

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.

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

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

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

For further information, you can contact 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