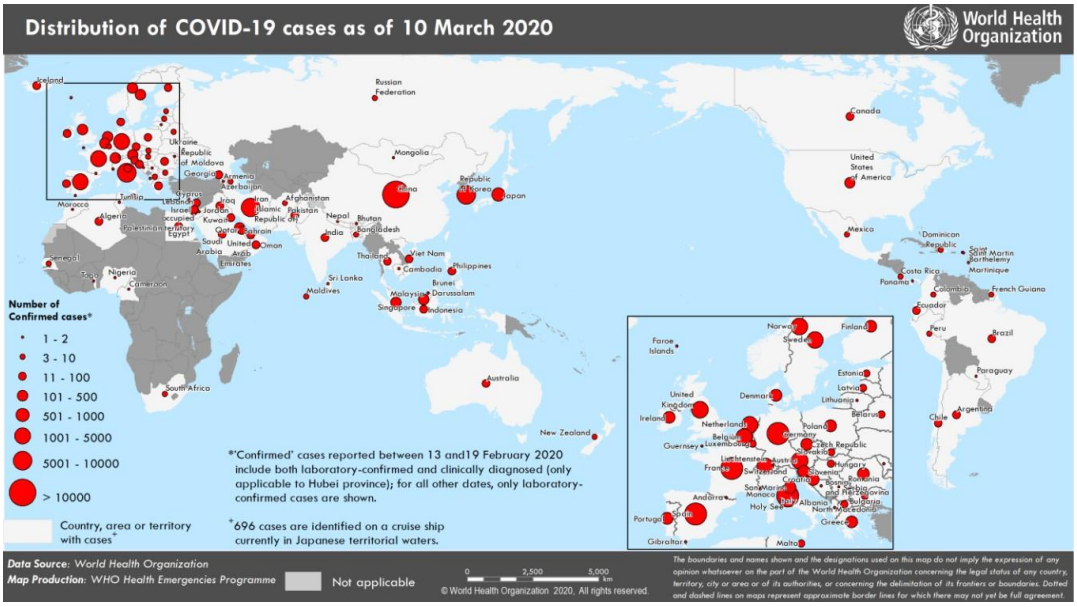
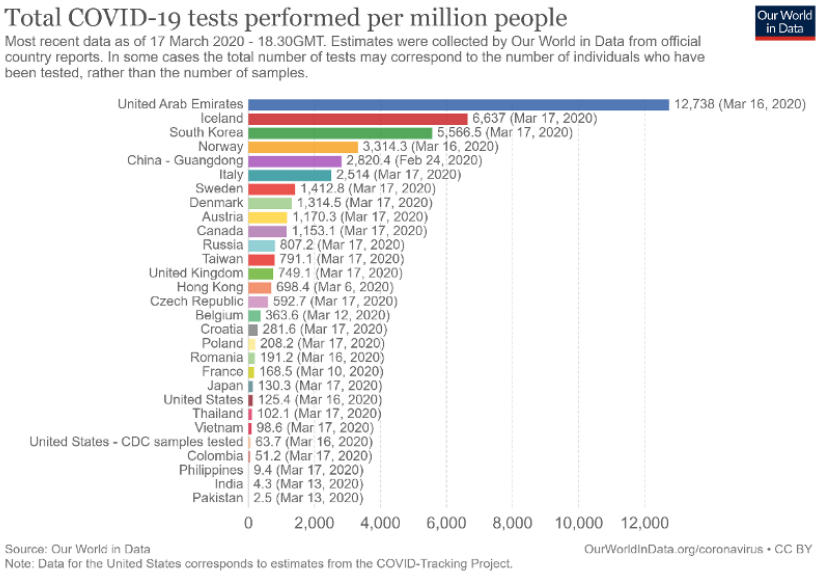
Diagnostic kit for anti-COVID-19 IGM / IGG Antibodies is now available



All protocols propose a standardized methodology to allow data and biological samples to be systematically collected, taking into consideration local setting and outbreak characteristics, and shared rapidly in a format that can be easily aggregated, tabulated and analyzed across many different settings globally.



COVID-19 Status by country

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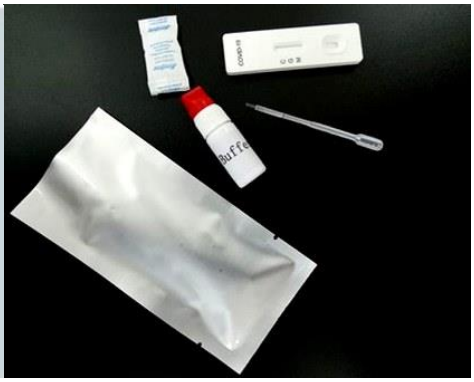
CIC Rotterdam (NL), Stationsplein 45, 4th Floor, 3013 AK Rotterdam, The Netherlands

COVID-19 IgG/IgM Rapid Test Kit (Whole Blood/Serum/Plasma) is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to 2019 Novel Coronavirusi in human whole blood, serum or plasma. This test provides only a preliminary test result. Therefore, any reactive specimen with the COVID-19 IgG/IgM Rapid Test kit (Whole Blood/Serum/Plasma) must be confirmed with alternative testing method(s) and clinical findings.

Please refer to the table below for sensitivity and specificity information:

Diagnostic Accuracy of anti-COVID-19 IGM / IGG Antibodies	
Parameters	**Performance (ongoing)**
Sensitivity	96.88%
Specificity	100%
False Positive	0%
False Negative	3.12%
Total Conformity	99%



Please be informed that this kit was developed to meet the emergent need of the outbreak. The regulatory process by national and international regulatory authorities are under process. The test kit is produced by JIANGSU KONSUNG BIO-MEDICAL SCIENCE AND TECHNOLOGYCO.,LTD. It is reliable, accurate, safe, convenient, stable and has high clinical application value.

ORDER NOW: +30 210 94 001 33

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The certifications of the production company and the test anti-COVID-19 IGM / IGG

CE

Declaration of Conformity

according to Directive 98/79/EC, on in vitro diagnostic medical devices

Maker (Name,Address)	**JIANG SU KONSUNG BIO-MEDICAL SCIENCE AND TECHNOLOGY Co.,LTD** NO.8,SHENGCHANG WEST ROAD,DANYANG ECONOMY DEVELOPMENT ZONE, JIANGSU PROVINCE,CHINA	
Authorized Representative	SHANGHAI INTERNATIONAL HOLOING CORP.GMBH(EUROPE) EFFESTRASSE 80,20532 HAMBURG,GERMANY TEL:+49-40-2513175 FAX:+49-40-255726	
Medical device	Description	One Step Test for Novel Coronavirus(2019-nCoV) IgG antibody (Colloidal Gold) One Step Test for Novel Coronavirus(2019-nCoV) IgM antibody (Colloidal Gold) One Step Test for Novel Coronavirus(2019-nCoV) IgM/IgG antibody (Colloidal Gold)
	Classification of products according to directive	Others
	Batch/serial No.Type,production term(if applicable)	
Applicable coordination standards	EN ISO 14971:2012 / EN ISO 23640:2015 / EN ISO 13485:2016 EN ISO13612:2002 / EN ISO15223-1:2012 / EN ISO18113-2:2011 EN 1041:2008 / EN ISO18113-1:2011 / EN ISO18113-3:2011 IEC 61010-1:2010 / IEC 61010-2-101:2015 / IEC 61010-2-081:2015 IEC 61326-1:2013 / IEC 61326-2-2:2013	

WE, JIANGSU KONSUNG BIO-MEDICAL SCIENCE AND TECHNOLOGY CO., LTD, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES; MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 98/79/EC OF 27 OCTOBER 1998 CONCERNING MEDICAL DEVICES;INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

General Manager:

Danyang 2020.2.11
(place and date of issue)

(name and signature or equ... marking of authorized pe...

File NO:KF-CE-53005-01 REV:1.0 revision date: 2020/2/17

ISO

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