



List-of-authorized-Serology-Antibody-Test-Kits-03072020

No.	SAHPRA Licence Holder	Product Name	Product Description	Original Manufacturer	Status
1	Tiptop Trade (Pty) Ltd	Orient Gene Covid-19 Rapid Test Kit	Point-of-care Serology Antibody Rapid Test Kit	Zhejiang Orient Gene Biotech	Section 21 Authorisation: MD21.202006/07

List-of-authorized-Molecular-Test-Kits- 03072020

No.	SAHPRA Licence Holder	Product Name	Product	Original Manufacturer
1	Abbott Laboratories South Africa (Pty) Ltd	Abbott RealTime SARS-CoV-2 Assay	RT-PCR	Abbott Molecular Inc
2	ACS Pharma Access Health Solutions (Pty)Ltd	ACS 2019-nCovid Nucleic acid-based diagnostic reagent kit	PCR	Sansure Biotech Inc
3	BECTON DICKINSON PTY LTD	Viasure SARS-CoV-2 S gene Real Time PCR Detection Kit	RT-PCR	CerTest BIOTEC S.L.
4	BECTON DICKINSON PTY LTD	BD SARS-CoV-2 reagents for BD MAX™ system	RT-PCR	GeneOhm Sciences Canada Inc. t/a bd diagnostics
5	Biomerieux South Africa (Pty) Ltd	SARS-CoV-2-R-GENE, SARS-CoV-2 nucleic acid IVD, kit, nucleic acid technique (NAT), 120 tests	RT-PCR	bioMérieux SA
6	Biomerieux South Africa (Pty) Ltd	ARGENE® SARS-COV-2 R-GENE	RT-PCR	bioMérieux SA
7	Biomerieux South Africa (Pty) Ltd	BioFire COVID-19 Test	RT-PCR	BioFire Defense, LLC
8	Biomerieux South Africa (Pty) Ltd	Biofire respiratory panel	PCR	Biofire Diagnostics, LLC
9	Celtic Molecular Diagnostics (Pty) Ltd	Genesig RT PCR Assay	PCR	Primerdesign Ltd
10	CEPHEID	Xpert® Xpress SARS-CoV-2	RT- PCR	Cepheid
11	EUROIMMUN Medical Laboratory Diagnosti	SARS-CoV-2 Real time PCR	RT-PCR	Medizinische Labordiagnostika AG, Deutschland
12	HAIN LIFESCIENCES SA (Pty) Ltd	Genesig Real-Time PCR Coronavirus (COVID-19) CE IVD	PCR	Primer Design Ltd
13	Hea.IT (Pty) Ltd	iAMP COVID-19 Detection Kit	RT -PCR	ATILA BIOSYSTEMS INC
14	Humor Diagnostica (Pty) Ltd	GeneFinder COVID 19 PLUS	Reagents	Osang Healthcare Co., Ltd
15	Imperial Logistics South Africa (Pty) Ltd	COVID-19 (SARS-CoV-2) nucleic acid test kit	PCR	Wuhan EasyDiagnosis Biomedicine Co., Ltd
16	Inqaba Biotechnical Industries (Pty) Ltd	Allplex 2019-NCoV Assay	PCR	Seegene Inc.
17	LABOTEC (Pty) Ltd	Novel Corona virus (2019-nCov) Realtime multiplex RT PCR KIT	RT- PCR	Liferiver -Shanghai ZJ Biotech
18	LTC Tech SA (Pty) Ltd	TaqPath™ COVID-19 CE-IVD RT-PCR Kit	PCR	Life Technologies Corporation (Pleasanton)
19	LTC Tech SA (Pty) Ltd	TaqPath™ COVID-19 Combo Kit 1000	PCR	Life Technologies Corporation (Pleasanton)
20	LTC Tech SA (Pty) Ltd	TaqPath™ COVID-19 Combo Kit 100	PCR	Life Technologies Corporation (Pleasanton)
21	Mbabala Consulting (Pty) Ltd	Multiple respiratory virus nuceic acid IVD kit, nucleic acid technique (NAT)	Coronavirus	Shanghai ZJ Bio-Tech
22	PerkinElmer South Africa Pty Ltd	PerkinElmer® SARS-CoV-2 Real-time RT-PCR Assay	RT- PCR	Suzhou SYM-BIO Lifescience Co. Ltd
23	Roche Diagnostics (Pty) Ltd	cobas SARS-CoV-2	RT-PCR	Roche Diagnostics GmbH
24	RX MEDICAL	Logix Smart Coronavirus Disease 2019 (COVID-19) ki	RT -PCR	Co-Diagnostics, Inc
25	South Africa Seaways	GeneFinder COVID-19 Plus RealAmp Kit	PCR	Osang Healthcare Co Ltd
26	Supra Healthcare Johannesburg (Pty) Ltd	SARS-CoV-2 Nucleic Acid Detection Kit	RT-PCR	Bioer Technology Co., Ltd.
27	Supra Healthcare Johannesburg (Pty) Ltd	Novel Corona Virus (2019-nCov) Nucleic Ac Detection KitAutomatic Nucleic Acid Extractor	RT-PCR	Xi'an TianLong Science and Technology corporate limited.
28	Supra Healthcare Johannesburg (Pty) Ltd	RT-PCR kit for detecting 2019-nCoV	RT-PCR	BGI Europe A/S
29	Supra Healthcare Johannesburg (Pty) Ltd	abTES™ COVID-19 qPCR I Kit	RT-PCR	AIT Biotech Pte. Ltd.
30	Supra Healthcare Johannesburg (Pty) Ltd	COVID-19 (SARS-CoV-2) Nucleic Acid Test Kit	RT-PCR	Wuhan EasyDiagnosis Biomedicine Co., Ltd
31	Tokabio (Pty) Ltd	Reagents for DNA and/or RNA extraction and preparation: bacteria and/or virus	PCR	Sansure Biotech Inc
32	Trendline Trading (Pty) Ltd	Real-time fluorescent RT-PCR kit for detecting 2019-nCoV	RT-PCR	BGI Biotechnology (Wuhan) Co., Ltd.
33	Whitehead Scientific (Pty) Ltd	2019-nCoV CDC EUA Kit, 500 rxn	RT-PCR	Integrated DNA Technologies Inc
34	Whitehead Scientific (Pty) Ltd	Mag-Bind® Viral DNA/RNA 96 Kit, 12 x 96 Preps (#M6246-03)	RT-PCR	Omega BioTek Inc
35	Whitehead Scientific (Pty) Ltd	CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel	RT-PCR	QuantaBio