



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2021-2094**

11 2 AUG 2021

TO: ALL HEALTHCARE PROFESSIONALS AND GENERAL PUBLIC

SUBJECT: List of COVID-19 Test Kits with FDA Special Certification and Performance Validation Conducted and/or Recommended by the Research Institute for Tropical Medicine (RITM)

On 23 March 2021, the Food and Drug Administration (FDA) issued FDA Memorandum No. 2021-009 entitled "Minimum Performance Requirements for COVID-19 Test Kits Used for SARS-CoV-2 Infection". This issuance provides that compliance to the minimum performance requirements for sensitivity and specificity based on the performance validation conducted by the Research Institute for Tropical Medicine (RITM) shall be required prior to the issuance of Special Certification for all COVID-19 test kits.

In view of the above and in the interest of protecting public health and safety, the FDA hereby announces the list of COVID-19 test kits that have passed the performance validation conducted and/or recommended by the RITM and were issued with FDA Special Certification in accordance with the abovementioned FDA Memorandum as of 2 August 2021.

List of Approved PCR Based Test Kits for Commercial Use

	Product Name	Name & Address of Manufacturer	Name of Importer/Distributor	Specimen	RITM Validated Result Sensitivity	RITM Validated Result Specificity
1.	SARS-CoV-2 Fluorescent PCR Kit	Maccura Biotechnology Co., Ltd. 16# Baichuan Road, High-Tech Zone, 611731 Chengdu, People's Republic of China	Assurance Controls Technologies Co., Inc.	Oropharyngeal swabs and Sputum	96.23%	100%
2.	BioFire Respiratory Panel 2.1 (RP2.1)	BioFire Diagnostic, LCC. 515 Colorow Drive, Salt Lake City, Utah, 84108, USA	Biomerieux Philippines Corporation	Nasopharyngeal swab	100%	100%



3.	i-DENSY PACK UNIVERSAL REAGENT (i-DENSY PACK UNIVERSAL SARS-CoV-2 DETECTION SYSTEM)	ARKRAY INDUSTRY INC. Lot 22 Phase 1A, First Philippine Industrial Park, Brgy. Sta. Anastacia, Sto. Tomas, Batangas	ARKRAY Industry Inc	Nasopharyngeal swab	100%	100%
4.	SARS-CoV-2 DETECTION PRIMER PROBE SET REAGENT (i-DENSY PACK UNIVERSAL SARS-CoV-2 DETECTION SYSTEM)	ARKRAY INDUSTRY INC. Lot 22 Phase 1A, First Philippine Industrial Park, Brgy. Sta. Anastacia, Sto. Tomas, Batangas	ARKRAY Industry Inc	Nasopharyngeal swab	100%	100%
5.	SARS-COV- 2 Nucleic Acid Detection Kit (PCR- Fluorescent Probe Method)	Zybio Inc.-Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, Chongqing, China	Sahar International Trading Inc	Nasal/throat swabs	100%	100%
6.	Xpert Xpress SARS-CoV-2	Cepheid AB- Röntgenvägen 5, 171 54 Solna, Sweden	Macare Medicals, Inc	Nasopharyngeal, oropharyngeal, nasal, or mid- turbinate swab or nasal wash/aspirate specimens	100%	99%

List of Approved Antigen Test Kits for Commercial Use

	Product Name	Name & Address of Manufacturer	Name of Importer/ Distributor	Specimen	RITM Validated Result Sensitivity	RITM Validated Result Specificity
1.	Panbio™ COVID-19 Ag Rapid Test Device	Abbot Rapid Diagnostics Jena GmbH Orlaweg 1 07743 Jena, Germany	Sunfu Solutions Inc.	Nasopharyngeal Swab	CT < 30 (97.83%)	100%
2.	Panbio™ COVID-19 Ag Rapid Test Device	Abbot Diagnostics Korea Inc. 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyenoggi-do 17099, Republic of Korea	Sunfu Solutions Inc	Nasopharyngeal Swab	CT < 30 (97.83%)	100%
3.	SOFIA 2 SARS Antigen FIA	Quidel Corporation 10165 McKellar Court, San Diego, CA 92121 USA	LABx CORP.	Nasopharyngeal /Nasal Swab	CT < 30 (92.86%)	100%
4.	Panbio™ COVID-19 Ag Rapid Test Device	Abbott Rapid Diagnostics Jena GmbH-Orlaweg 1 07743 Jena, Germany	Allied Hospital Supply International Corp	Nasopharyngeal swab	CT < 30 (97.83%)	100%
5.	STANDARD™ Q COVID-19 Ag TEST KIT	SD Biosensor, Inc-C-4&5 Floor, 16, Deogyong-daero 1556beong-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, Republic of Korea	Trulaboratories Corporation	Nasopharyngeal swab	CT<30 93.1%	100%
6.	Panbio™ COVID-19 Ag Rapid Test Device	Abbott Rapid Diagnostics Jena GmbH-Orlaweg 1 07743 Jena, Germany	Allied Hospital Supply International Corp.	Nasal swab	CT < 30 (90.5%)	99.20%
7.	NowCheck COVID-19 Antigen Test	BioNote Inc-22 Samsung 1-ro-4-gil, Hwaseong-Si, Gyeonggido, 18449 Republic of Korea	Biologic Life Sciences Corp.	Nasopharyngeal swab	CT < 30 (91.4%)	97.30%


8.	Novel Coronavirus (2019-nCoV) Antigen Detection Kit (Colloidal Gold Method) // Wondfo 2019-nCoV Antigen Test (Lateral flow)	Guangzhou Wondfo Biotech Co., -Guangzhou Wondfo Biotech Co., Ltd. – No. 8 Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, P.R. China	Tradematchers, Inc.	Nasopharyngeal or Oropharyngeal swabs	CT < 30 (92.2%)	100%
9.	Novel Coronavirus (2019-nCoV) Antigen Detection Kit (Colloidal Gold Method) // Wondfo 2019-nCoV Antigen Test (Lateral flow)	Guangzhou Wondfo Biotech Co., -Guangzhou Wondfo Biotech Co., Ltd. – No. 8 Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, P.R. China	LabSolution Technologies Inc.	Nasopharyngeal or Oropharyngeal swabs	CT < 30 (92.2%)	100%
10.	Novel Coronavirus (2019-nCoV) Antigen Detection Kit (Colloidal Gold Method) // Wondfo 2019-nCoV Antigen Test (Lateral flow)	Guangzhou Wondfo Biotech Co., -Guangzhou Wondfo Biotech Co., Ltd. – No. 8 Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, P.R. China	Alcheon Medical Corporation	Nasopharyngeal or Oropharyngeal swabs	CT < 30 (92.2%)	100%

List of Approved Antibody Rapid Test Kits for Commercial Use

	Product Name	Name & Address of Manufacturer	Name of Importer/ Distributor	Specimen	RITM Validated Result Sensitivity	RITM Validated Result Specificity
1.	VivaDiag™ COVID-19 IgM/IgG Rapid Test	Vivachek Biotech Hangzhou Co. Ltd. Level 2, Block 2, 146 East Chaofeng Rd., Yuhang Economy Development Zone, Hangzhou, 311100, Zhejiang China	Philippine Blue Cross Biotech Corporation	Whole Blood / Serum / Plasma and Fingertip Blood	92.00%	99.33%
2.	NADAL COVID-19 IgG/IgM Test	Nal Von Minden GmbH- Carl-Zeiss-Str. 12, 47445 Moers, Germany	Diagnostika Pilipinas, Inc.	Human whole blood, serum or plasma	92.67%	100.00%

The above list shall be regularly updated. For reference, please click the link: <https://docs.google.com/spreadsheets/d/13S12QST9RK1yX1ipUhqhmngwq3rdtbLRnDWPg8-OSqo/edit#gid=0>.

For more information and inquiries, kindly contact the FDA – Center for Device Regulation, Radiation Health, and Research through e-mail at cdrhr@fda.gov.ph or call (02) 8857-1900 loc. 8301.


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