

World Health Organization
External Quality Assessment Programme for the Detection of
SARS-CoV-2 by RT-PCR
(2020)

This panel contains five samples of dried extracted coronavirus RNA (including SARS-CoV-2 RNA in different dilutions and other currently circulating human coronavirus RNA) and a positive control of SARS-CoV-2 RNA. Participants are expected to undertake SARS-CoV-2 detection test for all RNA samples. For WHO technical guidance of laboratory testing for COVID-19 in humans, please visit the following website:

<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance>

Please read the instructions and return the completed result form/ questionnaire (Part 6-8) within 4 weeks after sample reception:

Enquiry/ result submission : 1012e@dh.gov.hk

Address : Public Health Laboratory Services Branch
 Centre for Health Protection
 9/F, Public Health Laboratory Centre
 382 Nam Cheong Street, Shek Kip Mei, Kowloon
 Hong Kong SAR

1. Panel contents

This panel of EQAP samples consists of the following items. Please notify us immediately if the contents are not correct.

Labels	Contents
WHO SARS-CoV-2 EQAP (2020) Sample ID: 2020-XX (XX = 01 to 05) Vacuum dried extracted RNA	5 vials, vacuum dried extracted RNA

Extra positive control of SARS-CoV-2 RNA:

Labels	Contents
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WHO External Quality Assessment Programme for the Detection of SARS-CoV-2 by RT-PCR
WHO-SARS-CoV-2-EQAP-01-2020-04-16

WHO SARS-CoV-2 EQAP (2020) Positive control Vacuum-dried extracted RNA	1 vial, vacuum dried SARS-CoV-2 extracted RNA (positive control)
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If not processed immediately, please store the panel contents at -70°C or according to your current laboratory practice.

2. Safety precautions

The EQAP samples contain material of biological origin and should be handled and disposed of according to your laboratory safety procedures. Contamination control for liquid handling should be employed.

3. Reconstitution of dried extracted coronavirus RNA

Reconstitute the total contents of each vial with 50µl PCR grade water. Vortex for 5 sec to allow complete reconstitution. Centrifuge the vials for a few seconds before opening.

No extraction is required. Perform detection of SARS-CoV-2 RNA (5 samples in total) with the assays currently used in your laboratory.

4. Storage and stability

Reconstituted RNA shall be stored at -70°C or according to your current laboratory practice. Repeated freezing and thawing should be avoided.

5. Instructions for reporting results

1. Test the panel with the current assay(s) used in your laboratory. **Enter your designated 'lab code' at the top right corner of 'Result form'.** (For WHO Flu EQAP participants, same lab code is used.)
2. Report the test results in Part 6.
Write down the Ct (cycle threshold) values if real-time PCR has been performed.
Participants are expected to provide the qualitative results in 'Overall Result' by selecting from the drop down list or type in the results.
3. Please complete and provide your valuable information in
Part 7 'Information on the detection method(s) of SARS-CoV-2' and
Part 8 'Short questionnaire on the implementation of molecular detection of SARS-CoV-2'
4. For submission, please send the file as an attachment to 1012e@dh.gov.hk

Result form: WHO SARS-CoV-2 EQAP (2020)		Please enter your Lab Code:	140
Date of dispatch:	17/04/2020	(DD/MM/YYYY)	
Date of panel received:	24/04/2020	(Please enter the date of panel received)	
Deadline for submitting results:	22/05/2020	(Within 4 weeks after the date of panel reception)	
Results reporting date:	20/05/2020		
Test performed by:			
Results reported by:	(10)/(2e)		

6. Results

Sample Number	Individual RT-PCR Results [Please fill in Ct values (for real-time PCR), POS/ NEG (for conventional PCR) or leave blank if not tested]									Overall Result	Remarks
	Method 1: Gene target(s), please select			Method 2: Gene target(s), please select			Method 3: Gene target(s), please select				
	E	RdRP Sarbeco	RdRP SARS-CoV-2	Gene target 1	Gene target 2	Gene target 3	Gene target 1	Gene target 2	Gene target 3		
2020-01	23.99	33.78	27.88							SARS-CoV-2 detected	
2020-02	27.72	36.77	31.06							SARS-CoV-2 detected	
2020-03										SARS-CoV-2 NOT detected	
2020-04										SARS-CoV-2 NOT detected	
2020-05	23.84	31.16	27.12							SARS-CoV-2 detected	

7. Information on the detection method(s) of SARS-CoV-2

Please select the appropriate options from the list and/or provide method/kit information below:

Method: Target gene(s)	Conventional/Real-time	In-House/Commercial	Assay (select when applicable)	Algorithm	Brand/ model name of machine	Remarks
Method 1:						
E		In-house	Charité, Germany Two PCRs of which RdRP with Sarbeco and SARS-CoV-2		Roche LC 480	
RdRP Sarbeco			List of commercial assay			
RdRP SARS-CoV-2						
Method 2:						
Gene target 1			List of in-house assay			
Gene target 2						
Gene target 3			List of commercial assay			
Method 3:						
Gene target 1			List of in-house assay			
Gene target 2						
Gene target 3			List of commercial assay			
Reference/ Remarks*						
40:4740:46A40:46						
Reference/ 40:46Remarks/ 47:68						
Genotypic testing performed:		Yes/No				
a) Method of genotypic detection:				If others, please specify		
b) Brand/ model name of machine:						
c) Results:						
d) Results:						

Sample Number	Genotypic testing result (nucleotide changes detected)*	Reduced inhibition Yes/No	Remarks
NAI01G-2019 (Flu A/H1N1m00)			
NAI02G-2019 (Flu A/H1N1m00)			
NAI03G-2019 (Flu A/H3)			
NAI04G-2019 (Flu B/Vicmagata lineage)			

Phenotypic testing performed: Yes/No

a) Method of phenotypic detection: _____ In-house/ Commercial _____

b) Substrate used: _____ Substrate (supplier) _____

c) NAI tested: _____

d) Results

Sample Number	Oseltamivir		Zanamivir		Remarks
	IC50 nM	Interpretation	IC50 nM	Interpretation	
NAI01F-2019 (Flu A/H1N1m00)					
NAI02F-2019 (Flu A/H1N1m00)					
NAI03F-2019 (Flu A/H3)					
NAI04F-2019 (Flu B/Vicmagata lineage)					

*Any additional results are also welcome.

8. Short questionnaire on the implementation of molecular detection of SARS-CoV-2 (For information purpose) - can select more than 1 option in Q 1., 2., 4., 8. and

1. Major concern(s) in launching/ implementing the molecular detection of SARS-CoV-2?

- Establishing procedures/ guidelines on specimen collection/ shipping/ storage
- Insufficient viral transport media
- Establishing/ designing the standard detection methods
- Insufficient personal protective equipment (PPE)
- Insufficient equipment
- Insufficient primers/ probes/ testing reagent
- Insufficient positive control
- Need for specific staff training
- Operate in proper biosafety level as required by national legislation
- Operate in compliance with the quality management system. (Please indicate if applicable): _____

Additional comments: Contamination of ordered primers and probes from company with RNA synthetic SARS-CoV-2 positive control produced at the company buy not ordered by us.

2. What are the sources of the specimens for testing in your laboratory?

- Outbreak investigation (including those meeting case definition and contact tracing)
- Specimens from influenza surveillance
- Others, please specify: Hospitalized patients, healthcare workers, military personnel, educational personnel
- Unknown, please explain: _____

Additional comments:

3. Are you testing all specimens coming in?

- Yes
- No (If No, what is the criteria of prioritization of specimens for testing, please describe): _____

Additional comments:

4. What are the common type of specimens accepted for the molecular detection of SARS-CoV-2 in your laboratory?

- Nasopharyngeal swab
- Nasal swab
- Throat swab
- Sputum
- Tracheal aspirate
- Saliva
- Bronchoalveolar lavage
- Stool
- Urine
- Blood
- Others, please specify: _____ sewage

Additional comments:

5. What is the usual daily sample load/ current maximum daily testing capacity for SARS-CoV-2 in your laboratory?

Daily sample load	Maximum daily testing capacity
<input type="radio"/> < 50	<input type="radio"/> < 50
<input checked="" type="radio"/> 51-200	<input type="radio"/> 51-200
<input type="radio"/> 201-500	<input type="radio"/> 201-500
<input type="radio"/> 501-1000	<input checked="" type="radio"/> 501-1000
<input type="radio"/> 1001-2000	<input type="radio"/> 1001-2000
<input type="radio"/> >2000	<input type="radio"/> >2000

Additional comments: for week commencing 11 May 2020

6. What is the usual turnaround time for the molecular detection of SARS-CoV-2 in your laboratory?

- < 24h
- 25h - 48h
- 49h - 72h
- After 72h

Additional comments:

7. BSL requirement if any in your country?

For PCR	For virus isolation
<ul style="list-style-type: none"> <input checked="" type="radio"/> Biosecurity level: BSL2 <input type="radio"/> Biosecurity level: BSL3 <input type="radio"/> Unknown 	<ul style="list-style-type: none"> <input type="radio"/> Biosecurity level: BSL2 <input checked="" type="radio"/> Biosecurity level: BSL3 <input type="radio"/> Unknown

Additional comments:

8. Which type(s) of quality control(s) is/are included in the molecular detection of SARS-CoV-2 in your laboratory?

- Extraction control
- Positive control for PCR
- Negative control for PCR
- Internal (inhibitor) control for PCR
- Not applicable

Additional comments:

9. Has the detection method(s) been validated against other common respiratory pathogens?

- Other human coronaviruses
- Other common respiratory pathogens e.g. seasonal influenza viruses
- Commercial kit: as specified by the manufacturer
- Validation in progress. (Please specify if applicable): _____

Additional comments:

Please send the file as an attachment to: 191291@dh.gov.hk

1. Own design: please type in free text
2. Protocols created by WHO (not indicative of preference, order by country):
 China CDC, China CDC, China ORF1ab and N
 Institut Pasteur, Paris, France Two targets in RdRP
 Charité, Germany RdRP, E, N
 HKU, Hong Kong SAR ORF1b-nsp14, N
 National Institute of Infectious Diseases, Japan Pancorona and multiple targets
 National Institute of Health, Thailand
 US CDC, USA
 US CDC, USA Three targets in N gene

**Assays collated on FIND (As of 16/4/2020, in alphabetic order):
Please select from the list. If others, please type in free text:**

- 1 [1drop Inc. 1copy™ COVID-19 qPCR Kit \(CE-IVD\)](#)
- 2 [3B BlackBio Biotech India Ltd TRUPCR® SARS-CoV-2 RT qPCR Kit \(IVD India\)](#)
- 3 [3D Medicines 3DMed 2019-nCoV RT-qPCR Detection Kit \(RUO\)](#)
- 4 [3D Medicines ANDIS® SARS-CoV-2 RT-qPCR Detection Kit \(US FDA-EUA - CE-IVD\)](#)
- 5 [A*ccelerate Technology A*STAR Fortitude Kit 2.0 \(Singapore HSA\)](#)
- 6 [AB ANALITICA srl REALQUALITY RQ-2019-nCoV \(CE-IVD\)](#)
- 7 [AB ANALITICA srl REALQUALITY RQ-SARS-CoV-2 \(RUO\)](#)
- 8 [Abacus Diagnostica GenomEra SARS-CoV-2 \(RUO\)](#)
- 9 [Abbott Diagnostics Inc. ID NOW COVID-19 \(US FDA-EUA\)](#)
- 10 [Abbott Molecular Inc. Abbott RealTime SARS-CoV-2 EUA test \(US FDA-EUA - CE-IVD\)](#)
- 11 [Absea Biotechnology Ltd The non-invasive MEGA test of SARS-CoV-2 \(mucosal swabs\) \(in development\)](#)
- 12 [Abwiz Bio RabWiz Ultra Sensitive COIV-19 Viral Antigen Test Kit \(ELISA\) \(in development\)](#)
- 13 [Academia Sinica Anti-SARS-CoV-2 nucleocapsid protein human IgM/IgG rapid detection kit \(In development\)](#)
- 14 [Access Bio Korea, Inc. CareStart™ COVID-19 IgM/IgG \(in development\)](#)
- 15 [AccuBioTech Co. Ltd Accu-Tell COVID-19 IgG/IgM Rapid Test Cassette \(CE-IVD\)](#)
- 16 [Acumen Research Laboratories Pte Ltd Acu-Corona 2.0 \(Singapore HSA\)](#)
- 17 [Acumen Research Laboratories Pte Ltd Acu-Corona \(RUO\)](#)

- 18 [ADT Biotech LyteStar 2019-nCoV RT-PCR Kit 1.0 \(RUO\)](#)
- 19 [Advanced Molecular Diagnostics Zena Max – SARS-COV-2 Real Time PCR Detection Kit \(CE-IVD\)](#)
- 20 [AITbiotech abTES COVID-19 qPCR I Kit \(CE-IVD\)](#)
- 21 [AIVD Biotech Inc. COVID-19 IgG/IgM Rapid Test \(colloidal gold-based\) \(in development\)](#)
- 22 [Aldatu Biosciences PANDAA qDx SARS-CoV-2 \(In development\)](#)
- 23 [altona Diagnostics RealStar® SARS-CoV-2 RT-PCR Kit \(RUO\)](#)
- 24 [AmonMed Biotechnology Co., Ltd COVID-19 Antigen Test Kit \(Rare Earth Nano Fluorescence Immunochromatography\) \(CE-IVD\)](#)
- 25 [AmonMed Biotechnology Co., Ltd COVID-19 IgM/IgG test kit \(Colloidal Gold\) \(CE-IVD\)](#)
- 26 [AmonMed Biotechnology Co., Ltd COVID-19 IgM/IgG test kit \(Rare Earth Nano Fluorescence Immunochromatography\) \(CE-IVD\)](#)
- 27 [AmonMed Biotechnology Co., Ltd COVID-19/Influenza A virus/Influenza B virus IgM combo test kit \(Rare Earth Nano Fluorescence Immunochromatography\) \(CE-IVD\)](#)
- 28 [AmonMed Biotechnology Co., Ltd COVID-19/Influenza A virus/Influenza B virus test kit \(Rare Earth Nano Fluorescence Immunochromatography\) \(CE-IVD\)](#)
- 29 [Amoy Diagnostics Co., Ltd AmoyDx® Novel Coronavirus \(2019 nCoV\) Detection Kit \(CE-IVD\)](#)
- 30 [Amplicon Ltd AmpliTest SARS-CoV-2 \(Real Time PCR\) \(CE-IVD\)](#)
- 31 [AmpliGene India Biotech Pvt. Ltd AmpEZ Rapid and sensitive Real time COVID-2019 test \(RUO\)](#)
- 32 [Anatolia Geneworks Bosphore Novel Coronavirus \(2019-nCoV\) Detection Kit \(lab-based\) \(CE-IVD\)](#)
- 33 [Anbio \(Xiamen\) Biotechnology Co., Ltd COVID-19 Hybrid Capture Fluorescence Immunoassay Test \(China FDA-EUA\)](#)
- 34 [Anhui Anlong Gene Technology Co., Ltd Detection Kit for 2019-nCoV nucleic acid \(Fluorescence PCR\) \(CE-IVD\)](#)
- 35 [Anhui Deep Blue Medical Technology Co., Ltd Colloidal gold strip for SARS-CoV-2 IgG & IgM \(RUO\)](#)
- 36 [Anhui Deep Blue Medical Technology Co., Ltd COVID-19 \(SARS-CoV-2\) IgG/IgM Antibody Test Kit \(CE-IVD\)](#)
- 37 [AniCon Labor GmbH Kylit® SARS-CoV-2 Confirmation RT-qPCR \(CE-IVD\)](#)
- 38 [AniCon Labor GmbH Kylit® SARS-CoV-2 Screening RTU RT-qPCR \(CE-IVD\)](#)
- 39 [Anlongen nCoV-19 Nucleic Acid qPCR Kit \(China FDA-EUA - CE-IVD\)](#)
- 40 [Anomalous Materials Pte Ltd 2019-nCoV IgG/IgM Rapid Testing Kit \(CE-IVD\)](#)
- 41 [Appolon Biotech Detection Kit for 2019 Novel Coronavirus \(2019-nCoV\) RNA \(PCR-Fluorescence Probing\) \(China FDA-EUA - CE-IVD\)](#)
- 42 [Aptamer Group Ltd ADx SARS Co V-2 Virus Antigen Rapid Point of Care Test \(in development\)](#)
- 43 [Assure Tech. \(Hangzhou\) Co., Ltd COVID-19 Antigen Rapid Test Device \(in development\)](#)
- 44 [Assure Tech. \(Hangzhou\) Co., Ltd COVID-19 IgG/IgM Rapid Test Device \(CE-IVD\)](#)
- 45 [Atila BioSystems, Inc. Atila iAMP COVID-2019 Detection Kit \(RUO\)](#)
- 46 [Ativa Medical Ativa Enhanced Screen \(In development\)](#)
- 47 [Attomarker Ltd Quantitative Immuno-kinetic assay for Covid-19 IgG+IgM+IgA for a multiantigen panel with CRP \(automated\) \(in development\)](#)
- 48 [Aura Biotechnologies Ltd Quick COVID-19 Colorimetric LAMP PCR \(in development\)](#)
- 49 [Aura Biotechnologies Ltd Quick COVID-19 Realtime Multiplex PCR \(in development\)](#)
- 50 [Aurora Biomed Inc. SARS-COV-2 Detection Kit for the VERSA Viral Detection workstation \(in development\)](#)
- 51 [AusDiagnostics SARS-CoV-2, Influenza and RSV 8-well \(RUO\)](#)
- 52 [Avioq Bio-Tech Co., Ltd Novel Coronavirus \(2019-nCoV\) Antibody IgG/IgM Assay Kit \(Colloidal Gold\) \(RUO\)](#)
- 53 [Bai-care \(Tianjin\) Biotechnology Co., Ltd Multiplex Nucleic Acid Detection Kit for Respiratory Pathogens \(CE-IVD\)](#)
- 54 [Baiba Phytopharm, Co, Ltd Baiba Rapid COVID-19 IgM/IgG test kit \(in development\)](#)
- 55 [Bao Ruiyuan Biotech \(Beijing\) Co., Ltd. Novel Coronavirus\(2019-nCoV\)Nucleic Acid Detection Kit-Multiple Fluorescence PCR \(RUO\)](#)
- 56 [Beijing Abace Biology Co., Ltd COVID-19 Antibody \(IgG/IgM\) Test Kit \(Colloidal Gold Immunochromatography\) \(CE-IVD\)](#)
- 57 [Beijing Abace Biology Co., Ltd COVID-19 IgG Antibody Test Kit \(ELISA\) \(CE-IVD\)](#)
- 58 [Beijing Abace Biology Co., Ltd COVID-19 IgM Antibody Test Kit \(ELISA\) \(CE-IVD\)](#)
- 59 [Beijing Abace Biology Co., Ltd COVID-19 Viral Antigen Test Kit \(Colloidal Gold Immunochromatography\) \(CE-IVD\)](#)
- 60 [Beijing Abace Biology Co., Ltd COVID-19 Viral Antigen Test Kit \(ELISA\) \(CE-IVD\)](#)
- 61 [Beijing Applied Biological Technologies Co., Ltd Multiple Real-Time PCR Kit for Detection of 2019-nCoV \(China FDA-EUA - CE-IVD\)](#)
- 62 [Beijing Beier Bioengineering Co., Ltd Multiple Real-time PCR kit for Detection of SARS-CoV-2 RNA \(in development\)](#)
- 63 [Beijing Biochem Hengye Science & Technology Development Co., Ltd SARS-CoV-2 Real-Time RT-PCR Kit \(RUO\)](#)
- 64 [Beijing Bohui Innovation Biotechnology Automated SARS-CoV-2 NAT \(RUO\)](#)
- 65 [Beijing Bohui Innovation Biotechnology Fully Automated 26 Plex RES Panel Assay \(RUO\)](#)
- 66 [Beijing Diagreat Biotechnologies Co., Ltd 2019-nCoV IgG Antibody Determination Kit \(CE-IVD\)](#)
- 67 [Beijing Diagreat Biotechnologies Co., Ltd 2019-nCoV IgM Antibody Determination Kit \(CE-IVD\)](#)
- 68 [Beijing Genskey Medical Technology Co., Ltd SARS-CoV-2 Nucleic Acid Detection Kit \(RT-qPCR with Taqman-Probe\) \(RUO\)](#)
- 69 [Beijing Hotgen Biotech Co., Ltd Coronavirus disease \(COVID-19\) Antibody Test \(Colloidal Gold\) \(CE-IVD\)](#)
- 70 [Beijing Hotgen Biotech Co., Ltd Coronavirus disease \(COVID-19\) Antibody Test \(Enzyme-Linked Immunosorbent Assay\) \(CE-IVD\)](#)
- 71 [Beijing Hotgen Biotech Co., Ltd Coronavirus disease \(COVID-19\) Antibody Test \(Up-converting Phosphor Technology\) \(CE-IVD\)](#)
- 72 [Beijing Hotgen Biotech Co., Ltd Coronavirus disease\(COVID-19\) Nucleic Acid Test Kit \(PCR-Fluorescent Probe Method\) \(CE-IVD\)](#)
- 73 [Beijing Infervision Technology Co. Ltd InferRead CT Pneumonia \(In development\)](#)
- 74 [Beijing Kewei Clinical Diagnostic Reagent Inc. Kewei COVID-19 Antigen ELISA Test Kit \(CE-IVD\)](#)
- 75 [Beijing Kewei Clinical Diagnostic Reagent Inc. Kewei COVID-19 Antigen Rapid Test Kit \(Colloidal Gold\) \(CE-IVD\)](#)
- 76 [Beijing Kewei Clinical Diagnostic Reagent Inc. Kewei COVID-19 Antigen Rapid Test Kit \(Fluorescence\) \(CE-IVD\)](#)
- 77 [Beijing Kewei Clinical Diagnostic Reagent Inc. Kewei COVID-19 IgG ELISA Test Kit \(CE-IVD\)](#)
- 78 [Beijing Kewei Clinical Diagnostic Reagent Inc. Kewei COVID-19 IgG/IgM Rapid Test Kit \(Colloidal Gold\) \(CE-IVD\)](#)
- 79 [Beijing Kewei Clinical Diagnostic Reagent Inc. Kewei COVID-19 IgG/IgM Rapid Test Kit \(Fluorescence\) \(CE-IVD\)](#)
- 80 [Beijing Kewei Clinical Diagnostic Reagent Inc. Kewei COVID-19 IgM ELISA Test Kit \(CE-IVD\)](#)
- 81 [Beijing Kinhawk Pharmaceutical Co., Ltd 2019-nCoV ORF1ab/N Gene Detection Kit \(Fluorescence PCR Method\) \(RUO\)](#)
- 82 [Beijing Microread Genetics Co., Ltd COVID-19 \(SARS-CoV-2\) Detection Kit \(LAMP\) - lab-based or near-POC \(CE-IVD\)](#)
- 83 [Beijing NaGene Diagnosis Reagent Co., Ltd Multiple Real-Time PCR kit for Detection of 2019-nCoV \(RUO\)](#)
- 84 [Beijing Savant Biotechnology Co., Ltd SARS-Cov-2 Antigen Fluorescence Rapid Detection Kit \(CE-IVD\)](#)
- 85 [Beijing Tigsun Diagnostics Co. Ltd Tigsun COVID-19 Combo IgM/IgG Rapid Test \(Lateral Flow Method\) \(CE-IVD\)](#)
- 86 [Beijing Wantai Biological Pharmacy Enterprise Co., Ltd Wantai SARS-CoV-2 Ab ELISA \(RUO\)](#)
- 87 [Beijing Wantai Biological Pharmacy Enterprise Co., Ltd Wantai SARS-CoV-2 Ab Rapid Test \(RUO\)](#)
- 88 [Beijing Wantai Biological Pharmacy Enterprise Co., Ltd Wantai SARS-CoV-2 IgM ELISA \(RUO\)](#)
- 89 [Beijing Wantai Biological Pharmacy Enterprise Co., Ltd Wantai SARS-CoV-2 RT-PCR Kit \(RUO\)](#)
- 90 [BGI Health \(HK\) Co. Ltd. Real-time fluorescent RT-PCR kit for detecting 2019 nCoV \(China FDA-EUA\)](#)
- 91 [Blocan Diagnostics Inc. Tell Me Fast Novel Coronavirus \(COVID-19\) IgG/IgM Ab Test \(CE-IVD\)](#)
- 92 [Bioeksen R&D Technologies Bio-Speedy SARS-CoV-2 \(2019-nCoV\) qPCR Detection Kit \(CE-IVD\)](#)
- 93 [BioFire Defense, LLC BioFire COVID-19 Test \(US FDA-EUA\)](#)
- 94 [BIOHIT HealthCare \(Hefei\) Co., Ltd SARS-CoV-2 IgM/IgG antibody test kit \(Colloidal Gold Method\) \(CE-IVD\)](#)
- 95 [Biolidics Ltd 2019-nCoV IgG/IgM Antibody Detection Kit \(Singapore HSA - CE-IVD\)](#)
- 96 [BIOMAXIMA S.A. 2019-nCoV IgG/IgM Rapid Test Cassette \(CE-IVD\)](#)
- 97 [BIOMAXIMA S.A. SARS-CoV-2 Real Time PCR LAB-KIT™ \(CE-IVD\)](#)

- 98 [BioMedomics, Inc. COVID-19 IgM-IgG Dual Antibody Rapid Test \(CE-IVD\)](#)
- 99 [Biomeme COVID-19 Go Strips \(RUO\)](#)
- 100 [bioMérieux SA SARS-COV-2 R-GENE® \(ref 423717\) \(RUO\)](#)
- 101 [bioMérieux SA SARS-COV-2 R-GENE® \(ref 432720\) \(CE-IVD\)](#)
- 102 [BIONEER Corporation AccuPower® COVID-19 Real-Time RT-PCR kit \(lab-based automated kit: NCV-1111\) \(CE-IVD\)](#)
- 103 [BIONEER Corporation AccuPower® SARS-CoV-2 Real-Time RT-PCR kit \(manual kit: SCV-2122\) \(CE-IVD\)](#)
- 104 [Bloneer Inc., part of BIONEER Corp. SCVR-2122 AccuPower® SARS-CoV-2 Real-Time RT-PCR Kit \(50 tests\) \(RUO\)](#)
- 105 [Biotech & Biomedicine \(Shenyang\) Group Ltd Colorimetric and Isothermal Detection Kit for COVID-19 Coronavirus \(CE-IVD\)](#)
- 106 [Biotech & Biomedicine \(Shenyang\) Group Ltd Real Time PCR Detection Kit For COVID-19 Coronavirus \(CE-IVD\)](#)
- 107 [Bio-Techne Ella / Simple Plex COVID-19 16x4 Standard Panel \(RUO\)](#)
- 108 [BIOTECON Diagnostics GmbH Acu-Corona™ 2.0/3.0 SARS-CoV-2 Real-time PCR Kits \(RUO\)](#)
- 109 [BIOTECON Diagnostics GmbH microproof SARS-CoV-2 Screening/Identification Kits \(RUO\)](#)
- 110 [BIOTECON Diagnostics GmbH virusproof SL SARS-CoV-2 Real-time PCR Kit \(RUO\)](#)
- 111 [BluSense Diagnostics ApS ViroTrack COVID IgA+IgM/IgG/Total Ig Ab \(RUO\)](#)
- 112 [Boditech Inc. ExAmplar COVID-19 real-time PCR kit \(L\) \(RUO\)](#)
- 113 [Boditech Med, Inc. AFAS COVID-19 Ab, IgM/IgG \(automated\) \(RUO\)](#)
- 114 [Boditech Med, Inc. AFAS COVID-19, Viral Antigen \(automated\) \(RUO\)](#)
- 115 [Boditech Med, Inc. Ichroma COVID-19, viral antigen \(manual\) \(RUO\)](#)
- 116 [Boditech Med, Inc. Ichroma COVID-19 Ab, IgM/IgG \(manual\) \(RUO\)](#)
- 117 [Bright Line Research Rona 19 Screen Coronavirus \(SARS-CoV-2\) IgG/IgM Rapid Test \(in development\)](#)
- 118 [BTNX Inc. Rapid Response COVID-19 IgG/IgM Test Cassette \(Whole Blood/Serum/Plasma\) \(RUO\)](#)
- 119 [Camtech Diagnostics Pte Ltd Camtech COVID-19 Rapid Test Kit](#)
- 120 [Canary Health Technologies AiroStotleCV19 \(Breath VOCs\) \(In development\)](#)
- 121 [Cancer Rop Co., Ltd. Q-Sens® 2019-nCoV Detection Kit \(CE-IVD\)](#)
- 122 [Canvax Biotech qMAXsentm Coronavirus \(SARS-CoV-2\) RT-qPCR Detection Kit \(WHO EU\)](#)
- 123 [CapitalBio Technology Respiratory Virus Nucleic Acid Detection Kit \(Isothermal Amplification Chip Method\) \(automated near-POC NAT - China-FDA\)](#)
- 124 [Caspr Biotech Phantom 1.0 Dx \(near-POC\) \(In development\)](#)
- 125 [Cellex Inc. Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test \(US FDA-EUA - CE-IVD\)](#)
- 126 [CellSafe FastRT-qPCR COVID19 detection kit \(RUO\)](#)
- 127 [CellSafe Qplex COVID-19 RT-qLAMP Assay \(RUO\)](#)
- 128 [CellSafe UltraFast RT-qLAMP COVID19 Detection kit \(RUO\)](#)
- 129 [Cepheid Xpert Xpress SARS-CoV-2 \(US FDA-EUA\)](#)
- 130 [CerTest Biotec, S.L. VIASURE SARS-CoV-2 Real Time PCR Detection Kit \(CE-IVD\)](#)
- 131 [CerTest Biotec, S.L. VIASURE SARS-CoV-2 S gene Real Time PCR Detection Kit adapted for BD MAX™ System \(CE-IVD\)](#)
- 132 [CerTest Biotec, S.L. VIASURE SARS-CoV-2 S gene Real Time PCR Detection Kit \(CE-IVD\)](#)
- 133 [Changsha Sinocare Inc. SARS-CoV-2 Antibody Test Strip \(Colloidal Gold Method\) \(CE-IVD\)](#)
- 134 [Chaozhou Hyribio Biochemistry Ltd COVID-19 Real-Time PCR Kit \(manual & automated lab-based\) \(CE-IVD\)](#)
- 135 [Chengdu Fengji Biotechnology Co., Ltd of China 2019-nCoV Nucleic acid detection kit \(multiplex PCR fluorescent probe method\) \(RUO\)](#)
- 136 [ChromaCode, Inc. ChromaCode COVID-19 Six Target Single Well Assay \(RUO\)](#)
- 137 [Clonit quanty-CONV-19 \(CE-IVD\)](#)
- 138 [Co-diagnostics Logix Smart Coronavirus disease 2019 \(COVID-19\) \(CE-IVD\)](#)
- 139 [Core Technology Co., Ltd COVID-19 IgM/IgG Ab Test \(CE-IVD\)](#)
- 140 [Coris BioConcept COVID-19 Ag Respi-Strip \(CE-IVD\)](#)
- 141 [Coyote Bioscience 2019-nCoV Prep Free QPCR Assay \(near-POC\) \(In development\)](#)
- 142 [Creative Biolabs SARS-CoV-2 \(2019-nCoV\) Nucleoprotein Protein ELISA Kit \(RUO\)](#)
- 143 [Creative Biolabs SARS-CoV-2 \(2019-nCoV\) Spike Protein ELISA Kit \(RUO\)](#)
- 144 [Creative Diagnostics SARS-CoV-2 Antigen ELISA Kit \(RUO\)](#)
- 145 [Creative Diagnostics SARS-CoV-2 IgG ELISA Kit \(RUO\)](#)
- 146 [Creative Diagnostics SARS-CoV-2 IgM ELISA Kit \(RUO\)](#)
- 147 [Creative Diagnostics SARS-CoV-2 Total Antibody ELISA Kit \(RUO\)](#)
- 148 [Credo Diagnostics Biomedical VitaPCR COVID-19 assay \(RUO\)](#)
- 149 [CTK Biotech, Inc. Aridia COVID-19 Real Time PCR Test \(CE-IVD\)](#)
- 150 [CTK Biotech, Inc. OnSite COVID-19 IgG/IgM Rapid Test \(RUO\)](#)
- 151 [DAAN Gene Co., Ltd of Sun Yat-sen University Novel Coronavirus \(2019-nCoV\) Real Time Multiplex RT-PCR kit \(China FDA-EUA - CE-IVD\)](#)
- 152 [DART Diagnostics DART COVID-19 \(manual\) \(in development\)](#)
- 153 [DIA PRO Diagnostic BioProbes Srl COV19G.CE - ELISA COVID 19 IgG \(CE-IVD\)](#)
- 154 [DIA PRO Diagnostic BioProbes Srl COV19M.CE - ELISA COVID 19 IgM \(CE-IVD\)](#)
- 155 [DIA.PRO Diagnostic BioProbes Srl COV19CONF.CE - ELISA COVID 19 IgG Confirmatory \(CE-IVD\)](#)
- 156 [Diagnostics for the Real World Ltd SAMBA II COVID-19 Test \(near-POC NAT\) \(CE-IVD\)](#)
- 157 [DiaSorin Molecular, LLC Simplexa™ COVID-19 Direct RT-PCR Kit \(CE-IVD\)](#)
- 158 [Diatheva SRL COVID-19 PCR DIATHEVA Detection kit \(CE-IVD\)](#)
- 159 [DNA Software, Inc. Upper Respiratory Virus Panel, multiplex PCR, COVID-19, Influenza A B \(in development\)](#)
- 160 [DNA XPERTS XPERTS COVID19 - FAST RT-PCR KIT, Real time PCR kit for COVID19 detection \(RUO\)](#)
- 161 [DRG International, Inc. COVID-19 IgG, EIA-6146 \(CE-IVD\)](#)
- 162 [DRG International, Inc. COVID-19 IgM, EIA-6147 \(CE-IVD\)](#)
- 163 [Dynamiker Biotechnology \(Tianjin\) Co., Ltd Novel Coronavirus\(2019-nCoV\)RT-PCR Kit \(RUO\)](#)
- 164 [Dynamiker Biotechnology \(Tianjin\) Co., Ltd. 2019 nCoV IgG/IgM Rapid Test \(CE-IVD\)](#)
- 165 [Eagle Biosciences Inc. COVID-19 IgG ELISA Assay \(RUO\)](#)
- 166 [Eagle Biosciences Inc. COVID-19 IgM ELISA Assay \(RUO\)](#)
- 167 [Edinburgh Genetics Limited Edinburgh Genetics Complete Whole Blood Collection Kit \(RUO\)](#)
- 168 [Edinburgh Genetics Limited Edinburgh Genetics COVID-19 Colloidal Gold Immunoassay Testing Kit, IgG/IgM Combined \(CE-IVD\)](#)
- 169 [Edinburgh Genetics Limited Edinburgh Genetics COVID-19 Real-Time PCR Testing Kit \(China FDA-EUA - CE-IVD\)](#)
- 170 [Edinburgh Genetics Limited Edinburgh Genetics Virus Swab Sampling Kit \(RUO\)](#)
- 171 [Elabsience Novel Coronavirus \(SARS-CoV-2\) Nucleic Acid Assay Kit \(RT-PCR\) \(RUO\)](#)
- 172 [Elabsience SARS-CoV-2 \(2019-nCoV\) IgG/IgM Lateral Flow Assay Kit \(Whole Blood/ Serum/ Plasma\) \(RUO\)](#)
- 173 [Elisabeth Pharmacon spol. s.r.o. EilGene COVID19 BASIC A RT \(CE-IVD\)](#)
- 174 [Epitope Diagnostics, Inc. EDI™ Novel Coronavirus COVID-19 IgG ELISA Kit \(CE-IVD\)](#)
- 175 [Epitope Diagnostics, Inc. EDI™ Novel Coronavirus COVID-19 IgM ELISA Kit \(CE-IVD\)](#)
- 176 [Eryigit Endustriyel Makina ve Tibbi Cihazlar Senteligo Covid-19 qRT PCR Detection Kit \(CE-IVD\)](#)
- 177 [Eurobio Scientific EurobioPlex SARS-CoV-2 Multiplex \(CE\)](#)

- 178 [EUROIMMUN AG Anti-SARS-CoV-2 ELISA \(IgA\) \(manual, automated\) \(CE-IVD\)](#)
- 179 [EUROIMMUN AG Anti-SARS-CoV-2 ELISA \(IgG\) \(manual, automated\) \(CE-IVD\)](#)
- 180 [EUROIMMUN AG EURORealTime SARS-CoV-2 \(CE-IVD\)](#)
- 181 [FABPulous/DTwist BV DTwist](#)
- 182 [Fast Track Diagnostics Luxembourg S.à r.l., a Siemens Healthineers Company FTD-114 SARS-CoV-2 \(manual & lab-based NAT\) \(In development\)](#)
- 183 [FemtoDx COVID-19 Antibody Test \(in development\)](#)
- 184 [FemtoDx COVID-19 Rapid Home Nucleic Acid Test \(in development\)](#)
- 185 [Fluxergy LLC Fluxergy Sample-to-Answer SARS-CoV-2 RT-PCR \(In development\)](#)
- 186 [GenBody, Inc. GenBody COVID-19 IgM/IgG DUO \(RUO\)](#)
- 187 [GenBody, Inc. GenBody COVID-19 IgM/IgG \(CE-IVD\)](#)
- 188 [GenBody, Inc. GenBody FIA COVID-19 IgM/IgG \(manual\) \(RUO\)](#)
- 189 [Gencurix Inc. GenePro COVID-19 Detection Test v2 \(CE-IVD\)](#)
- 190 [Gencurix Inc. GenePro COVID-19 Detection Test \(CE-IVD\)](#)
- 191 [Gene Biosystems Gene Bio COVID-19 Qualitative Real Time PCR Kit Ver. 1.0 \(RUO\)](#)
- 192 [genedrive plc Genedrive®96 SARS-CoV-2 Kit \(In development\)](#)
- 193 [GeneFirst Ltd Respiratory Pathogen Panel \(RUO\)](#)
- 194 [GeneFirst Ltd The Novel Coronavirus \(2019-nCoV\) Nucleic Acid Test Kit \(RUO\)](#)
- 195 [GeneMatrix Inc. NeoPlex COVID-19 Detection Kit \(CE-IVD\)](#)
- 196 [GeneMe Advanced One Step FAST Covi19 KIT Two Genes Set \(CE-IVD\)](#)
- 197 [geneOmbio Technologies Pvt. Ltd geneOmbio COVID-19 rt-LAMP test \(RUO\)](#)
- 198 [General Biologicals Corporation GB SARS-CoV-2 Real Time RT-PCR \(RUO\)](#)
- 199 [GeneReach Biotechnology Corporation POCKIT™ Central SARS-CoV-2 \(orf 1ab\) Premix Reagent \(RUO\)](#)
- 200 [Genesystem, Co. Ltd SMARTCHECK SARS-CoV2 Detection Kit \(RUO\)](#)
- 201 [GeneTex International Corporation ACE2 antibody \[N1N2\], N-term \(GTX101395\) \(RUO\)](#)
- 202 [GeneTex International Corporation SARS-CoV / SARS-CoV-2 \(COVID-19\) nucleocapsid antibody \[6H3\] \(GTX632269\) ELISA \(RUO\)](#)
- 203 [GeneTex International Corporation SARS-CoV / SARS-CoV-2 \(COVID-19\) spike antibody \[1A9\] \(GTX632604\) \(RUO\)](#)
- 204 [GeneTex International Corporation SARS-CoV-2 \(COVID-19\) nucleocapsid antibody \(GTX135357\) ELISA \(RUO\)](#)
- 205 [GeneTex International Corporation SARS-CoV-2 \(COVID-19\) nucleocapsid protein \(GTX135357-pro\) \(RUO\)](#)
- 206 [GeneTex International Corporation SARS-CoV-2 \(COVID-19\) spike antibody \(GTX135360\) ELISA \(RUO\)](#)
- 207 [Genetic Signatures Limited EasyScreen™ Pan-Coronavirus/SARS-CoV-2 Detection Kit \(RUO\)](#)
- 208 [Genitech NSAN Pharmaceutical Pvt. Ltd COVID-19 IgG/IgM Rapid Test Cassette \(Whole Blood/Serum/Plasma\) \(CE-IVD\)](#)
- 209 [GenMark Diagnostics ePlex® SARS-CoV-2 Test \(US-FDA EUA\)](#)
- 210 [GenomCan Inc. Fluorescent PCR Probe Detection Kit for SARS-CoV-2 \(CE-IVD\)](#)
- 211 [Genomica Sau CLART COVID-19 \(CE-IVD\)](#)
- 212 [Genomica Sau qCOVID-19 \(CE-IVD\)](#)
- 213 [Genomictree, Inc. AccuraTect RT-qPCR SARS-CoV-2 \(CE-IVD\)](#)
- 214 [GenScript 2019-nCoV qRT-PCR Detection Assay \(RUO\)](#)
- 215 [Gensure Biotech, Inc. OZO Diamond - OZO SARS-CoV-2 IgM + IgG Method \(CE-IVD\)](#)
- 216 [Gensure Biotech, Inc. OZO Gold - OZO SARS-CoV-2 IgG Method \(CE-IVD\)](#)
- 217 [Gensure Biotech, Inc. OZO Silver - OZO SARS-CoV-2 IgM Method \(CE-IVD\)](#)
- 218 [gerbion GmbH & Co., KG virellaSARS-CoV-2 seqc real time RT-PCR Kit 2.0 \(CE-IVD\)](#)
- 219 [Getein Biotech, Inc. Novel Coronavirus \(2019-nCoV\) Real-time RT-PCR Kit \(CE-IVD\)](#)
- 220 [Getein Biotech, Inc. One Step Test for Novel Coronavirus \(2019-nCoV\) IgM/IgG Antibody \(Colloidal Gold\) \(CE-IVD\)](#)
- 221 [GNA Biosolutions GmbH SARS-CoV-2 Detection Kit on portable PCA Analyzer \(In development\)](#)
- 222 [Goldsite Diagnostics Inc. SARS-CoV-2 IgG/IgM Kit \(manual\) \(CE-IVD\)](#)
- 223 [Great Basin – Vela Operations SARS-CoV-2 Direct Test \(in development\)](#)
- 224 [Guangdong Huayin Medicine Science Co., Ltd Detection Kit for 2019-nCoV RNA \(RT-PCR Fluorescence Probing\) \(Lyophilised\) \(in development\)](#)
- 225 [Guangzhou Darui Biotechnology Co.,Ltd 2019 Novel Coronavirus \(2019-nCoV\) IgG Antibody Detection Kit \(ELISA Method\) \(RUO\)](#)
- 226 [Guangzhou Darui Biotechnology Co.,Ltd 2019 Novel Coronavirus \(2019-nCoV\) IgM Antibody Detection Kit \(ELISA Method\) \(RUO\)](#)
- 227 [Guangzhou Darui Biotechnology Co.,Ltd Novel Coronavirus 2019-nCoV IgG Antibody Detection Kit \(Colloidal Gold Method\) \(RUO\)](#)
- 228 [Guangzhou Darui Biotechnology Co.,Ltd Novel Coronavirus 2019-nCoV IgM Antibody Detection Kit \(Colloidal Gold Method\) \(RUO\)](#)
- 229 [Guangzhou Fenghua Bioengineering, Co. LTD Combined Detection Kit for Novel Coronavirus \(2019-nCoV\) IgM/IgG Antibody \(RUO\)](#)
- 230 [Guangzhou FuleGen Co., Ltd RT-qPCR based SARS-CoV-2 detection kit with SPRS \(Spike-in Reference Standard\) \(In development\)](#)
- 231 [Guangzhou HEAS BioTech Co., Ltd 2019 Novel Coronavirus \(2019-nCoV\) RNA ASSAY \(PCR Fluorescent Probe Method\) \(RUO\)](#)
- 232 [Guangzhou Hyrbio Medicine Technology Ltd Respiratory Virus \(IFVa/b + COVID-19\) Real-Time PCR Kit \(in development\)](#)
- 233 [Guangzhou Supbio Biotechnologies, Inc Supbio SARS-CoV-2 \(ORF1ab/N\) \(Nucleic Acid Detection Kit / PCR-Fluorescent\) \(RUO\)](#)
- 234 [Guangzhou Tebsun Bio-Tech Development Co., Ltd SARS-CoV-2 Nucleic Acid Test \(LAMP\) \(RUO\)](#)
- 235 [Guangzhou Wondfo Biotech Co., Ltd Finecare SARS-CoV-2 Antibody Test \(manual\) \(RUO\)](#)
- 236 [Guangzhou Wondfo Biotech Co., Ltd Wondfo SARS-CoV-2 Nucleic Acid Detection Kit \(RUO\)](#)
- 237 [Hangzhou AllTest Biotech Co., Ltd 2019-nCoV IgG/IgM Rapid Test Cassette \(CE-IVD\)](#)
- 238 [Hangzhou Bigfish Bio-tech Co., Ltd LAMP kit for qualitative detection of SARS-CoV-2 \(in development\)](#)
- 239 [Hangzhou Bigfish Bio-tech Co., Ltd The golden standard of SARS-CoV-2 viral nucleic acid detection \(in development\)](#)
- 240 [Hangzhou Biotest Biotech Co., Ltd COVID-19 IgG/IgM Rapid Test Cassette \(Whole Blood/Serum/Plasma\) \(CE-IVD\)](#)
- 241 [Hangzhou Clongene Biotech Co., Ltd 2019-nCoV IgG/IgM Rapid Test \(CE-IVD\)](#)
- 242 [Hangzhou Dan Wei Biotechnology Co.Ltd 2019-nCoV Direct RT-qPCR Kit \(in development\)](#)
- 243 [Hangzhou Laihe Biotech Co., Ltd LYHER Novel Coronavirus\(2019-nCoV\) IgM/IgG Antibody Combo Test Kit \(Colloidal Gold\) \(Australia TGA - CE-IVD\)](#)
- 244 [Hangzhou Matrix Biotechnology Co., Ltd 2019-nCoV Rapid Test Kit \(RUO\)](#)
- 245 [Hangzhou Matrix Biotechnology Co., Ltd 2019-nCoV Rapid Test Kit \(RUO\)](#)
- 246 [Hangzhou Really Tech Co., Ltd 2019-nCoV LgG/LgM Rapid Test Device \(CE-IVD\)](#)
- 247 [Hangzhou Testsea Biotechnology Co., Ltd New Coronavirus COVID-19 Nucleic Acid Detection Kit \(Fluorescent PCR Method\) \(RUO\)](#)
- 248 [Hecin Scientific, Inc. COVID-19 IgM Antibody Rapid Test Kit \(China FDA - CE-IVD\)](#)
- 249 [Hibergene Hibergene \(lab-based or near-POC\) \(In development\)](#)
- 250 [Hologic Panther Fusion SARS-CoV-2 assay \(US FDA-EUA\)](#)
- 251 [Humasis Humasis COVID-19 IgG/IgM Test \(Korea MFDS - CE-IVD\)](#)
- 252 [Hunan Lituo Biotechnology Co., Ltd COVID-19 IgG/IgM Detection Kit \(Colloidal Gold\) \(CE-IVD\)](#)
- 253 [Hunan Yonghe-Sun Biotechnology Co., Ltd SARS-COV-2 specific antibody test kit \(Immunochromatography\) \(RUO\)](#)
- 254 [Huwel Lifesciences Pvt. Ltd. Quantiplus CORONA Virus \(2019nCoV\) detection kit \(in development\)](#)
- 255 [ICBFM LAMP kit for qualitative detection of SARS-CoV-2 \(RUO\)](#)
- 256 [InBios International, Inc. InBios International Smart Detect SARS-CoV-2 rRT-PCR Kit \(RUO\)](#)
- 257 [InDevR Inc. COVID Serology Kit: Multiplexed Immunoassay \(in development\)](#)

- 258 [Innovita \(Tangshan\) Biological Technology Co., Ltd Novel Coronavirus \(2019-nCoV\) Nucleic Acid Test Kit \(Multiple Fluorescence PCR\) \(RUO\)](#)
- 259 [Innovita Biological Technology Co. Ltd 2019-nCoV Ab Test \(Colloidal Gold\) \(IgM/IgG Whole Blood/Serum/Plasma Combo\) \(CE-IVD\)](#)
- 260 [Intavis Peptide Services GmbH & Co. KG Covid19-hullB CelluSpot™ Array \(RUO\)](#)
- 261 [Intavis Peptide Services GmbH & Co. KG Covid19-hullS CelluSpot™ Array \(RUO\)](#)
- 262 [InTec Products, Inc. Rapid SARS-CoV-2 Antibody \(IgM/IgG\) \(CE-IVD\)](#)
- 263 [InTec Products, Inc. Rapid SARS-CoV-2 Antibody Test \(CE-IVD\)](#)
- 264 [Intrasense SA Myrian Covid-19 \(China FDA-EUA - US FDA-EUA - CE-IVD\)](#)
- 265 [IVDbio Inc. Machine-Free, Fast and Accurate Nucleic Acid Diagnoses System for COVID-19 \(in development\)](#)
- 266 [Jiangsu Bioperfectus Technologies Co. Ltd PerfectLyo SARS-COV-2 Real Time PCR kit \(RUO\)](#)
- 267 [Jiangsu Bioperfectus Technologies Co. Ltd PerfectPOC Novel Corona Virus \(SARS-CoV-2\) Ag Rapid Test Kit \(CE-IVD\)](#)
- 268 [Jiangsu Bioperfectus Technologies Co. Ltd PerfectPOC Novel Corona Virus \(SARS-CoV-2\) IgM/IgG Rapid Test Kit \(CE-IVD\)](#)
- 269 [Jiangsu Bioperfectus Technologies Co. Ltd PerfectQ COVID-19 Coronavirus Real Time PCR Kit \(RUO\)](#)
- 270 [Jiangsu Microdiag Biomedicine Technology Co., Ltd Detection of 2019 novel coronavirus \(2019-nCoV\) by LFD RT-RAA \(RUO\)](#)
- 271 [Jiangsu Microdiag Biomedicine Technology Co., Ltd Novel coronavirus 2019-nCoV nucleic acid detection kit \(rRT-PCR method\) \(RUO\)](#)
- 272 [Jiangsu Qitian Gene Biotechnology Co., Ltd Fluorescent RAA Detection for 2019-nCoV \(RUO\)](#)
- 273 [Jiangsu Superbio Biomedical Technology \(Nanjing\) Co., Ltd Fast SARS-CoV-2 IgM/IgG Antibody Detection Kit \(Colloidal Gold\) \(RUO\)](#)
- 274 [JinHuan Medical Instrument Co., Ltd \(COVID-19\) IgM/IgG Antibody Fast Detection Kit \(Colloidal Gold\) \(CE-IVD\)](#)
- 275 [JN Medsys ProTect Covid-19 RT-qPCR kit \(RUO\)](#)
- 276 [Kephra Diagnostics Kdx COVID-19 Antigen Detection Rapid Test \(in development\)](#)
- 277 [Kephra Diagnostics Kdx COVID-19 IgG and IgM ELISA \(manual\) \(in development\)](#)
- 278 [Kephra Diagnostics Kdx COVID-19 IgG/IgM Rapid Detection Test Kit \(in development\)](#)
- 279 [Kephra Diagnostics Kdx COVID-19 IgG/IgM Rapid Detection Test Kit \(in development\)](#)
- 280 [KH Medical Co. Ltd RADi COVID-19 Detection Kit and RADi COVID-19 Triple Detection Kit \(CE-IVD\)](#)
- 281 [KogeneBiotech Co. Ltd PowerChek™ 2019-nCoV Real-time PCR Kit \(Korea MFDS-EUA - CE-IVD\)](#)
- 282 [KRISHGEN BioSystems Human Anti-SARS-CoV-2 \(Covid-19\) IgG/IgM Rapid Test \(CE-IVD\)](#)
- 283 [KRISHGEN BioSystems Human Anti-SARS-CoV-2 \(Covid-19\) IgM Rapid Test \(RUO\)](#)
- 284 [KRISHGEN BioSystems Human Anti-SARS-CoV-2 \(Covid-19\) Nucleocapsid Protein IgG ELISA \(manual\) \(RUO\)](#)
- 285 [KRISHGEN BioSystems Human Anti-SARS-CoV-2 \(Covid-19\) Spike Protein IgG ELISA \(manual\) \(RUO\)](#)
- 286 [KRISHGEN BioSystems Human SARS-CoV-2 \(Covid-19\) ELISA \(manual\) \(RUO\)](#)
- 287 [KRISHGEN BioSystems SARS-CoV-2 \(Covid-19\) Real-Time PCR Kit \(as per CDC Atlanta guidelines\) \(CE-IVD\)](#)
- 288 [KRISHGEN BioSystems Human SARS-CoV-2 \(Covid-19\) Qualitative ELISA \(manual\) \(RUO\)](#)
- 289 [KrosGen Biotech KrosQuanT SARS-COV-2 \(2019 nCoV\) Realtime PCR Kit \(CE-IVD\)](#)
- 290 [Landcent Europe B.V. Real time RT-PCR Kit for the detection of SARS-CoV-2 \(in development\)](#)
- 291 [Leadgene Biomedical, Inc. Leadgene® SARS/SARS-CoV-2 Antigen Rapid Test Kit \(in development\)](#)
- 292 [Leadgene Biomedical, Inc. Leadgene® SARS/SARS-CoV-2 IgG/IgM Rapid Test Kit \(in development\)](#)
- 293 [Lifeassay Diagnostics Pty Ltd Test-it COVID-19 IgM/IgG Lateral Flow Assay \(in development\)](#)
- 294 [Liming Bio-Products Co., Ltd COVID-19 Antigen Rapid Test Device \(CE-IVD\)](#)
- 295 [Liming Bio-Products Co., Ltd COVID-19 IgG/IgM Combo Rapid Test Device \(CE-IVD\)](#)
- 296 [Liming Bio-Products Co., Ltd COVID-19 IgG/IgM Combo Rapid Test Device \(CE-IVD\)](#)
- 297 [Liming Bio-Products Co., Ltd SrongStep® Novel Coronavirus \(SARS-CoV-2\) Multiplex Real-Time PCR Kit \(CE-IVD\)](#)
- 298 [LOMINA AG SARS-CoV-2 \(COVID19\) IgM/IgG Antibody Fast Detection Kit \(CE-IVD\)](#)
- 299 [Lumex Instruments Microchip RT-PCR COVID-19 detection system \(RUO\)](#)
- 300 [Luminex Corp. ARIES SARS-CoV-2 Assay \(US FDA\)](#)
- 301 [Luminex Corp. NxTAG CoV Extended Panel \(RUO\)](#)
- 302 [Luminostics, Inc. CLIP-COVID19 \(smartphone-read out high sensitivity antigen detection test\) \(in development\)](#)
- 303 [LumiQuick Diagnostics Inc. QuickProfile™ 2019-nCoV IgG/IgM Combo Test Card \(CE-IVD\)](#)
- 304 [Mabsky Bio-Tech Co., Ltd COVID-19 virus \(2019-nCoV\) Dual-Detection Kit \(CE-IVD\)](#)
- 305 [Mabsky Bio-Tech Co., Ltd COVID-19 virus \(2019-nCoV\) Triple-Detection Kit \(Real-Time PCR Method\) \(CE-IVD\)](#)
- 306 [Mabsky Bio-Tech Co., Ltd Influenza A virus, Influenza B virus & COVID-19 virus \(2019-nCoV\) Triple-Detection Kit \(CE-IVD\)](#)
- 307 [Maccura Biotechnology Co., Ltd SARS-CoV-2 Fluorescent PCR \(China FDA-EUA - CE-IVD\)](#)
- 308 [Mammoth Biosciences SARS-CoV-2 DETECTR \(in development\)](#)
- 309 [Medical & Biological Laboratories Co., Ltd FLUOROSEARCH Novel Coronavirus \(SARS-CoV-2\) Detection Kit \(RUO\)](#)
- 310 [Medical Innovation Ventures Sdn Bhd. GenoAmp® Real-Time RT-PCR SARS-CoV-2 \(CE-IVD\)](#)
- 311 [Medical System Coronavirus PCR test \(China FDA - CE-IVD\)](#)
- 312 [MedicalSystem Biotechnology Co., Ltd COVID-19 IgM/IgG Rapid Test Cassette \(CE-IVD\)](#)
- 313 [Mediclone Biotech Pvt Ltd @sight COVID-19 IgG/IgM Rapid Test Kit \(in development\)](#)
- 314 [Medigen Vaccine Biologics Corp. MVC SARS-CoV-2 Convective PCR Diagnostic Device/Kit \(RUO\)](#)
- 315 [Medigen Vaccine Biologics Corp. MVC SARS-CoV-2 Real-Time PCR Diagnostic Kit \(RUO\)](#)
- 316 [MedStar Medical Co., Ltd One-step Direct Realtime PCR Test Kit of 2019-nCoV Coronavirus \(in development\)](#)
- 317 [Mei Ning Kang Cheng China Biotechnology R&D Center, Inc. Corona Virus Disease 2019 \(COVID-19\) IgM/IgG Detection Kit \(RUO\)](#)
- 318 [MiCo Biomed Co. Ltd VERI-QTM PCR 316 COVID-19 detection system \(CE-IVD\)](#)
- 319 [Mikrogen GmbH ampliCube Coronavirus Panel \(CE-IVD\)](#)
- 320 [Mikrogen GmbH ampliCube Coronavirus SARS-CoV-2 \(CE-IVD\)](#)
- 321 [Mobidiag Novadiag® COVID-19 + InfA/B \(lab-based & near-POC\) \(in development\)](#)
- 322 [Module Innovations Private Ltd nCoVSENSe: IgM/ IgG test for spike and N-protein of SARS-CoV 2 \(manual\) \(in development\)](#)
- 323 [Mokobio Biotechnology R&D Center SARS-CoV-2 IgM & IgG Quantum Dot Immunoassay \(CE-IVD\)](#)
- 324 [Molbio Diagnostics Pvt Ltd Truenat SARS CoV-2 \(lab-based or near-POC\) \(India DCGI\)](#)
- 325 [Mologic Ltd Mologic COVID-19 Rapid Test \(in development\)](#)
- 326 [MP Biomedicals MP Rapid 2019-nCoV IgG/IgM \(CE-IVD\)](#)
- 327 [Mylab Discovery Solutions Pvt Ltd PathoDetect CoVID-19 Detection Kit \(RUO\)](#)
- 328 [nal von minden GmbH NADAL® COVID-19 IgG/IgM Test \(243003N-25, 243002N-20, 243001N-10\) \(CE-IVD\)](#)
- 329 [Nanjing BioPoint Diagnostics BioPoint SARS-CoV-2 dlG/total antibody rapid test \(in development\)](#)
- 330 [Nanjing Vazyme Medical Technology Co., Ltd 2019-Novel Coronavirus \(2019-nCoV\) Triplex RT-qPCR Detection Kit \(CE-IVD\)](#)
- 331 [NanoBio Lab, A*STAR Research Entities Isothermal Exponential Amplification for COVID-19 Detection \(RUO\)](#)
- 332 [NanoEnTek COVID-19 IgG/IgM Duo \(automated\) \(CE-IVD\)](#)
- 333 [Nantong Egens Biotechnology Co., Ltd COVID-19 IgG/IgM Rapid Test Kit \(Colloidal Gold\) \(CE-IVD\)](#)
- 334 [National Institute for Control of Vaccines and Biologicals Accupid nCoV 2019 Detection Kit \(RUO\)](#)
- 335 [Naturituous LLC Viralert COVID-19 IgG/IgM Antibody Rapid Test Kit \(RUO\)](#)
- 336 [Next Pharma Inc. DiaCarta's QuantiVirusTMSARS-CoV-2 Test \(US FDA-EUA - CE-IVD\)](#)
- 337 [Ningbo Health Gene Technologies Co. Ltd. SARS-CoV-2 Virus Detection Diagnostic Kit \(RT- qPCR Method\) \(RUO\)](#)

- 338 [Nirmidas Biotech, Inc. pGOLD COVID-19 IgG/IgM/IgA Microarray Test \(RUO\)](#)
- 339 [Nirmidas Biotech, Inc. Rapid COVID-19 \(SARS-CoV-2\) IgM/IgG Antibody Detection Kit](#)
- 340 [Norgen Biotek Corp 2019-nCoV TaqMan RT-PCR Kit \(Catalog# TM67100\) \(RUO\)](#)
- 341 [Novacyt/primerdesign_genesig Real-Time PCR COVID-19 \(USA FDA-EUA - WHO-EUL - CE-IVD\)](#)
- 342 [NovaTec Immundiagnostica GmbH NovaLisa® COVID-19 \(SARS-CoV-2\) IgA \(RUO\)](#)
- 343 [NovaTec Immundiagnostica GmbH NovaLisa® COVID-19 \(SARS-CoV-2\) IgG \(RUO\)](#)
- 344 [NovaTec Immundiagnostica GmbH NovaLisa® COVID-19 \(SARS-CoV-2\) IgM \(RUO\)](#)
- 345 [OPTOLANE Technologies Inc. Dr. PCR COVID-19 Viral Load 20K \(lab-based\) \(RUO\)](#)
- 346 [OsangHealthcare GeneFinder COVID-19 Plus RealAmp Kit \(CE-IVD\)](#)
- 347 [Paragon Genomics Inc. CleanPlex SARS-CoV-2 Research and Surveillance NGS Panel \(RUO\)](#)
- 348 [PaxGen Bio Co. Ltd PaxView COVID-19 real time RT-PCR \(RUO\)](#)
- 349 [PCL Inc. PCL COVID19 Ag Rapid FIA \(CE-IVD\)](#)
- 350 [PCL Inc. PCL COVID19 IgG/IgM Rapid Gold \(Korea MFDS - CE-IVD\)](#)
- 351 [PCL Inc. PCLMD™ nCoV one step RT-PCR Kit \(Korea MFDS - CE-IVD\)](#)
- 352 [PDF 2pg flyer](#)
- 353 [PEPperPRINT GmbH PEPperCHIP® SARS-CoV-2 Proteome Microarray \(manual\) \(CE-IVD\)](#)
- 354 [PerGrande BioTech Development Co., Ltd SARS-CoV-2 Antibody Detection Kit \(Colloidal Gold Immunochromatographic assay\) \(CE-IVD\)](#)
- 355 [PerkinElmer Inc. PerkinElmer® SARS-CoV-2 Realtime RT-PCR Assay \(CE-IVD\)](#)
- 356 [PharmaAct AG COVID-19 rapid test \(CE-IVD\)](#)
- 357 [Pinpoint Science Inc. Pinpoint Covid-19 Screening Assay – Electrical detection of SARS-CoV-2 nucleocapsid protein using nanosensors and aptamer \(in development\)](#)
- 358 [Pinpoint Science Inc. Pinpoint Covid-19 Screening Assay \(in development\)](#)
- 359 [Pishtaz Teb SARS-CoV-2 IgG ELISA Kit \(CE-IVD\)](#)
- 360 [Pishtaz Teb SARS-CoV-2 IgM ELISA Kit \(CE-IVD\)](#)
- 361 [PlexBio Co., Ltd PlexBio CoVid19/SARS/Influenza A, B Detection kit \(in development\)](#)
- 362 [Prantae Solutions Pte Ltd EyeRa-Covid \(in development\)](#)
- 363 [Predigen Inc. HR-PreV \(in development\)](#)
- 364 [Premier Medical Corporation Pvt. Ltd SureStatus COVID-19 \(SARS-CoV-2\) Card Test \(in development\)](#)
- 365 [Premier Medical Corporation Pvt. Ltd SureStatus COVID-19 \(SARS-CoV-2\) EIA Test \(in development\)](#)
- 366 [PRIMA Lab S.A. PRIMA COVID-19 IgG/IgM Rapid Test \(For Professional Use\) \(CE-IVD\)](#)
- 367 [PRIME4DIA Co., Ltd P4DETECT COVID-19 Ag \(RUO\)](#)
- 368 [PRIME4DIA Co., Ltd P4DETECT COVID-19 IgM/IgG \(RUO\)](#)
- 369 [PRIME4DIA Co., Ltd P4DETECT COVID-19 SAg \(RUO\)](#)
- 370 [Progenie Molecular S.L.U. RealCycler CORO \(CE-IVD\)](#)
- 371 [Promis Diagnostics SensDect RT-qPCR SARS CoV-2 \(RUO\)](#)
- 372 [QIAGEN GmbH QIAstat-Dx Respiratory Panel 2019-nCoV \(US FDA-EUA - CE-IVD\)](#)
- 373 [Qingdao Hightop Biotech Co., Ltd Hightop COVID-19 IgM/IgG Ab Rapid Test Kit \(in development\)](#)
- 374 [Qingdao Jianma Gene Technology Co., Ltd. COVID-19 Nucleic Acid Detection Kit \(Rapid PCR Fluorescence Method\) \(RUO\)](#)
- 375 [Quansys Biosciences Human COVID-19 \(2-plex\) \(in development\)](#)
- 376 [QuantuMDx QPOC™ Point of Care NAT for SARS-CoV-2 \(In development\)](#)
- 377 [QuantuMDx QuantuMDx NAT for SARS-CoV-2 \(In development\)](#)
- 378 [Quidel Lyra SARS-CoV-2 Assay \(US FDA-EUA\)](#)
- 379 [QuikPath Pte Ltd QuikPath Covid-19 POC molecular test \(in development\)](#)
- 380 [Quotient Limited SA Mosaic™ COVID-19 Antibody Microarray \(in development\)](#)
- 381 [RainSure Scientific Co., Ltd RainSure COVID-19 dPCR Detection Kit \(lab-based\) \(RUO\)](#)
- 382 [Randox Laboratories Ltd Extended Coronavirus Array \(lab-based or near-POC\) \(RUO\)](#)
- 383 [Rapid Bio LLC Rapid test for IgM/IgG antibodies against SARS-COV-2 \(RUO\)](#)
- 384 [RapiGEN Inc. BIOCREDIT COVID-19 Ag \(CE-IVD\)](#)
- 385 [RapiGEN Inc. BIOCREDIT COVID-19 IgG \(RUO\)](#)
- 386 [RapiGEN Inc. BIOCREDIT COVID-19 IgG+IgM Duo \(CE-IVD\)](#)
- 387 [RayBiotech Coronavirus \(SARS-CoV-2\) IgM/IgG Test Kit \(Colloidal Gold\) \(CE-IVD\)](#)
- 388 [R-Biopharm AG RIDA® GENE SARS-CoV-2 RUO \(PG6815RUO\) \(RUO\)](#)
- 389 [Regulatory contact](#)
- 390 [RetroVirox Inc. SARS-CoV-2 Pseudovirus assay for Neutralizing Antibodies \(RUO\)](#)
- 391 [Ring Biotechnology Co., Ltd COVID-19 IgM/IgG Rapid Test Kit \(CE-IVD\)](#)
- 392 [Roche Molecular Diagnostics cobas® SARS-CoV-2 \(for use on the cobas® 6800/8800 Systems\) \(US FDA-EUA - WHO EUL\)](#)
- 393 [RPC Diagnostic Systems Anti-SARS-CoV-2 enzyme immunoassay for the detection of antibodies to SARS-CoV-2 \(COVID-19\) \(in development\)](#)
- 394 [Sacace BIOTECNOLOGIES SARS-CoV-2 Real-TM \(CE-IVD\)](#)
- 395 [Sansure Biotech, Inc. Novel Coronavirus \(2019-nCoV\) Nucleic Acid Diagnostic Kit \(PCR-Fluorescence Probing\) \(China FDA-EUA - CE-IVD\)](#)
- 396 [Scope Fluidics SA PCR|COV \(in development\)](#)
- 397 [SD BIOSENSOR Inc. STANDARD M nCoV Real-Time Detection Kit \(Korea MFDS-EUA - CE-IVD\)](#)
- 398 [SD BIOSENSOR, Inc. STANDARD F COVID-19 Ag FIA \(CE-IVD\)](#)
- 399 [SD BIOSENSOR, Inc. STANDARD Q COVID-19 Ag Test \(CE-IVD\)](#)
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- 402 [Seegene, Inc. Allplex 2019-nCoV assay \(Korea MFDS-EUA - CE-IVD\)](#)
- 403 [Selfdiagnostics Deutschland GmbH Multitest \(in development\)](#)
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- 407 [Sentinel CH STAT-NAT® Covid-19 HK and STAT-NAT® Covid-19 B \(CE-IVD\)](#)
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EUA: Emergency Use Authorization
HSA: Health & Safety/Sciences Authority
MFDS: Ministry of Food & Drug Safety
NRA: National Regulatory Authority
RUO: Research Use Only
TGA: Therapeutic Goods Administration
WHO EUL: World Health Organization Emergency Use Listing Procedure

Sources:
<https://www.finddx.org/covid-19/pipeline/>

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