

Update on COVID-19 in vitro diagnostics listed by National Regulatory Authorities in IMDRF jurisdictions

Several National Regulatory Authorities (NRAs) have established assessment procedures for listing/authorizing COVID-19 in vitro diagnostics (IVD). The links provided below present information on IVDs authorized for use in the International Medical Device Regulators Forum (IMDRF)¹ jurisdictions² along with other useful information on policies and guidance.

Any feedback on the format of this update is welcome. We will provide updated versions as new information becomes available.

Disclaimer: WHO does not endorse any of the lists provided by NRAs. This information is provided exclusively to assist stakeholders with identifying the links to the various lists.

1. United States of America:

Information on product authorized by the FDA can be found here:

<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov>

<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2>

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency>

Coronavirus (COVID-19) Diagnostic Tests Hotline:

For test developers and labs who have questions about the EUA process or spot shortages of testing supplies, contact our toll-free phone line 24 hours a day: 1-888-INFO-FDA (1-888-463-6332), then press star (*)

2. Canada:

As of 20 March 2 COVID-19 IVDs were authorized in Canada. For more information refer to this link:

<https://www.canada.ca/en/health-canada/news/2020/03/health-canada-expedites-access-to-covid-19-diagnostic-laboratory-test-kits-and-other-medical-devices.html>

<https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/health-professionals.html#dia>

3. Japan

As of 18 March no COVID-19 IVDs were authorized in Japan.

¹ For more information on the IMDRF please refer to this link: <http://www.imdrf.org/>

² For agencies who provided such information to WHO/RPQ

4. Australia

The TGA has approved the following tests for inclusion on the Australian Register of Therapeutic Goods (ARTG):

<https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia>

<https://www.tga.gov.au/legal-supply-covid-19-diagnostic-tests>

5. South Korea

As of 17 March the following products were allowed to be produced, distributed and used in S Korea for a limited time period.

No	Manufacturer	Product	Date of Approval	Target Gene
1	kogenebiotech	PowerCheckTM2019-nCoV RT PCR kit	4 February	RdRp, E
2	Seegene	AllplexTM2019-nCoV Assay	12 February	RdRp, E, N
3	SolGent Co.,Ltd.	DiaPlexQTMN Coronavirus Detection kit	27 February	ORF1a, N
4	SD BIOSENSOR	STANDARD M nCoV RT Detection kit	27 February	RdRp, E
5	BioSewoom Inc.	Real-Q 2019-nCoV Detection Kit	13 March	RdRp, E

6. Singapore:

The information on products authorized by HAS are publicly available on HAS's website below:

<https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation>

7. China:

The list of COVID-19 IVDs authorized in China is available at this link:

<http://www.nmpa.gov.cn/WS04/CL2056/375802.html>

The list of approved COVID-19 test kits is presented below:

No.	Product Name	Registrant	注册证号
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1	Novel Coronavirus 2019-nCoV RT-PCR Kit(Fluorescent PCR method)	Shanghai Liferiver Bio-Tech (United States) Corp.	国械注准20203400057
2	Novel Coronavirus 2019-nCoV RT-PCR Kit(Fluorescent PCR method)	Shanghai GeneoDx Biotech Co., Ltd.	国械注准20203400058
3	Novel Coronavirus 2019-nCoV nucleic acid detection kit (cPAS, combinatorial probe-anchor synthesis sequencing method)	BGI Tech (Wuhan) Co., Ltd.	国械注准20203400059
4	Novel Coronavirus 2019-nCov PCR Kit (fluorescent PCR method)	BGI Tech (Wuhan) Co., Ltd.	国械注准20203400060
5	Novel Coronavirus 2019-nCov PCR Kit (fluorescent PCR method)	Da An Gene Co., Ltd.	国械注准20203400063
6	Novel Coronavirus 2019-nCov PCR Kit (fluorescent PCR method)	Sansure Biotech	国械注准20203400064
7	Novel Coronavirus 2019-nCov PCR Kit (fluorescent PCR method)	Shanghai BioGerm	国械注准20203400065
8	Novel Coronavirus 2019-nCov Antibody Test Kit (colloidal gold method)	Guangzhou Wondfo Biotech Co., Ltd.	国械注准20203400176
9	Novel Coronavirus 2019-nCov Antibody Test Kit (colloidal gold method)	Innovita (Tangshan) Biotech Co., Ltd.	国械注准20203400177
10	Six - Respiratory - Virus Nucleic Acid Detection Kit (isothermal amplification chip method)	Chengdu Capital Biotech Co., Ltd.	国械注准20203400178
11	Novel Coronavirus 2019-nCov PCR Kit (fluorescent PCR method)	Beijing X-ABT Biotech Co., Ltd.	国械注准20203400179

12	Novel Coronavirus (2019-nCoV) IgM Antibody Test Kit (magnetic particle chemiluminescence method)	Bioscience (Chongqing) Biotech Co., Ltd.	国械注准20203400182
13	Novel Coronavirus (2019-nCoV) IgG Antibody Test Kit (magnetic particle chemiluminescence method)	Bioscience (Chongqing) Biotech Co., Ltd.	国械注准20203400183
14	Novel Coronavirus 2019-nCoV PCR Kit (fluorescent PCR method)	Maccura Biotech Co., Ltd.	国械注准20203400184
15	Novel Coronavirus (2019-nCoV) Antibody Test Kit (CLIA method)	Xiamen InnoDx Biotech Co., Ltd.	国械注准20203400198
16	Novel Coronavirus (2019-nCoV) IgM Antibody Test Kit (colloidal gold method)	Guangdong Hecin Biotech Co., Ltd.	国械注准20203400199
17	Novel Coronavirus 2019-nCoV PCR Kit (fluorescent PCR method)	Wuhan Easy Diagnosis Biomedicine Co., Ltd.	国械注准20203400212
18	Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Test Kit (colloidal gold method)	Nanjing Vazyme Biotech Co., Ltd.	国械注准20203400239
19	Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Test Kit (colloidal gold method)	Zhuhai Livzon Pharmaceutical Group Inc.	国械注准20203400240

8. Brazil

As of 23 March ANVISA approved 8 COVID-19 RDTs and 2 PCR assays. More information can be found at this link:

<https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus>

9. Russia:

As of 18 March 3 COVID-19 IVDs were authorized in Russia.

<https://iz.ru/988947/2020-03-19/roszdravnadzor-odobril-rossiisko-iaponskuiu-sistemu-opredeleniia-koronavirusa>