
- Clinical Report / For SARS-CoV-2 IgM/IgG Antibody Test
  @ATTIKON University General Hospital, Athens, Greece.

JOINSTAR

Manufacturer Declaration

10th, July 2020
Subject: Declaration of equivalence

To whom it may concern,

We undersigned, **JOINSTAR BIOMEDICAL TECHNOLOGY CO., LTD.**, an IVD manufacturer having its headquarters in *NO.519 XingGuo RD. Yuhang Economic and Technological Development Zone Hangzhou Zhejiang China*, here declare that the below products are both manufactured by us, and share the same design and specifications.

- Original: **Teste Rápido COVID-19**
  CE-IVD, ANVISA Registration Number: 80533420081
  ANVISA Link: *https://consultas.anvisa.gov.br/#/saude/25351474984202064/*
  *Chile ISP Listed Reference Link:
  https://www.minsal.cl/wp-content/uploads/2020/07/ListaTestRapidos16_07_2020.pdf

- Product: **SARS-CoV-2 IgM/IgG Antibody Test (Colloidal Gold)**
  CE-IVD / France Registration / AGEMED
  SARS-France Registration Link:
  https://covid-19.sante.gouv.fr/tests#8121496c-e073-414e-b745-704de9434655
  AGEMED Reference Link:
  https://agemed.gob.bo/#autorizacioncomercializacion/contenido

- Product: **SARS-CoV-2 IgM/IgG Antibody Test (Colloidal Gold)**
  CE-IVD
  Brand: reOpenTest
  Product Link: *https://www.reopentest.com/*
  ** the "reOpenTest" brand is fully owned by HANGZHOU FENHE TECHNOLOGY CO., LTD.

Yours sincerely,

CEO

Certificate of Registration

This is to certify that the Quality Management System of

Joinstar Biomedical Technology Co., Ltd.

Unified Social Credit Code： 913301005660614000

Operation Address : No.1 Factory Building, 4th Floor No.2 Factory Building, No.519, Xingguo Rd., Yuhang Economic and Technological Development Zone, Hangzhou City, Zhejiang Province, China

Registered Address : 10th Floor, Administration Building, No.519, Xingguo Rd., Yuhang Economic and Technological Development Zone, Hangzhou City, Zhejiang Province, China

applicable to

Design, Development, Production and Sales of SARS-CoV-2 IgM/IgG Antibody Test(Colloidal Gold)(Export to EU)

has been assessed and registered by NQA against the provisions of

ISO 13485: 2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

SNQA's website : www.snqa.com.cn

Managing Director

Certificate Number **47803**

Date: 06 July 2020

Valid Until: 06 July 2023

EAC Code: 13

UKAS MANAGEMENT SYSTEMS 015

ΕΛΛΗΝΙΚΟ ΙΝΣΤΙΤΟΥΤΟ ΜΕΛΕΤΗΣ ΤΗΣ ΣΗΨΗΣ
HELLENIC INSTITUTE FOR THE STUDY OF SEPSIS

Joinstar Biomedical Technology Co. Ltd
10th Floor, Comprehensive Building, No.519,
Xingguo Road,
Yuhang Economic and Technological Development Zone,
Hangzhou

Athens, July 1st 2020
No. 173

Dear Sirs,

PROGRESS REPORT

Please find attached the progress report for the conducted study "Clinical evaluation of the Joinstar SARS-CoV-2 IgM/IgG Antibody Test (Colloidal Gold)".

With best regards,

The President of the Board,

Evangelos J. Giamarellos-Bourboulis
Professor of Internal Medicine

The Secretary of the Board,

Kyriaki Kanellakopoulou
Professor of Internal Medicine

ΕΛΛΗΝΙΚΟ ΙΝΣΤΙΤΟΥΤΟ ΜΕΛΕΤΗΣ ΤΗΣ ΣΗΨΗΣ
HELLENIC INSTITUTE FOR THE STUDY OF SEPSIS
ΑΘΗΝΑ 2010

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88 MICHALAKOPOULOU STR., ATHENS 115 28
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Clinical evaluation of the Joinstar SARS-CoV-2 IgM/IgG Antibody Test (Colloidal Gold)

OBJECTIVE

To evaluate the Clinical performance of the Joinstar SARS-CoV-2 IgM/IgG Antibody Test (Colloidal Gold).

METHODOLOGY

This study was carried out using the JoinStar reader that is set at the central lab located at the Research Lab of Immunology of Infections of the 4th Department of Internal Medicine at ATTIKON University General Hospital, Athens, Greece.

The Clinical specificity was assessed by measuring antibody levels in 46 patients with non SARS-CoV-2 respiratory tract infections as confirmed by Film assay PCR. These samples (plasma EDTA) were collected between 2017-2018 and stored at -80^{0}C.

The Clinical sensitivity was assessed by measuring antibody levels in 74 patients with infection by SARS-CoV-2 (samples collected during the period March to May 2020 in 10 study sites of the Hellenic Sepsis Study Group). The diagnosis was confirmed by molecular detection of SARS-CoV-2 by RT-PCR using the material collected through one nasopharyngeal swab. Blood samples (plasma EDTA) for the antibody testing were drawn 7 days after hospital admission i.e. 8-23 days from start of symptoms of Covid-19.

All antibody testing was done on a single lot of reagents (Lot No COV 2005001G, Expiry 2021-05-07) in June 2020.

RESULTS

SARS-CoV-2 negative samples (n=46)

Patients code	Study cohort	Diagnosis by Film Array PCR	IgG	IgM
E006	PROMPT	Coronavirus OC43	Negative	Negative
E014	PROMPT	Human Rhinovirus/Enterovirus	Negative	Negative
E015	PROMPT	Human Rhinovirus/Enterovirus	Negative	Negative
E017	PROMPT	Human Rhinovirus/Enterovirus	Negative	Negative
E025	PROMPT	Human Rhinovirus/Enterovirus	Negative	Negative
E039	PROMPT	Human Rhinovirus/Enterovirus	Negative	Negative
E057	PROMPT	Coronavirus OC43	Negative	Negative
E066	PROMPT	Human Rhinovirus/Enterovirus	Negative	Negative
E072	PROMPT	Human Rhinovirus/Enterovirus	Negative	Negative
E073	PROMPT	Human Rhinovirus/Enterovirus	Negative	Negative
E079	PROMPT	Human Rhinovirus/Enterovirus	Negative	Negative
E092	PROMPT	Human Rhinovirus/Enterovirus	Negative	Negative
E096	PROMPT	Human Rhinovirus/Enterovirus	Negative	Negative
E097	PROMPT	Respiratory synsytia virus	Negative	Negative

E098	PROMPT	Coronavirus HKU1	Negative	Negative
E105	PROMPT	Human Rhinovirus/Enterovirus	Negative	Negative
E117	PROMPT	respiratory syncytial virus	Negative	Negative
E120	PROMPT	Coronavirus 229E	Negative	Negative
E146	PROMPT	Human Rhinovirus/Enterovirus	Negative	Negative
E152	PROMPT	Human Rhinovirus/Enterovirus	IgG+	Negative
E159	PROMPT	Human Rhinovirus/Enterovirus	Negative	Negative
E162	PROMPT	Adenovirus/human metapneumovirus	Negative	Negative
E163	PROMPT	Human Rhinovirus/Enterovirus	Negative	Negative
E167	PROMPT	Human Rhinovirus/Enterovirus	Negative	Negative
E175	PROMPT	Human Rinovirus/Enterovirus/Coronavirus 229E	Negative	Negative
E179	PROMPT	Human Rhinovirus/Enterovirus	Negative	Negative
E181	PROMPT	Coronavirus 229E	Negative	Negative
E183	PROMPT	Human Rhinovirus/Enterovirus	Negative	Negative
E187	PROMPT	Human Rhinovirus/Enterovirus	Negative	Negative
E198	PROMPT	Human metapneumovirus	Negative	Negative
E201	PROMPT	Coronovirus NL63	Negative	Negative
E206	PROMPT	Human Rhinovirus/Enterovirus	Negative	Negative
E209	PROMPT	Respiratory syncytial virus/ Human rhinovirus enterovirus	Negative	Negative
E211	PROMPT	Respiratory syncytial virus	Negative	Negative
E212	PROMPT	Human metapneumovirus	Negative	Negative
E213	PROMPT	Human metapneumovirus	Negative	Negative
E250	PROMPT	Coronavirus nl63	Negative	Negative
E256	PROMPT	Rhinovirus/ Enterovirus	Negative	Negative
E260	PROMPT	Human Rhinovirus/Enterovirus	Negative	Negative
E267	PROMPT	Human Rhinovirus/Enterovirus	Negative	Negative
E270	PROMPT	Adenovirus	Negative	Negative
E272	PROMPT	Human Rhinovirus/Enterovirus	Negative	Negative
E283	PROMPT	Respiratory syncytial virus	Negative	Negative
E288	PROMPT	Adenovirus/Human metapneumovirus	Negative	Negative
E289	PROMPT	Human Rhinovirus/Enterovirus	Negative	Negative
E299	PROMPT	Human Rhinovirus/Enterovirus	Negative	Negative
A14	PROMPT	Adenovirus	Negative	Negative

SARS-CoV-2 Positive samples (n=74)

Patient code	Study cohort	Diagnosis by nasal swab RT-PCR	IgG	IgM
ESC004	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC003	COVID-19	SARS-CoV-2	IgG +	
ESC005	COVID-19	SARS-CoV-2	Negative	Negative
ESC010	COVID-19	SARS-CoV-2	IgG +	
ESC006	COVID-19	SARS-CoV-2	IgG +	

ESC012	COVID-19	SARS-CoV-2	IgG +	
ESC009	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC008	COVID-19	SARS-CoV-2	IgG +	
ESC007	COVID-19	SARS-CoV-2	IgG +	
ESC014	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC017	COVID-19	SARS-CoV-2	IgG +	
ESC019	COVID-19	SARS-CoV-2	IgG +	
ESC039	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC041	COVID-19	SARS-CoV-2	IgG +	
ESC042	COVID-19	SARS-CoV-2	IgG +	
ESC043	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC046	COVID-19	SARS-CoV-2	IgG +	
ESC047	COVID-19	SARS-CoV-2	IgG +	
ESC045	COVID-19	SARS-CoV-2	IgG +	
ESC044	COVID-19	SARS-CoV-2	IgG +	
ESC051	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC049	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC053	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC056	COVID-19	SARS-CoV-2	IgG +	
ESC057	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC058	COVID-19	SARS-CoV-2	IgG +	
ESC059	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC061	COVID-19	SARS-CoV-2	IgG +	
ESC063	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC065	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC067	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC069	COVID-19	SARS-CoV-2	IgG +	
ESC070	COVID-19	SARS-CoV-2	IgG +	
ESC075	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC072	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC073	COVID-19	SARS-CoV-2	Negative	Negative
ESC071	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC076	COVID-19	SARS-CoV-2	IgG +	
ESC078	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC103	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC079	COVID-19	SARS-CoV-2	IgG +	
ESC080	COVID-19	SARS-CoV-2	IgG +	
ESC104	COVID-19	SARS-CoV-2	IgG +	
ESC107	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC109	COVID-19	SARS-CoV-2	IgG +	
ESC144	COVID-19	SARS-CoV-2	IgG +	
ESC111	COVID-19	SARS-CoV-2	IgG +	
ESC112	COVID-19	SARS-CoV-2	Negative	Negative
ESC113	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC115	COVID-19	SARS-CoV-2	IgG +	
ESC146	COVID-19	SARS-CoV-2	IgG +	

ESC147	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC116	COVID-19	SARS-CoV-2	IgG +	
ESC149	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC143	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC145	COVID-19	SARS-CoV-2	IgG +	
ESC152	COVID-19	SARS-CoV-2	IgG +	
ESC186	COVID-19	SARS-CoV-2	IgG +	
ESC171	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC113	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC188	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC213	COVID-19	SARS-CoV-2	IgG +	
ESC215	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC217	COVID-19	SARS-CoV-2	IgG +	
ESC232	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC240	COVID-19	SARS-CoV-2	IgG +	
ESC238	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC239	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC243	COVID-19	SARS-CoV-2	IgG +	
ESC244	COVID-19	SARS-CoV-2	IgG +	
ESC246	COVID-19	SARS-CoV-2	IgG +	
ESC248	COVID-19	SARS-CoV-2	IgG +	
ESC253	COVID-19	SARS-CoV-2	IgG +	IgM +
ESC254	COVID-19	SARS-CoV-2	IgG +	

PERFORMANCE SUMMARY

Covid 19 Negative group (n=46)

IgG positive = 1
IgM positive = 0
Overall Clinical Specificity = 97.8%

Covid 19 Positive group (n=74)

IgM only positive = 1
IgG only positive= 70
IgM/IgG positive = 71

Overall Clinical Sensitivity for IgM and/or IgG antibodies =95.9%

OVERALL SUMMARY

Using 120 clinically and microbiologically-defined patients with or without SARS-Cov-2 infection the Joinstar SARS-CoV-2 IgM/IgG Antibody Test (Colloidal Gold) gave an overall specificity of 97.8% and an overall sensitivity of 95.9%.