

## 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)<sup>1</sup> jurisdictions<sup>2</sup> along with other useful information on policies and guidance.

**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:

<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:

<https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html>

### 3. Japan

Information on products authorized by the Ministry of Health, Labour and Welfare (MHLW) of Japan can be found in the attached document.

### 4. Australia

<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

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

<sup>2</sup> For agencies who provided such information to WHO/RPQ

[https://www.mfds.go.kr/eng/brd/m\\_52/list.do](https://www.mfds.go.kr/eng/brd/m_52/list.do)

For further information, you can contact [policymfds@korea.kr](mailto:policymfds@korea.kr)

**6. Singapore:**

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

**7. China:**

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

**8. Brazil**

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

**9. Russia:**

<https://www.roszdravnadzor.ru/services/misearch>

For further information please contact [ValeevaAA@roszdravnadzor.ru](mailto:ValeevaAA@roszdravnadzor.ru)