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)\(^1\) jurisdictions 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:


   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:

   The following diagnostic devices have been submitted to Health Canada seeking approval for authorization for sale or import in Canada under the Interim Order:


3. Japan

   As of 31 March 2020 the Ministry of Health, Labour and Welfare (MHLW) of Japan approved the below products:

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\(^1\)For more information on the IMDRF please refer to this link: [http://www.imdrf.org/](http://www.imdrf.org/)

\(^2\)For agencies who provided such information to WHO/RPQ
Table 1: List of COVID-19 IVDs authorized in China

<table>
<thead>
<tr>
<th>No.</th>
<th>Product name</th>
<th>Marketing Authorization Holder</th>
<th>Date of authorization</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2019-nCoV Fluorescence Detection Real-time RT-PCR Kit</td>
<td>Sysmex Corporation</td>
<td>March 27, 2020</td>
</tr>
<tr>
<td>2</td>
<td>Loopamp Novel Coronavirus 2019 (SARS-CoV-2) Detection Kit</td>
<td>Eiken Chemical Co., Ltd.</td>
<td>March 31, 2020</td>
</tr>
</tbody>
</table>

4. Australia

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


5. South Korea

The products which were allowed to be produced, distributed and used in S Korea for a limited time period can be found here:

https://www.mfds.go.kr/eng/brd/m_52/list.do

For further information, you can contact policymfds@korea.kr

6. Singapore:

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


7. China:

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

https://mp.weixin.qq.com/s/8nXlXJbE95hp0gcqsqj3Sg

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

1. Nucleic acid test kits for 2019-nCoV:
   Test kits detecting of 2019-nCoV specific genes

   Intended use
In vitro qualitative detection of target genes of 2019-nCoV from specimen of pneumonia patients suspected of 2019-nCoV infection, patients suspected of clustered cases, and other individuals requiring test for diagnosis or differential diagnosis with 2019-nCoV infections.

Product list

- **Product Name:** Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)
  - **Manufacturer Name:** Shanghai ZJ Bio-Tech Co., Ltd.
  - **Manufacturing Site:** Building #26, 588 Xinjunhuan Road, Minhang District, 201114 Shanghai, China
  - **Applicable Specimen:** Oropharyngeal swabs, Sputum, Bronchoalveolar Lavage Fluid (BALF)
  - **Target Gene:** ORF1ab gene, N gene and E gene

- **Product Name:** Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)
  - **Manufacturer Name:** Shanghai GeneoDx Biotechnology Co., Ltd.
  - **Manufacturing Site:** 1st Floor, Building 3, Juke Bio-Park, 466 Yindu Road, Room 201, 203, 2nd Floor, Building 1, Juke Bio-Park, 466 Yindu Road, Room 104, 106, 108, Building 1, 2715 Longwu Road, Xuhui District, 200237 Shanghai, China
  - **Applicable Specimen:** Nasopharyngeal swabs, Sputum
  - **Target Gene:** ORF1ab gene and N gene

- **Product Name:** Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)
  - **Manufacturer Name:** BGI Biotechnology (Wuhan) Co., Ltd
  - **Manufacturing Site:** 5th floor Building B2, 1st floor Building B1, Zone B/C/D, Wuhan National Bioindustry Base, NO.666 Gaoxin Avenue, East Lake High-tech Development Zone, Wuhan, Hubei, China
  - **Applicable Specimen:** Oropharyngeal swabs, Bronchoalveolar Lavage Fluid (BALF)
  - **Target Gene:** ORF1ab gene

- **Product Name:** Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)
  - **Manufacturer Name:** Da An Gene Co., Ltd. of Sun Yat-sen University
  - **Manufacturing Site:** No.19, Xiangshan Road, Science Park, High&New Technology Development District, Guangzhou; No.6, Lizhishan Road, Science Park, High&New Technology Development District, Guangzhou, China
  - **Applicable Specimen:** Oropharyngeal swabs, Sputum
  - **Target Gene:** ORF1ab gene and N gene
• Product Name: Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)
  Manufacturer Name: Sansure Biotech Inc.
  Manufacturing Site: No. 680, Lusong Road, 410205 Changsha, Hunan, China
  Applicable Specimen: Oropharyngeal swabs, Bronchoalveolar Lavage Fluid (BALF)
  Target Gene: ORF1ab gene and N gene

• Product Name: Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)
  Manufacturer Name: Shanghai BioGerm Medical Biotechnology Co., Ltd
  Manufacturing Site: Room 1302, 1303, 1304, 1305, 1306, 1307, 1309, Building 3, No. 1588 Huhang Highway, Fengxian District, Shanghai, China
  Applicable Specimen: Oropharyngeal swabs, Nasopharyngeal swabs, Sputum
  Target Gene: ORF1ab gene and N gene

• Product Name: Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)
  Manufacturer Name: Beijing Applied Biological Technologies Co., Ltd.
  Manufacturing Site: Room A204, 3rd floor B304, 2nd floor D203, D203-1, No.29 Shengmingyuan Road, Science Park, Changping District, 102206 Beijing, China
  Applicable Specimen: Oropharyngeal swabs, Sputum
  Target Gene: ORF1ab gene, N gene and E gene

• Product Name: Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)
  Manufacturer Name: Maccura Biotechnology Co., Ltd.
  Manufacturing Site: 16#, Baichuan Road, Hi-tech Zone, 611731 Chengdu, Sichuan China
  Applicable Specimen: Oropharyngeal swabs, Sputum
  Target Gene: ORF1ab gene, N gene and E gene

• Product Name: Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)
  Manufacturer Name: Wuhan Easy Diagnosis Biomedicine Co., Ltd.
  Manufacturing Site: No. A8 2-2 Building, Optics Valley Biomedical Industry Park Phase II, No.858 Gaoxin Road, East Lake High-tech Development Zone, 430074 Wuhan, Hubei, China
  Applicable Specimen: Oropharyngeal swabs, Nasopharyngeal swabs, Sputum
  Target Gene: ORF1ab gene and N gene
Published on 06 April 2020: point 7 was amended

- Product Name: Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (Isothermal amplification-real time fluorometric PCR)
  Manufacturer Name: Ustar Biotechnologies (Hangzhou) Ltd.

  Manufacturing Site： Bldg C, Fl 1-2 and Bldg A, Fl 5, 399 Qiuyi Rd, Changhe Street, Binjiang Dist, 310052, Hangzhou, Zhejiang, China

  Applicable Specimen： Oropharyngeal swabs, Sputum

  Target Gene： ORF1ab gene and N gene

- Product Name: Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (hybridization capture immunofluorescence)
  Manufacturer Name: Anbio (Xiamen) Biotechnology Co., Ltd.

  Manufacturing Site： No.2016, Wengjiao West Road, Xinyang Street, Haicang District, 361026, Xiamen, Fujian, China

  Applicable Specimen： Oropharyngeal swabs, Sputum

  Target Gene： ORF1ab gene, N gene and E gene

- Product Name: Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)
  Manufacturer Name: Shanghai Fosun Long March Medical Science Co., Ltd.

  Manufacturing Site： No.830 Cheng Yin Road, Baoshan District, 200444 Shanghai, China

  Applicable Specimen： Oropharyngeal swabs, Sputum

  Target Gene： ORF1ab gene, N gene and E gene

- Product Name: Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (RNA capture probe method)
  Manufacturer Name: Shanghai Rendu Biotechnology Co., Ltd.

  Manufacturing Site： 3rd Floor, Building 10-B, 528 Ruiqing Rd., Zhangjiang Hi-Tech Park (East), Pudong, 201201, Shanghai, China；528 Ruiqing Rd., Building 8-A, 6th Floor, Zhangjiang Hi-Tech Park (East), Pudong, 201201 Shanghai, China; 590 Ruiqing Rd., Building 7, Suite 301, Zhangjiang Hi-Tech Park (East), Pudong, 201201 Shanghai, China

  Applicable Specimen： Oropharyngeal swabs, Sputum

  Target Gene： ORF1ab gene

- Product Name: Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (Dual amplification)
  Manufacturer Name: Wuhan Zhongzhi Biotechnologies INC.

  Manufacturing Site： Building A6-2, No. 858, Gaoxin Avenue, East Lake Hi-Tech Development Zone, 430075, Wuhan, Hubei, China
Applicable Specimen: Oropharyngeal swabs, Sputum

Target Gene: ORF1ab gene and E gene

- Product Name: Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (RNA isothermal amplification lateral flow assay)
  Manufacturer Name: Wuhan Zhongzhi Biotechnologies INC.

  Manufacturing Site: Building A6-2, No. 858, Gaoxin Avenue, East Lake Hi-Tech Development Zone, 430075, Wuhan, Hubei, China

  Applicable Specimen: Oropharyngeal swabs, Sputum

  Target Gene: ORF1ab gene and E gene

**Test kits detecting of 2019-nCoV nucleic acid through next generation sequencing**

**Intended use**

In vitro qualitative detection of nucleic acid of 2019-nCoV through next generation sequencing from specimens of pneumonia patients suspected of 2019-nCoV infection, patients suspected of clustered cases, and other individuals requiring test for diagnosis or differential diagnosis with 2019-nCoV infections. The kit is exclusively used in combination with the approved sequencing system and analysis software.

**Product list**

- Product Name: Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (combinatorial probe-anchor synthesis sequencing)
  Manufacturer Name: BGI Biotechnology(Wuhan) Co., Ltd

  Manufacturing Site: 5th floor Building B2, 1st floor Building B1, Zone B/C/D, Wuhan National Bioindustry Base, NO.666 Gaoxin Avenue, East Lake High-tech Development Zone, Hubei, China

  Applicable Specimen: Oropharyngeal swabs, Bronchoalveolar Lavage Fluid (BALF)

  Target: Whole genome

**Test kits detecting of 2019-nCoV and other virus**

**Intended use**

In vitro qualitative detections of S and N target genes of 2019-nCoV, as well as nucleic acid from Influenza A Virus, New Influenza A H1N1 Virus (2009), Influenza A H3N2 Virus, Influenza B Virus, Respiratory Syncytial Virus, from specimen of pneumonia patients suspected of 2019-nCoV infection, patients suspected of clustered cases, and other individuals requiring test for diagnosis or differential diagnosis with 2019-nCoV infections.

**Product list**
Published on 06 April 2020: point 7 was amended

- Product Name: Nucleic Acid reagent test kit for six respiratory viruses (constant temperature amplification chip)
  Manufacturer Name: Chengdu CapitalBio Biotechnology Co., Ltd.

  Manufacturing Site: Building 3-2 3rd floor, building 3-3, building 3-4(1st floor E-109, 2nd floor, top floor 3-3 to 3-5), building 4(101, 103), building 5, No.88, North Bayi Road, Yongning Town, Wenjiang District, Chengdu, Sichuan, China

  Applicable Specimen: Oropharyngeal swabs

  Target Gene: S gene and N gene from 2019-nCoV, and specific genes from the other five respiratory viruses

2. Anti-2019-nCoV antibody test kits

Intended use

In vitro qualitative detection of Anti-2019-nCoV antibody from specimen. It is only intended for the supplementary indicator for suspected cases of negative 2019-nCoV nucleic acid detection, or combination with nucleic acid detection in the diagnosis of suspected cases. Results from antibody testing should not be used as the sole basis to diagnose or exclude 2019-nCoV infection. It is not intended for screening in general population. Positive test results need further confirmation. Negative results do not exclude 2019-nCoV infection. These kits are for medical use only.

Product list

- Product Name: Antibody test kit for novel coronavirus 2019-nCoV (colloidal gold method)
  Manufacturer Name: Guangzhou Wondfo Biotech Co., Ltd.

  Manufacturing Site: No.8 Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, China

  Applicable Specimen: Serum, Plasma, Venous whole blood

  Target: Anti-2019-nCoV IgM/IgG antibody (no distinguishing between IgM and IgG antibody)

- Product Name: Antibody test kit for novel coronavirus 2019-nCoV (colloidal gold method)
  Manufacturer Name: INNOVITA(Tangshan) Biological Technology Co., Ltd.

  Manufacturing Site: No. 699 Juxin street, High-tech Industrial Development Zone, Qian’an 064400, Tangshan, Hebei, China

  Applicable Specimen: Serum, Plasma

  Target: Anti-2019-nCoV IgM and IgG antibody

- Product Name: IgM Antibody test kit for novel coronavirus 2019-nCoV (magnetic particle-based chemiluminescence immunoassay)
Manufacturer Name: Bioscience (Chongqing) Diagnostic Technology Co., Ltd.
Manufacturing Site: No.2, no.3, no.4, building 2, no.5, gangcheng donghuan road, jiangbei district, Chongqing, China
Applicable Specimen: Serum
Target: Anti-2019-nCoV IgM antibody
- Product Name: IgG Antibody test kit for novel coronavirus 2019-nCoV (magnetic particle-based chemiluminescence immunoassay)
  Manufacturer Name: Bioscience (Chongqing) Diagnostic Technology Co., Ltd.
  Manufacturing Site: No.2, no.3, no.4, building 2, no.5, gangcheng donghuan road, jiangbei district, Chongqing, China
  Applicable Specimen: Serum
  Target: Anti-2019-nCoV IgG antibody
- Product Name: Antibody test kit for novel coronavirus 2019-nCoV (chemiluminescence microparticle immunoassay)
  Manufacturer Name: Xiamen Innodx Biotech Co., Ltd.
  Manufacturing Site: Southern Area, A area and B area, Building 4, No. 130; Building 5, No. 130; 2/F, No. 124, Xinyuan Road, Xinyang Street, Haicang District, Xiamen, Fujian, China
  Applicable Specimen: Serum, Plasma
  Target: Anti-2019-nCoV total antibody
- Product Name: IgM antibody test kit for novel coronavirus 2019-nCoV (colloidal gold method)
  Manufacturer Name: Hecin Scientific, Inc.
  Manufacturing Site: 4F, Building 2, #1 Ruifa Rd, Luogang District, Guangzhou, China
  Applicable Specimen: Serum, Plasma
  Target: Anti-2019-nCoV IgM antibody
- Product Name: IgM/IgG antibody test kit for novel coronavirus 2019-nCoV (colloidal gold method)
  Manufacturer Name: Nanjing Vazyme Medical Technology Co., LTD.
  Manufacturing Site: Floor 1-3, Building C2, Red Maple Park of Technological Industry, Kechuang Road, Economy & Technology Development Zone, Nanjing, Jiangsu, China
  Applicable Specimen: Serum, Plasma
  Target: Anti-2019-nCoV IgM and IgG antibody
- Product Name: IgM/IgG antibody test kit for novel coronavirus 2019-nCoV (colloidal gold method)
  Manufacturer Name: Zhuhai Livzon Diagnostics Inc.
  Manufacturing Site: No. 266 Tongchang Road, Xiangzhou District, 519060 Zhuhai, Guangdong, China
  Applicable Specimen: Serum, Plasma, Venous whole blood
  Target: Anti-2019-nCoV IgM and IgG antibody

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:

The following COVID-19 IVDs were authorized in Russia:
https://www.roszdravnadzor.ru/services/misearch

For further information please contact ValeevaAA@roszdravnadzor.ru