



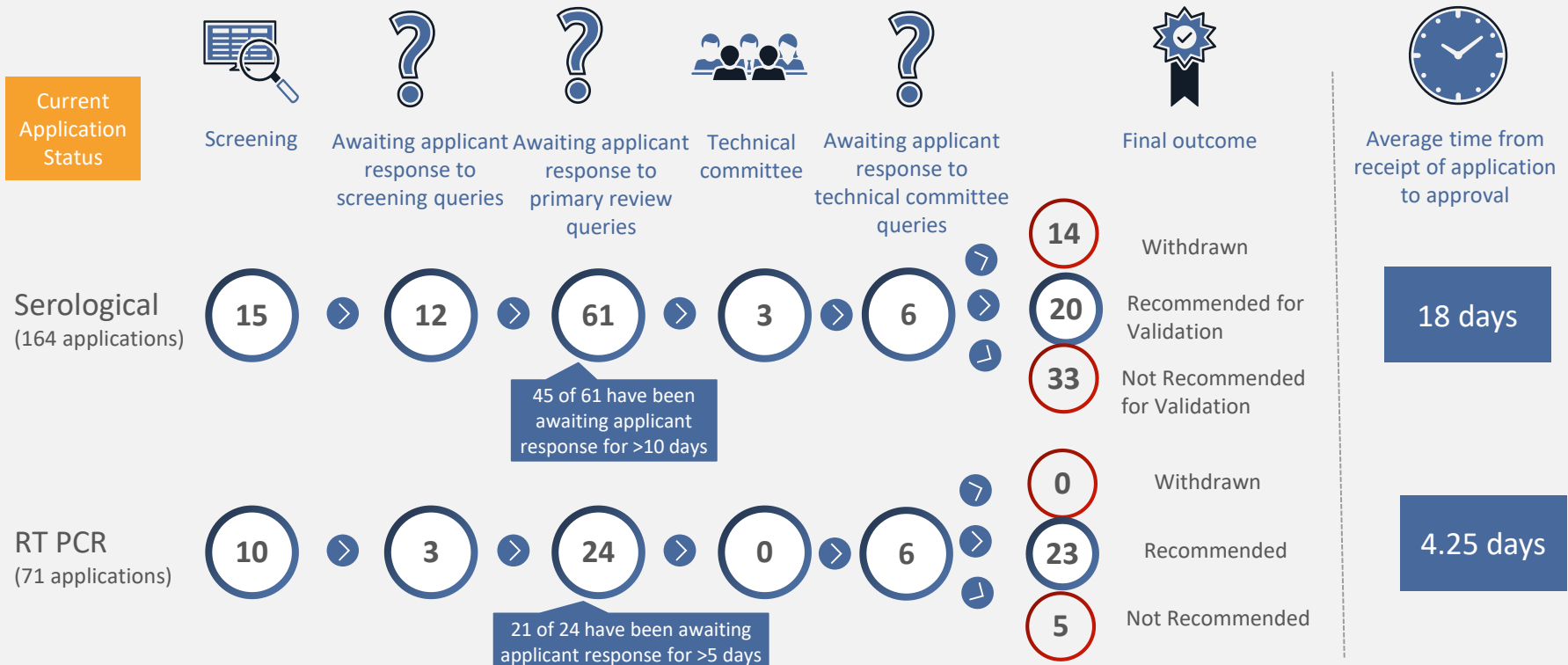
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## Update on COVID-19 Diagnostic tests

# Overview

- SAHPRA has received a total of 71 applications for molecular test kits (PCR) and **23 have been approved for use.**
- 164 applications for serological COVID-19 test kits have been received, these include both point-of-care serological test kits as well as laboratory-based serological test kits.
- To date 20 serological tests have been recommended for validation through the National Health Laboratory Services (NHLS).
  - 1 Serological Point of Care test has been authorized for secondary validation under the National guideline protocol
  - 3 laboratory-based serological test kits have been authorised for validation by the NHLS

# Status update on Covid19 Test Kits



# Approved molecular test kits – PCR

This list is also published on the SAHPRA website <http://www.sahpra.org.za/wp-content/uploads/2020/05/PCR-Tests-Authorised-for-Listing-by-SAHPRA-19.05.2020.pdf>

No.	COMPANY NAME	Product Name	Product Description	Original Manufacturer
1	Hea.IT (Pty) Ltd	iAMP COVID-19 Detection Kit	RT -PCR	ATILA BIOSYSTEMES INC
2	Supra Healthcare Johannesburg (Pty) Ltd	SARS-CoV-2 Nucleic Acid Detection Kit (Fluorescence RT-PCR)	RT-PCR	Bioer Technology Co., Ltd.
3	Supra Healthcare Johannesburg (Pty) Ltd	Novel Corona Virus (2019-nCov) Nucleic Ac Detection Kit Automatic Nucleic Acid Extractor	RT-PCR	Xi'an TianLong Science and Technology corporate limited.
4	Supra Healthcare Johannesburg (Pty) Ltd	RT-PCR kit for detecting 2019-nCoV	RT-PCR	BGI Europe A/S
5	Supra Healthcare Johannesburg (Pty) Ltd	abTES™ COVID-19 qPCR I Kit	RT-PCR	AIT Biotech Pte. Ltd.
6	Abbott Laboratories South Africa (Pty) Ltd	Abbott RealTime SARS-CoV-2 Assay	RT-PCR	Abbott Molecular Inc
7	CEPHEID	Xpert® Xpress SARS-CoV-2	RT- PCR	Cepheid
8	PerkinElmer South Africa Pty Ltd	PerkinElmer® SARS-CoV-2 Real-time RT-PCR Assay	RT- PCR	Suzhou SYM-BIO Lifescience Co. Ltd
9	LABOTEC (Pty) Ltd	Novel Corona virus (2019-nCov) Realtime multiplex RT PCR KIT	RT- PCR	Liferiver -Shanghai ZJ Biotech
10	Trendline Trading (Pty) Ltd	Real-time fluorescent RT-PCR kit for detecting 2019-nCoV	RT-PCR	BGI Biotechnology (Wuhan) Co., Ltd.
11	RX MEDICAL	Logix Smart Coronavirus Disease 2019 (COVID-19) ki	RT -PCR	Co-Diagnostics, Inc
12	Humor Diagnostica (Pty) Ltd	GeneFinder COVID 19 PLUS	Reagents	Osang Healthcare Co., Ltd
13	Whitehead Scientific (Pty) Ltd	2019-nCoV CDC EUA Kit, 500 rxn	PCR	Integrated DNA Technologies Inc
14	Whitehead Scientific (Pty) Ltd	Mag-Bind® Viral DNA/RNA 96 Kit, 12 x 96 Preps (#M6246-03)	PCR	Omega BioTek Inc
15	Whitehead Scientific (Pty) Ltd	CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel	PCR	QuantaBio
16	Roche Diagnostics (Pty) Ltd	cobas SARS-CoV-2	PCR	Roche Diagnostics GmbH
17	BECTON DICKINSON PTY LTD	Viasure SARS-CoV-2 S gene Real Time PCR Detection Kit	PCR	CerTest BIOTEC S.L.
18	Biomerieux South Africa (Pty) Ltd	SARS-CoV-2-R-GENE, SARS-CoV-2 nucleic acid IVD, kit, nucleic acid technique (NAT), 120 tests	PCR	bioMérieux SA
19	Biomerieux South Africa (Pty) Ltd	ARGENE® SARS-COV-2 R-GENE	PCR	bioMérieux SA
20	Biomerieux South Africa (Pty) Ltd	BioFire COVID-19 Test	PCR	BioFire Defense, LLC
21	Supra Healthcare Johannesburg (Pty) Ltd	COVID-19 (SARS-CoV-2) Nucleic Acid Test Kit	RT-PCR	Wuhan EasyDiagnosis Biomedicine Co., Ltd
22	BECTON DICKINSON PTY LTD	BD SARS-CoV-2 reagents for BD MAX™ system	RT-PCR	GeneOhm Sciences Canada Inc. t/a bd diagnostics
23	EUROIMMUN Medical Laboratory Diagnostics South Africa (Pty) Ltd	SARS-CoV-2 Real time PCR	RT-PCR	Medizinische Labordiagnostika AG, Deutschland



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THANK YOU