

ARTG	Sponsor	Manufacturer	Test Kit name	Type of test	TGA validation of analytical sensitivity (Inactivated virus)				Manufacturer provided evidence	
					Batch number	Compliance, of variants tested, to WHO LoD guidelines				Device quality
						Wild Type	Delta	Omicron		
374507	2San Pty Ltd	Hangzhou Laihe Biotech Co Ltd (China)	LYHER Novel Coronavirus (Covid-19) Antigen Test Kit (Colloidal Gold)	POCT					Clinical: Delta and Omicron Analytical: Delta and Omicron	
374507	2San Pty Ltd	Hangzhou Laihe Biotech Co Ltd (China)	LYHER Novel Coronavirus (Covid-19) Antigen Test Kit (colloidal Gold) Self-Test	Self-test					Clinical: Delta and Omicron Analytical: Delta and Omicron	
345192	Abbott Rapid Diagnostics Pty Ltd	Abbott Rapid Diagnostics Jena GmbH (Germany)	Panbio™ COVID-19 Ag Rapid Test Device (Nasopharyngeal)	POCT†					Clinical: Delta, Omicron, Alpha, Beta Analytical: Alpha, Beta, Gamma, Delta, Kappa, Zeta, Theta, Eta and Omicron	

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345192	Abbott Rapid Diagnostics Pty Ltd	Abbott Rapid Diagnostics Jena GmbH (Germany)	Panbio COVID-19 Antigen Self-test (Nasal)	Self-test	41ADG637 A	ü	ü	ü	ü	Clinical: Omicron, Alpha, Beta and Delta Analytical: Alpha, Beta, Gamma, Delta, Kappa, Zeta, Theta, Eta and Omicron
345192	Abbott Rapid Diagnostics Pty Ltd	Abbott Rapid Diagnostics Jena GmbH	Panbio COVID-19 Ag Rapid Test Device (Nasal)	POCT†						Clinical: Omicron, Alpha, Beta and Delta Analytical: Alpha, Beta, Gamma, Delta, Kappa, Zeta, Theta, Eta and Omicron
385179	Alpha-Medics	Qingdao Hightop Biotech Co Ltd (China)	SARS-CoV-2 Antigen Rapid Test	Self-test						Clinical: Delta, Omicron

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	Australia Pty Ltd								Analytical: Alpha, Beta, Gamma, Delta, and Omicron	
385179	Alpha-Medics Australia Pty Ltd	Qingdao Hightop Biotech Co Ltd (China)	SARS-CoV-2 Antigen Rapid Test (without software)	Self-test					Clinical: Delta, Omicron Analytical: Alpha, Beta, Gamma, Delta, and Omicron	
386690	Alpha-Medics Australia Pty Ltd	Hangzhou Sejoy Electronics & Instruments Co Ltd	SARS-CoV-2 Antigen Saliva Lolly Test	Self-test					Clinical: Omicron Analytical: Beta, Gamma, Delta, Omicron	
386690	Alpha-Medics Australia Pty Ltd	Hangzhou Sejoy Electronics & Instruments Co Ltd	SARS-CoV-2 Antigen Saliva Lolly Test (without software)	Self-test					Clinical: Omicron Analytical: Beta, Gamma, Delta, Omicron	

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376310	AM Diagnostics	Hangzhou Alltest Biotech Co Ltd (China)	All Test COVID-19 Antigen Rapid Test (Swab) (INCP-502)	POCT					Clinical: Analytical: Alpha*, Beta*, Gamma*, Delta, and Omicron	
376310	AM Diagnostics	Hangzhou Alltest Biotech Co Ltd (China)	All Test COVID-19 Antigen Rapid Test (Oral fluid) (ICOV-802)	POCT†					Clinical: Analytical: Alpha*, Beta*, Gamma*, Delta, and Omicron	
376310	AM Diagnostics	Hangzhou Alltest Biotech Co Ltd (China)	All Test SARS-CoV-2 Antigen Rapid Test (Nasal Swab) Self-Test (INCP-502H)	Self-test					Clinical: Analytical: Alpha*, Beta*, Gamma*, Delta, and Omicron	
376310	AM Diagnostics	Hangzhou Alltest Biotech Co Ltd (China)	All Test COVID-19 Antigen Rapid Test (Oral Fluid) Self-Test (ICOV-802H)	Self-test	ATCOV211 10029	ü	ü	ü	ü	Clinical: Analytical: Alpha*, Beta*, Gamma*, Delta, and Omicron

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376310	AM Diagnostics	Hangzhou Alltest Biotech Co Ltd	My Covid Test Antigen Rapid Test (Oral Fluid) Self-Test (ICOV-802H)	Self-test†					Clinical: Analytical: Alpha*, Beta*, Gamma*, Delta, and Omicron	
333341	APAC Security Pty Ltd	Hangzhou Clongene Biotech Co Ltd (China)	Clungene COVID-19 Antigen Rapid Test	POCT†					Clinical: Delta and Omicron Analytical: Alpha, Beta, Gamma, Delta, and Omicron	
333341	APAC Security Pty Ltd	Hangzhou Clongene Biotech Co Ltd (China)	Clungene COVID-19 Antigen Rapid Test (Self - testing)	Self-test	2022020145	ü	ü	ü	ü	Clinical: Delta and Omicron Analytical: Alpha, Beta, Gamma, Delta, and Omicron
346587	Atomo Diagnostics	Access Bio Inc (United States Of America)	Atomo Covid-19 Antigen Test	POCT						Clinical: Delta, Omicron

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	cs Limited								Analytical: Alpha*, Beta*, Delta*, Kappa*, Epsilon*, Lambda* and Omicron	
382031	AusDiagnos tics Pty Ltd	Acon Biotech (Hangzhou) Co Ltd (China)	Flowflex SARS-CoV-2 Antigen Rapid Test (Self Testing)	Self-test					Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Kappa*, Eta*, Mu*, Epsilon*, Iota*, Lambda*, Zeta* Theta*, Delta and Omicron	
385653	Australia Biotech Pty Ltd	Guangzhou Wondfo Biotech Co Ltd (China)	Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)	Self-test					Clinical: Delta, Omicron Analytical: Alpha, Beta, Delta, Omicron	

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375418	Australia Health Products Central Pty Ltd	Hangzhou Testsea Biotechnology Co Ltd (China)	Cellife Covid-19 Antigen Test Cassette	POCT					Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Kappa*, Mu*, Lambda*, Iota*, Epsilon*, Eta*, Theta*, Zeta*, Delta and Omicron	
375418	Australia Health Products Central Pty Ltd	Hangzhou Testsea Biotechnology Co Ltd (China)	Cellife Covid-19 Antigen Test Cassette for Self	Self-test					Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Kappa*, Mu*, Lambda*, Iota*, Epsilon*, Eta*, Theta*, Zeta*, Delta and Omicron	

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344030 Cancelled by sponsor	Becton Dickinson Pty Ltd	Becton Dickinson and Company (United States Of America)	BD Veritor™ System for Rapid Detection of SARS-CoV-2	POCT	1155606	ü	ü	ü	ü	Clinical: Delta Analytical: Alpha, Beta, Gamma, Kappa, Iota, and Omicron.
334043	BGI Health (AU) Company Pty Ltd	BGI Europe A/S (Denmark)	SARS-CoV-2 Virus Antigen Detection Kit (Colloidal Gold Method)	Self-test						Clinical: Delta and Omicron Analytical: Delta
334043	BGI Health (AU) Company Pty Ltd	BGI Europe A/S (Denmark)	SARS-CoV-2 Virus Antigen Detection Kit (Colloidal Gold Method)	POCT						Clinical: Delta and Omicron Analytical: Delta
387550	BGI Health (AU)	Innovita (Tangshan) Biological	2019 nCoV Ag Test (Latex Chromatography Assay) – Self- test	Self-test						Clinical: Delta, and Omicron

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	Company Pty Ltd	Technology Co Ltd (China)							Analytical: Delta, Beta and Omicron	
387550	BGI Health (AU) Company Pty Ltd	Innovita (Tangshan) Biological Technology Co Ltd (China)	2019 nCoV Ag Test (Latex Chromatography Assay) – POCT	POCT					Clinical: Delta, Beta and Omicron Analytical: Delta, Beta and Omicron	
387020	Big Start Pty Ltd	Guangzhou Decheng Biotechnology Co Ltd (China)	2019-nCoV Ag Rapid Test Kit	Self-test					Clinical: Delta, Omicron Analytical: Alpha, Kappa, Delta, Omicron	
345219	Bioclect Pty Ltd	SD Biosensor Inc (Korea - Republic of)	STANDARD™ Q COVID-19 Ag Test	POCT	58327KAA C1	ü	ü	ü	ü	Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Delta, Kappa*, Epsilon*, Iota*,

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					Batch number	Compliance, of variants tested, to WHO LoD guidelines			Device quality	
						Wild Type	Delta	Omicron		
										Lambda*, Zeta*, Delta and Omicron
374065	Cole Workwear PL	Guangzhou Decheng Biotechnology Co Ltd (China)	2019-nCoV Ag Saliva Rapid Test Card	POCT	05821068C	ü	ü	ü	ü	Clinical: Delta, Omicron Analytical: Beta*, Gamma*, Epsilon*, Alpha, Kappa, Delta and Omicron
374065	Cole Workwear PL	Guangzhou Decheng Biotechnology Co Ltd (China)	V-Chek COVID-19 Antigen Saliva Test	Self-test†						Clinical: Delta, Omicron Analytical: Beta*, Gamma*, Epsilon*, Alpha, Kappa, Delta and Omicron
374574	Compliance Management Solutions	Hangzhou Alltest Biotech Co Ltd	SARS-CoV-2 Antigen Rapid Test INCP-502-N	POCT	ATNCP211 10034	ü	ü	ü	ü	Clinical: Delta, Omicron

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										Analytical: Alpha, Beta, Gamma, Delta, Omicron
374574	Compliance Management Solutions	Hangzhou Alltest Biotech Co Ltd	COVID-19 Antigen Rapid Test (Oral Fluid) ICOV-802	POCT						Clinical: Delta, Omicron Analytical: Alpha, Beta, Gamma, Delta, Omicron
374574	Compliance Management Solutions	Hangzhou AllTest Biotech Co.,Ltd	JusChek COVID-19 Antigen Rapid Test (Oral Fluid) ICOV-802H	Self-test						Clinical: Delta, Omicron Analytical: Alpha, Beta, Gamma, Delta, Omicron
374574	Compliance Management Solutions	Hangzhou AllTest Biotech Co.,Ltd	JusChek SARS-CoV-2 Antigen Rapid Test (Nasal Swab) INCP-502H	Self-test†						Clinical: Delta, Omicron Analytical: Alpha, Beta, Gamma, Delta, Omicron

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374574	Compliance Management Solutions	Hangzhou Alltest Biotech Co Ltd	JusChek SARS-CoV-2 Antigen Rapid Test INCP-502-N	POCT†					Clinical: Delta, Omicron Analytical: Alpha, Beta, Gamma, Delta, Omicron	
374574	Compliance Management Solutions	Hangzhou Alltest Biotech Co Ltd	JusChek COVID-19 Antigen Rapid Test ICOV-802 (Oral Fluid)	POCT					Clinical: Delta, Omicron Analytical: Alpha, Beta, Gamma, Delta, Omicron	
374574	Compliance Management Solutions	Hangzhou AllTest Biotech Co.,Ltd	Beright SARS-CoV-2 Antigen Rapid Test INCP-502-N	POCT†					Clinical: Delta, Omicron Analytical: Alpha, Beta, Gamma, Delta, Omicron	

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374574	Compliance Management Solutions	Hangzhou AllTest Biotech Co.,Ltd	Beright COVID-19 Antigen Rapid Test ICOV-802 (Oral Fluid)	POCT					Clinical: Delta, Omicron Analytical: Alpha, Beta, Gamma, Delta, Omicron	
384660	Dexcon Pty Ltd	Hangzhou Realy Tech Co Ltd (China)	Novel coronavirus (SARS-Cov-2) Antigen Rapid tests device (nasal swab)	Self-test					Clinical: Alpha, Beta, Gamma, Delta, Epsilon and Omicron Analytical: Alpha, Beta, Gamma, Delta, Epsilon and Omicron	
382615	Doncaster Australia Pty Ltd	Hangzhou Realy Tech Co Ltd (China)	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	POCT					Clinical: Delta and Omicron Analytical: Alpha, Beta, Gamma, Delta, Epsilon and Omicron	

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382615	Doncaster Australia Pty Ltd	Hangzhou Realy Tech Co Ltd (China)	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	Self-test					Clinical: Delta and Omicron Analytical: Alpha, Beta, Gamma, Delta, Epsilon	
346643 Cancelled by sponsor	Emergency Technology Pty Ltd	Assure Tech (Hangzhou) Co Ltd (China)	COVID-19 Antigen Rapid Test Device	POCT					Clinical: Analytical: Delta*, Kappa*, Alpha*, Beta*, Gamma*, Omicron	
372335	Emergency Technology Pty Ltd	Assure Tech (Hangzhou) Co Ltd (China)	Ecotest COVID-19 Antigen Saliva Test Kit	POCT†					Clinical: Delta, Omicron, BA.4 and BA.5 Analytical: Omicron, Delta, Alpha, Beta, and Gamma	

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372335	Emergence Technology Pty Ltd	Assure Tech (Hangzhou) Co Ltd (China)	Ecotest COVID-19 Antigen Saliva Test kit (COV-S35Pen)	Self-test	I2110184	ü	ü	ü	ü	Clinical: Delta, Omicron, BA.4 and BA.5 Analytical: Omicron, Delta, Alpha, Beta, and Gamma
372335	Emergence Technology Pty Ltd	Assure Tech (Hangzhou) Co Ltd (China)	Ecotest COVID-19 Antigen Nasal Test Kit	POCT						Clinical: Delta, Omicron, BA.4 and BA.5 Analytical: Omicron, Delta, Alpha, Beta, and Gamma
372335	Emergence Technology Pty Ltd	Assure Tech (Hangzhou) Co Ltd (China)	Ecotest COVID-19 Antigen Nasal Test Self Test	Self-test						Clinical: Delta, Omicron, BA.4 and BA.5 Analytical: Omicron, Delta,

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									Alpha, Beta, and Gamma	
375754	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Guangzhou Wondfo Biotech Co Ltd (China)	2019-nCoV Antigen Test (Lateral Flow Method)	POCT	W19611112	ü	ü	ü	ü	Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Kappa*, Delta and Omicron
374693	Eurofins Technologies Australia Pty Ltd	Hangzhou Alltest Biotech Co Ltd (China)	SARS-CoV-2 Antigen Rapid Test (Swab)	POCT						Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Delta and Omicron
374693	Eurofins Technologies Australia Pty Ltd	Hangzhou Alltest Biotech Co Ltd (China)	GSD NovaGen SARS CoV-2 Ag Rapid Test (Nasal swab) Self-testing	Self-test						Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Delta and Omicron

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384538	Gardian Technologies Pty Ltd	Jiangsu Medomics Medical Technology Co Ltd (China)	Gardian T3 COVID-19-SARS-CoV-2 Antigen Saliva	Self-test					Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Kappa*, Epsilon*, Eta*, Iota*, Lambda*, Mu*, Delta, Omicron, BA.4, BA.5, BA.2.75	
365551	Haemokenesis Pty Ltd	RapiGEN Inc (Korea - Republic of)	BIOCREDIT COVID-19 Ag	POCT					Clinical: Delta, Omicron Analytical: Kappa*, Epsilon*, Eta*, Lambda*, Alpha, Beta, Gamma, Delta, Omicron, Zeta,	

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335597 Cancelled by sponsor	Haemokinesis Pty Ltd	PCL Inc (Korea - Republic of)	PCL COVID19 Rapid FIA	POCT					Clinical: Analytical: Alpha*, Beta*, Gamma*, Delta*, Omicron*	
370592	Health Vision Australasia Pty Ltd	Arista Biotech Pte Ltd (Singapore)	ARISTA™ COVID-19 Antigen Rapid Test	POCT					Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Epsilon*, Lambda*, Delta and Omicron	
345031	Hough Pharma Pty Ltd	BIOHIT HealthCare (Hefei) Co Ltd	SARS-CoV-2 Antigen Rapid Test Kit: Point of care testing	POCT					Clinical: Analytical: Alpha*, Beta*, Gamma*, Delta*, Lambda*, Omicron*	

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345031	Hough Pharma Pty Ltd	BIOHIT HealthCare (Hefei) Co Ltd (China)	SARS-CoV-2 Antigen Quantitative Assay Kit (Enzyme-linked Immunoassay)	Lab					Clinical: Analytical: Alpha*, Beta*, Gamma*, Delta*, Lambda*, Omicron*	
345031	Hough Pharma Pty Ltd	BIOHIT HealthCare (Hefei) Co Ltd (China)	SARS-CoV-2 Antigen Rapid Test (Colloidal Gold Method)	POCT	YPSA21100 2	ü	ü	ü	ü	Clinical: Analytical: Alpha*, Beta*, Gamma*, Delta*, Lambda*, Omicron*
345031	Hough Pharma Pty Ltd	BIOHIT HealthCare (Hefei) Co Ltd	Hough Covid-19 Home Test	Self-test						Clinical: Analytical: Alpha*, Beta*, Gamma*, Delta*, Lambda*, Omicron*

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336146	Innovation Scientific Pty Ltd	Innovation Scientific Pty Ltd	InnoScreen COVID-19 Antigen Rapid Test Device	POCT†						Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Delta, Kappa*, Epsilon*, Iota*, Lambda*, Zeta*, Delta and Omicron
336146	Innovation Scientific Pty Ltd	Innovation Scientific Pty Ltd (Australia)	InnoScreen COVID-19 Antigen Rapid Test Device (Self Test)	Self-test	SR2021100079	ü	ü	ü	ü	Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Delta, Kappa*, Epsilon*, Iota*, Lambda*, Zeta*, Delta and Omicron
385429	Jamach Pty Ltd	Hangzhou Testsea	Jamach COVID-19 Antigen Test Cassette	Self-test						Clinical: Delta, Omicron

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		Biotechnology Co Ltd (China)							Analytical: Alpha*, Beta*, Gamma*, Kappa*, Mu*, Lambda*, Epsilon*, Eta*, Zeta*, Iota*, Theta*, Delta and Omicron	
343293 Cancelled by Sponsor	Life Bioscience Pty Ltd	BioNote Inc (Korea - Republic of)	NowCheck COVID-19 Antigen Test	POCT					Clinical: Analytical: Gamma*, Alpha, Beta, Delta, Omicron	
385275	LRY Group of Companies Pty Ltd	Jiangsu Well Biotech Co Ltd (China)	Orawell COVID-19 Ag Rapid Saliva Test (SELF-TEST KIT)	Self-test					Clinical: Delta Analytical: *Kappa, *Epsilon, *Lambda, Alpha, Beta, Gamma, Delta	

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332961	MD Solutions Australasia Pty Ltd	CTK Biotech Inc (United States Of America)	Aria and OnSite Covid-19 Rapid AG Test	POCT	F0415S2D00D	ü	ü	ü	ü	Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Delta, Omicron
332961	MD Solutions Australasia Pty Ltd	CTK Biotech Inc	OnSite COVID-19 Ag Self Test	Self-test†						Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Delta, Omicron
383823	MD Solutions Australasia Pty Ltd	Philosys Co Ltd (Korea - Republic of)	Gmate COVID-19 Ag Saliva	Self-test						Clinical: Analytical: Alpha, Beta, Delta
374063 Cancelled	Medi-Stats ANZ Pty Ltd	Empowered Diagnostics LLC (United States Of America)	CovClear COVID-19 Antigen Test	POCT						Clinical: Analytical: Delta

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333344	Medsupply Australia Pty Ltd	HANGZHOU BIOTEST BIOTECH NO LTD (China)	COVID-19 Antigen Rapid Test Cassette	POCT	COVN2111 010-S	ü	ü	ü	ü	Clinical: Delta, Omicron Analytical: Alpha, Beta, Gamma, Delta, Omicron
333344	Medsupply Australia Pty Ltd	HANGZHOU BIOTEST BIOTECH CO LTD	RightSign COVID-19 Antigen Rapid Test Cassette	Self-test†						Clinical: Delta, Omicron Analytical: Alpha, Beta, Gamma, Delta, Omicron
373711	MP Biomedicals Australasia Pty Ltd	MP Biomedicals Asia Pacific	Rapid SARS-CoV-2 Antigen Test Card	POCT	8AL10-020	ü	ü	ü	ü	Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Epsilon*, Iota*, Kappa*, Theta*, Eta*, Zeta*, Delta, Omicron

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373711	MP Biomedicals Australasia Pty Ltd	MP Biomedicals Asia Pacific Pte Ltd (Singapore)	Rapid SARS-COV-2 Antigen Test Card Self-test	Self-test†					Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Epsilon*, Iota*, Kappa*, Theta*, Eta*, Zeta*, Delta, Omicron	
349933	Nature's Family Australia Pty Ltd	GenBody Inc (Korea - Republic of)	GenBody COVID-19 Ag	POCT	FMFA25211	ü	ü	ü	ü	Clinical: Delta, Omicron Analytical: Alpha, Beta, Gamma, Delta, Epsilon, Eta, Iota, Zeta, Omicron
383887	Nature's Family Australia Pty Ltd	GenBody Inc	Covid-19 Ag Home Test	Self-test	FXFGS27221	ü	ü	ü	ü	Clinical: Delta, Omicron Analytical: Alpha, Beta, Gamma, Delta, Omicron

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386305	Nuex Medical Melbourne	Hangzhou Testsea Biotechnology Co Ltd	COVID-19 Antigen Test Cassette - Self Test	Self-test						Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Kappa*, Mu*, Lambda*, Delta, Omicron
346588	Ortho-Clinical Diagnostics Australia Pty Ltd	Ortho-Clinical Diagnostics	VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack, Calibrators, Controls, Extraction buffer	Lab						Clinical: Analytical: Alpha*, Gamma*, Delta*, Kappa*
382250	Medco Solutions (Orvarto Healthcare Pty Ltd)	Acon Biotech (Hangzhou) Co Ltd (China)	Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	Self-test	COV2015130	ü	ü	ü	ü	Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Epsilon*, Mu*, Zeta*, Eta*, Theta*, Iota*, Lambda*,

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										Kappa*, Delta, Omicron
380739	Pale Blue Medical Trading Pty Ltd (formerly Jeninno Solutions Pty Ltd)	Jiangsu Medomics medical technology Co Ltd (China)	SARS-CoV-2 antigen Test Kit (LFIA)	POCT						Clinical: Delta, Omicron Analytical: Alpha, Beta, Gamma, Delta, Kappa, Epsilon, Iota, Omicron
342512	Pantonic Health Pty Ltd	Access Bio Inc	CareStart™ COVID-19 Antigen test kit	POCT	CM21J05	ü	ü	ü	ü	Clinical: Omicron Analytical: Alpha*, Beta*, Delta*, Kappa*, Epsilon*, Lambda*, Omicron
342512	Pantonic Pty Ltd	Access Bio Inc (United States Of America)	CareStart COVID-19 Antigen Home Test	Self-test	CM21J01	ü	ü	ü	ü	Clinical: Omicron Analytical: Alpha*, Beta*, Delta*,

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									Kappa*, Epsilon*, Lambda*, Omicron	
373151	Pharma Soul Pty Ltd	Hangzhou Testsea Biotechnology Co Ltd (China)	Testsea SARS-CoV-2 Antigen Test Kit	POCT						Clinical: Delta, Omicron Analytical: Delta and Omicron
373151	Pharma Soul Pty Ltd	Hangzhou Testsea Biotechnology Co Ltd (China)	TESTSEALABS COVID-19 Antigen Test Cassette	Self-test						Clinical: Analytical: Delta and Omicron
374627	Pharma Soul Pty Ltd	iXensor Co Ltd (Taiwan)	PixoTest® COVID-19 AG Test Kit	POCT						Clinical: Delta and Omicron Analytical: Alpha, Beta, Gamma, Delta, Omicron

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					Batch number	Compliance, of variants tested, to WHO LoD guidelines				Device quality
						Wild Type	Delta	Omicron		
385550	Plus Medical Pty Ltd	Hangzhou Testsea Biotechnology Co Ltd (China)	SecurePlus COVID-19 Antigen Test Cassette	Self-test					Clinical: Delta and Omicron Analytical: Alpha, Beta, Gamma, Delta, Omicron	
342390	Point Of Care Diagnostics Australia Pty Ltd	Quidel Corporation (United States Of America)	Sofia® SARS Antigen FIA	POCT	706953	ü	ü	ü	ü	Clinical: Omicron Analytical: Alpha*, Beta*, Gamma*, Delta* and Omicron
383819	ProcureNet APAC Pty Ltd	Hangzhou Testsea Biotechnology Co Ltd (China)	Medriva COVID-19 Rapid Antigen Test	Self-test						Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Omicron*, Kappa*, Mu*, Epsilon*, Eta*, Iota*, Theta*, Zeta*, Delta

ARTG	Sponsor	Manufacturer	Test Kit name	Type of test	TGA validation of analytical sensitivity (Inactivated virus)				Manufacturer provided evidence	
					Batch number	Compliance, of variants tested, to WHO LoD guidelines				Device quality
						Wild Type	Delta	Omicron		
395414	Rapant Pty Ltd	Hangzhou Realy Tech Co Ltd (China)	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab)	Self-test					Clinical: Delta, Omicron Analytical: Delta, Omicron	
352250	Roche Diagnostics Australia Pty Limited	SD Biosensor Inc (Korea - Republic of)	SARS-CoV-2 Rapid Antigen Test	POCT†					Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Kappa*, Epsilon*, Iota*, Lambda*, Zeta*, Delta, Omicron	
352250	Roche Diagnostics Australia Pty Limited	SD Biosensor Inc	SARS-CoV-2 Rapid Antigen Test Nasal	POCT†					Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Kappa*, Epsilon*, Iota*, Lambda*,	

ARTG	Sponsor	Manufacturer	Test Kit name	Type of test	TGA validation of analytical sensitivity (Inactivated virus)				Manufacturer provided evidence	
					Batch number	Compliance, of variants tested, to WHO LoD guidelines				Device quality
						Wild Type	Delta	Omicron		
									Zeta*, Delta, Omicron	
352250	Roche Diagnostics Australia Pty Limited	SD Biosensor Inc	SARS-CoV-2 Antigen Self Test Nasal	Self-test	QC038105 2I	ü	ü	ü	ü	Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Kappa*, Epsilon*, Iota*, Lambda*, Zeta*, Delta, Omicron
336661	Roche Diagnostics Australia Pty Limited	Roche Diagnostics GmbH (Germany)	Elecsys SARS-CoV-2 Antigen assay	Lab	N/A					Analytical: Alpha*, Beta*, Gamma*, Delta*, Kappa*, Zeta*, Theta*, Eta* and Epsilon*

ARTG	Sponsor	Manufacturer	Test Kit name	Type of test	TGA validation of analytical sensitivity (Inactivated virus)				Manufacturer provided evidence	
					Batch number	Compliance, of variants tested, to WHO LoD guidelines				Device quality
						Wild Type	Delta	Omicron		
387390	Safe Interact Pty Ltd	Meril Diagnostics Pvt Ltd (India)	COVIFIND COVID-19 Antigen Self-Test	Self-test					Clinical: Delta and Omicron Analytical: Delta	
334501	Solasta Life Pty Ltd	Hangzhou Realy Tech Co Ltd	Novel Coronavirus (SARS-CoV-2) Antigen rapid test	POCT					Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Epsilon*, Delta, Omicron	
334501	Solasta Life Pty Ltd	Hangzhou Realy Tech Co Ltd	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab)	Self-test					Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Epsilon*, Delta, Omicron	

ARTG	Sponsor	Manufacturer	Test Kit name	Type of test	TGA validation of analytical sensitivity (Inactivated virus)				Manufacturer provided evidence	
					Batch number	Compliance, of variants tested, to WHO LoD guidelines				Device quality
						Wild Type	Delta	Omicron		
384537	Sonictec Pty Ltd	Hangzhou Realy Tech Co Ltd (China)	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device	Self-test					Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Epsilon*, Delta, Omicron	
395590	Sonictec Pty Ltd	Hangzhou Fantttest Biotech Co Ltd (China)	Fantttest: Covid-19/Influenza A&B Antigen Test Kit	Self-test COMBO					Clinical: Delta, Omicron Analytical: Gamma, Delta, Omicron Influenza: Influenza A (H1N1, H3N2), Influenza B (Victoria, Yamagata)	
348890	Stonestar Wholesale Pty Ltd	VivaChek Biotech (Hangzhou) Co Ltd (China)	VivaDiag™ SARS-CoV-2 Ag Rapid Test	POCT					Clinical: Delta, Omicron	

ARTG	Sponsor	Manufacturer	Test Kit name	Type of test	TGA validation of analytical sensitivity (Inactivated virus)				Manufacturer provided evidence	
					Batch number	Compliance, of variants tested, to WHO LoD guidelines				Device quality
						Wild Type	Delta	Omicron		
										Analytical: Alpha*, Beta*, Gamma*, and Epsilon*, Delta, Omicron
348890	Stonestar Wholesale Pty Ltd	VivaChek Biotech (Hangzhou) Co Ltd (China)	VivaDiag Pro SARS-CoV-2 Ag rapid test	Self-test						Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Epsilon*, Delta, Omicron
347092	SureScreen Australia Pty Limited	BTNX Inc (Canada)	Surescreen Diagnostics COVID-19 Antigen Rapid Test Rapid Response™ COVID-19 Antigen Rapid Test Device	POCT	I2108208	ü	ü	ü	ü	Clinical: Omicron Analytical: Alpha*, Beta*, Gamma*, Delta, Omicron
347092	SureScreen Australia	BTNX Inc (Canada)	Rapid Response COVID-19 Antigen Rapid Test Cassette - At Home	Self-test†						Clinical: Omicron Analytical: Alpha*, Beta*, Gamma*, Delta, Omicron

ARTG	Sponsor	Manufacturer	Test Kit name	Type of test	TGA validation of analytical sensitivity (Inactivated virus)				Manufacturer provided evidence	
					Batch number	Compliance, of variants tested, to WHO LoD guidelines				Device quality
						Wild Type	Delta	Omicron		
	Pty Limited									
387662	SureScreen Australia Pty Limited	SureScreen Diagnostics Ltd (United Kingdom)	SARS-CoV-2 Antigen Rapid test Cassette (Nasal Swab) (Gold)	Self-test					Clinical: Analytical: Delta, Omicron	
387662	SureScreen Australia Pty Limited	SureScreen Diagnostics Ltd (United Kingdom)	SARS-CoV-2 Antigen Rapid test Cassette (Nasal Swab) (Gold)	POCT					Clinical: Analytical: Delta, Omicron	
387662	SureScreen Australia Pty Limited	SureScreen Diagnostics Ltd (United Kingdom)	SARS-CoV-2 Antigen Rapid test Cassette (Nasal Swab) (Gold) with RhinoSwab Junior	Self-test					Clinical: Analytical: Delta, Omicron	

ARTG	Sponsor	Manufacturer	Test Kit name	Type of test	TGA validation of analytical sensitivity (Inactivated virus)				Manufacturer provided evidence	
					Batch number	Compliance, of variants tested, to WHO LoD guidelines				Device quality
						Wild Type	Delta	Omicron		
345191	Suretest	Beijing Wantai Biologicalpharmacy Enterprise Co Ltd	Wantai SARS-CoV-2 Ag Rapid Test (Colloidal Gold)	POCT	JNA202110801	ü	ü	ü	ü	Clinical: Delta, Omicron Analytical: *Delta and *Omicron
385370	Talbot Medical Pty Ltd	Maccura Biotechnology Co Ltd (China)	Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Assay Kit	Self-test						Clinical: Delta, Omicron Analytical: Delta, Omicron
391125	Talbot Medical Pty Ltd	Guangzhou Decheng Biotechnology Co Ltd (China)	WhistlingTest 2019-nCoV Saliva Ag EASY TEST	Self-test						Clinical: Analytical: Delta, Alpha, Kappa
395591	Touch Biotechnology Pty Ltd	Vitrosens Biyoteknoloji LTD STI (Turkey)	TouchBio SARS-CoV-2 & FLU A/B Antigen Combo Test (nasal)	Self-test COMBO						Clinical: Alpha, Beta, Delta, Eta, Omicron Analytical: Delta, Omicron

ARTG	Sponsor	Manufacturer	Test Kit name	Type of test	TGA validation of analytical sensitivity (Inactivated virus)				Manufacturer provided evidence	
					Batch number	Compliance, of variants tested, to WHO LoD guidelines				Device quality
						Wild Type	Delta	Omicron		
									Influenza: Influenza A (H1N1, H3N2), Influenza B (Victoria, Yamagata)	
388031	VITRYL AUS PTY LTD	Labnovation Technologies Inc (China)	SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography)	Self-test					Clinical: Delta, and Omicron Analytical: Delta and Omicron	
377136	Well Biotech Pty Ltd	Jiangsu Well Biotech Co Ltd (China)	Orawell COVID-19 Ag Rapid Saliva Test Device (Self test)	Self-test					Clinical: Delta, Omicron Analytical: Alpha, Beta, Gamma, Delta, and Omicron	