

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					<b>Clinical:</b> Delta <b>Analytical:</b> 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					<b>Clinical:</b> Delta <b>Analytical:</b> Delta and Omicron*	
345192	Abbott Rapid Diagnostics Pty Ltd	Abbott Rapid Diagnostics Jena GmbH (Germany)	Panbio™ COVID-19 Ag Rapid Test Device (Nasopharyngeal)	POCT†					<b>Clinical:</b> Delta, Omicron, Alpha, Beta <b>Analytical:</b> Alpha, Beta, Gamma, Delta, Kappa, Zeta, Theta, Eta and Omicron	
345192	Abbott Rapid Diagnostics Pty Ltd	Abbott Rapid Diagnostics Jena GmbH (Germany)	Panbio COVID-19 Antigen Self-test (Nasal)	Self-test	41ADG637A	✓	✓	✓	✓	<b>Clinical:</b> Omicron, Alpha, Beta <b>Analytical:</b> 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†						<b>Clinical:</b> Omicron, Alpha, Beta <b>Analytical:</b> 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						<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> Alpha, Beta, Gamma, Delta, and Omicron

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	Australia Pty Ltd									
386690	Alpha-Medics Australia Pty Ltd	Hangzhou Sejoy Electronics & Instruments Co Ltd	SARS-CoV-2 Antigen Saliva Lolly Test	Self-test						<b>Clinical:</b> Omicron <b>Analytical:</b> Beta, Gamma, Delta, Omicron
376310	AM Diagnostics	Hangzhou Alltest Biotech Co Ltd (China)	All Test COVID-19 Antigen Rapid Test (Swab) (INCP-502)	POCT						<b>Clinical:</b> <b>Analytical:</b> 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†						<b>Clinical:</b> <b>Analytical:</b> 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						<b>Clinical:</b> <b>Analytical:</b> 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	ATCOV21110029	✓	✓	✓	✓	<b>Clinical:</b> <b>Analytical:</b> 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†					<b>Clinical:</b> <b>Analytical:</b> Alpha*, Beta*, Gamma*, Delta, and Omicron	
333341	APAC Security Pty Ltd	Hangzhou Clongene Biotech Co Ltd (China)	Clungene COVID-19 Antigen Rapid Test	POCT†					<b>Clinical:</b> Delta and Omicron <b>Analytical:</b> 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	✓	✓	✓	✓	<b>Clinical:</b> Delta and Omicron <b>Analytical:</b> Alpha, Beta, Gamma, Delta, and Omicron
346587	Atomo Diagnostics Limited	Access Bio Inc (United States Of America)	Atomo Covid-19 Antigen Test	POCT						<b>Clinical:</b> <b>Analytical:</b> Alpha*, Beta*, Delta* Kappa*, Epsilon*, Lambda* and Omicron
382031	AusDiagnosti cs Pty Ltd	Acon Biotech (Hangzhou) Co Ltd (China)	Flowflex SARS-CoV-2 Antigen Rapid Test (Self Testing)	Self-test						<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> Alpha*, Beta*, Gamma*, Kappa*, Eta*, Mu*, Epsilon*, Iota*, Lambda*, Zeta* Theta*, Delta and Omicron

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385653	Australia Biotech Pty Ltd	Guangzhou Wondfo Biotech Co Ltd (China)	Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)	Self-test					<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> Alpha, Beta, Delta, Omicron	
375418	Australia Health Products Central Pty Ltd	Hangzhou Testsea Biotechnology Co Ltd (China)	Cellife Covid-19 Antigen Test Cassette	POCT					<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> 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					<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> Alpha*, Beta*, Gamma*, Kappa*, Mu*, Lambda*, Iota*, Epsilon*, Eta*, Theta*, Zeta*, Delta and Omicron	
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	✓	✓	✓	✓	<b>Clinical:</b> Delta <b>Analytical:</b> Alpha, Beta, Gamma, Kappa, Iota, and Omicron.
387550	BGI Health (AU) Company Pty Ltd	Innovita (Tangshan) Biological Technology Co Ltd (China)	2019 nCoV Ag Test (Latex Chromatography Assay) – Self-test	Self-test						<b>Clinical:</b> Delta, and Omicron <b>Analytical:</b> Delta, Beta and Omicron

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387550	BGI Health (AU) Company Pty Ltd	Innovita (Tangshan) Biological Technology Co Ltd (China)	2019 nCoV Ag Test (Latex Chromatography Assay) – POCT	POCT						<b>Clinical:</b> Delta, Beta and Omicron <b>Analytical:</b> Delta, Beta and Omicron
387020	Big Start Pty Ltd	Guangzhou Decheng Biotechnology Co Ltd (China)	2019-nCoV Ag Rapid Test Kit	Self-test						<b>Clinical:</b> Delta <b>Analytical:</b> Alpha, Kappa, Delta, Omicron
345219	Bioclect Pty Ltd	SD Biosensor Inc (Korea - Republic of)	STANDARD™ Q COVID-19 Ag Test	POCT	58327KAAC 1	✓	✓	✓	✓	<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> Alpha*, Beta*, Gamma*, Delta, Kappa*, Epsilon*, Iota*, Lambda*, Zeta*, Delta and Omicron
374065	Cole Workwear PL	Guangzhou Decheng Biotechnology Co Ltd (China)	2019-nCoV Ag Saliva Rapid Test Card	POCT	05821068C	✓	✓	✓	✓	<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> 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†						<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> Beta*, Gamma*, Epsilon*, Alpha, Kappa, Delta and Omicron

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374574	Compliance Management Solutions	Hangzhou Alltest Biotech Co Ltd	SARS-CoV-2 Antigen Rapid Test INCP-502-N	POCT	ATNCP21110034	✓	✓	✓	✓	<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> Alpha, Beta, Gamma, Delta, Omicron
374574	Compliance Management Solutions	Hangzhou Alltest Biotech Co Ltd	COVID-19 Antigen Rapid Test (Oral Fluid) ICOV-802	POCT						<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> 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						<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> 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†						<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> Alpha, Beta, Gamma, Delta, Omicron
374574	Compliance Management Solutions	Hangzhou Alltest Biotech Co Ltd	JusChek SARS-CoV-2 Antigen Rapid Test INCP-502-N	POCT†						<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> 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						<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> Alpha, Beta, Gamma, Delta, Omicron

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374574	Compliance Management Solutions	Hangzhou AllTest Biotech Co.,Ltd	Beright SARS-CoV-2 Antigen Rapid Test INCP-502-N	POCT†					<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> Alpha, Beta, Gamma, Delta, Omicron	
374574	Compliance Management Solutions	Hangzhou AllTest Biotech Co.,Ltd	Beright COVID-19 Antigen Rapid Test ICOV-802 (Oral Fluid)	POCT					<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> 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					<b>Clinical:</b> Alpha, Beta, Gamma, Delta, Epsilon and Omicron <b>Analytical:</b> 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					<b>Clinical:</b> Delta and Omicron <b>Analytical:</b> 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)	Self-test					<b>Clinical:</b> Delta and Omicron <b>Analytical:</b> Alpha, Beta, Gamma, Delta, Epsilon	
346643	Emergence Technology Pty Ltd	Assure Tech (Hangzhou) Co Ltd (China)	COVID-19 Antigen Rapid Test Device	POCT					<b>Clinical:</b>	

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



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374693	Eurofins Technologies Australia Pty Ltd	Hangzhou Alltest Biotech Co Ltd (China)	SARS-CoV-2 Antigen Rapid Test (Swab)	POCT					<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> 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					<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> Alpha*, Beta*, Gamma*, Delta and Omicron	
384538	Gardian Technologies Pty Ltd	Jiangsu Medomics Medical Technology Co Ltd (China)	Gardian T3 COVID-19-SARS-CoV-2 Antigen Saliva	Self-test					<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> Alpha*, Beta*, Gamma*, Kappa*, Epsilon*, Eta*, Iota*, Lambda*, Mu*, Delta and Omicron	
365551	Haemokinesiss Pty Ltd	RapiGEN Inc (Korea - Republic of)	BIOCREDIT COVID-19 Ag	POCT					<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> Kappa*, Epsilon*, Eta*, Lambda*, Alpha, Beta, Gamma, Delta, Omicron, Zeta,	
335597 SUSPENDED	Haemokinesiss Pty Ltd	PCL Inc (Korea - Republic of)	PCL COVID19 Rapid FIA	POCT					<b>Clinical:</b> <b>Analytical:</b> Alpha*, Beta*, Gamma*, Delta*, Omicron*	

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370592	Health Vision Australasia Pty Ltd	Arista Biotech Pte Ltd (Singapore)	ARISTA™ COVID-19 Antigen Rapid Test	POCT					<b>Clinical:</b> Delta, Omicron  <b>Analytical:</b> 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					<b>Clinical:</b>  <b>Analytical:</b> Alpha*, Beta*, Gamma*, Delta*, Lambda*, Omicron*	
345031	Hough Pharma Pty Ltd	BIOHIT HealthCare (Hefei) Co Ltd (China)	SARS-CoV-2 Antigen Quantitative Assay Kit (Enzyme-linked Immunoassay)	Lab					<b>Clinical:</b>  <b>Analytical:</b> 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	YPSA211002	✓	✓	✓	✓	<b>Clinical:</b>  <b>Analytical:</b> Alpha*, Beta*, Gamma*, Delta*, Lambda*, Omicron*
345031	Hough Pharma Pty Ltd	BIOHIT HealthCare (Hefei) Co Ltd	Hough Covid-19 Home Test	Self-test						<b>Clinical:</b>  <b>Analytical:</b> 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†					<b>Clinical:</b> Delta, Omicron  <b>Analytical:</b> 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	✓	✓	✓	✓	<b>Clinical:</b> Delta, Omicron  <b>Analytical:</b> Alpha*, Beta*, Gamma*, Delta, Kappa*, Epsilon*, Iota*, Lambda*, Zeta*, Delta and Omicron
385429	Jamach Pty Ltd	Hangzhou Testsea Biotechnology Co Ltd (China)	Jamach COVID-19 Antigen Test Cassette	Self-test						<b>Clinical:</b> Delta, Omicron  <b>Analytical:</b> Alpha*, Beta*, Gamma*, Kappa*, Mu*, Lambda*, Epsilon*, Eta*, Zeta*, Iota*, Theta*, Delta and Omicron
380739	Jeninno Solutions Pty Ltd	Jiangsu Medomics medical technology Co Ltd (China)	SARS-CoV-2 antigen Test Kit (LFIA)	POCT						<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> Alpha, Beta, Gamma, Delta, Kappa, Epsilon, Iota, Omicron
343293 Cancelled	Life Bioscience Pty Ltd	BioNote Inc (Korea - Republic of)	NowCheck COVID-19 Antigen Test	POCT						<b>Clinical:</b>  <b>Analytical:</b> Gamma*, Alpha, Beta, Delta, Omicron

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<b>by Sponsor</b>										
<b>385275</b>	LRY Group of Companies Pty Ltd	Jiangsu Well Biotech Co Ltd (China)	Orawell COVID-19 Ag Rapid Saliva Test (SELF-TEST KIT)	Self-test						<b>Clinical:</b> Delta <b>Analytical:</b> *Kappa, *Epsilon, *Lambda, Alpha, Beta, Gamma, Delta
<b>332961</b>	MD Solutions Australasia Pty Ltd	CTK Biotech Inc (United States Of America)	Aria and OnSite Covid-19 Rapid AG Test	POCT	F0415S2D00 D	✓	✓	✓	✓	<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> Alpha*, Beta*, Gamma*, Delta, Omicron
<b>332961</b>	MD Solutions Australasia Pty Ltd	CTK Biotech Inc	OnSite COVID-19 Ag Self Test	Self-test†						<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> Alpha*, Beta*, Gamma*, Delta, Omicron
<b>383823</b>	MD Solutions Australasia Pty Ltd	Philosys Co Ltd (Korea - Republic of)	Gmate COVID-19 Ag Saliva	Self-test						<b>Clinical:</b> <b>Analytical:</b> Alpha, Beta, Delta
<b>374063</b> <b>Cancelled</b>	Medi-Stats ANZ Pty Ltd	Empowered Diagnostics LLC (United States Of America)	CovClear COVID-19 Antigen Test	POCT						<b>Clinical:</b> <b>Analytical:</b> Delta

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333344	Medsupply Australia Pty Ltd	HANGZHOU BIOTEST BIOTECH NO LTD (China)	COVID-19 Antigen Rapid Test Cassette	POCT	COVN21110 10-S	✓	✓	✓	✓	<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> Alpha, Beta, Gamma, Delta, Omicron
333344	Medsupply Australia Pty Ltd	HANGZHOU BIOTEST BIOTECH CO LTD	RightSign COVID-19 Antigen Rapid Test Cassette	Self-test†						<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> 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	✓	✓	✓	✓	<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> Alpha*, Beta*, Gamma*, Epsilon*, Iota*, Kappa*, Theta*, Eta*, Zeta*, Delta, Omicron
373711	MP Biomedicals Australasia Pty Ltd	MP Biomedicals Asia Pacific Pte Ltd (Singapore)	Rapid SARS-COV-2 Antigen Test Card Self-test	Self-test†						<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> 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	✓	✓	✓	✓	<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> Alpha, Beta, Gamma, Delta, Epsilon, Eta, Iota, Zeta, Omicron

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383887	Nature's Family Australia Pty Ltd	GenBody Inc	Covid-19 Ag Home Test	Self-test	FXFGS27221	✓	✓	✓	✓	<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> Alpha, Beta, Gamma, Delta, Omicron
386305	Nuex Medical Melbourne	Hangzhou Testsea Biotechnology Co Ltd	COVID-19 Antigen Test Cassette - Self Test	Self-test						<b>Clinical:</b> Delta <b>Analytical:</b> 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						<b>Clinical:</b> <b>Analytical:</b> Alpha*, Gamma*, Delta*, Kappa*
382250	Medco Solutions	Acon Biotech (Hangzhou) Co Ltd (China)	Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	Self-test	COV2015130	✓	✓	✓	✓	<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> Alpha*, Beta*, Gamma*, Epsilon*, Mu*, Zeta*, Eta*, Theta*, Iota*, Lambda*, Kappa*, Delta, Omicron
342512	Pantonic Health Pty Ltd	Access Bio Inc	CareStart™ COVID-19 Antigen test kit	POCT						<b>Clinical:</b> <b>Analytical:</b> Alpha*, Beta*, Delta*, Kappa*, Epsilon*, Lambda*, Omicron

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342512	Pantonic Pty Ltd	Access Bio Inc (United States Of America)	CareStart COVID-19 Antigen Home Test	Self-test						<b>Clinical:</b> Alpha*, Beta*, Delta*, Kappa*, Epsilon*, Lambda*, Omicron
373151	Pharma Soul Pty Ltd	Hangzhou Testsea Biotechnology Co Ltd (China)	Testsea SARS-CoV-2 Antigen Test Kit	POCT						<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> Delta and Omicron
373151	Pharma Soul Pty Ltd	Hangzhou Testsea Biotechnology Co Ltd (China)	TESTSEALABS COVID-19 Antigen Test Cassette	Self-test						<b>Clinical:</b> <b>Analytical:</b> Delta and Omicron
374627	Pharma Soul Pty Ltd	iXensor Co Ltd (Taiwan)	PixoTest® COVID-19 AG Test Kit	POCT						<b>Clinical:</b> Delta and Omicron <b>Analytical:</b> Alpha, Beta, Gamma, Delta, Omicron
385550	Plus Medical Pty Ltd	Hangzhou Testsea Biotechnology Co Ltd (China)	SecurePlus COVID-19 Antigen Test Cassette	Self-test						<b>Clinical:</b> Delta and Omicron <b>Analytical:</b> Alpha, Beta, Gamma, Delta, Omicron

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342390	Point Of Care Diagnostics Australia Pty Ltd	Quidel Corporation (United States Of America)	Sofia® SARS Antigen FIA	POCT	706953	✓	✓	✓	✓	<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> 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						<b>Clinical:</b> Delta <b>Analytical:</b> Alpha*, Beta*, Gamma*, Omicron*, Kappa*, Mu*, Epsilon*, Eta*, Iota*, Theta*, Zeta*, Delta
352250	Roche Diagnostics Australia Pty Limited	SD Biosensor Inc (Korea - Republic of)	SARS-CoV-2 Rapid Antigen Test	POCT†						<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> 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†						<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> Alpha*, Beta*, Gamma*, Kappa*, Epsilon*, Iota*, Lambda*, Zeta*, Delta, Omicron
352250	Roche Diagnostics Australia Pty Limited	SD Biosensor Inc	SARS-CoV-2 Antigen Self Test Nasal	Self-test	QC0381052I	✓	✓	✓	✓	<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> Alpha*, Beta*, Gamma*, Kappa*, Epsilon*, Iota*, Lambda*, Zeta*, 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		
336661	Roche Diagnostics Australia Pty Limited	Roche Diagnostics GmbH (Germany)	Elecsys SARS-CoV-2 Antigen assay	Lab	N/A				<b>Analytical:</b> Alpha*, Beta*, Gamma*, Delta*, Kappa*, Zeta*, Theta*, Eta* and Epsilon*	
387390 Cancelled	Safe Interact Pty Ltd	Meril Diagnostics Pvt Ltd (India)	COVIFIND COVID-19 Antigen Self-Test	Self-test					<b>Clinical:</b> Delta and Omicron <b>Analytical:</b> Delta	
334501	Solasta Life Pty Ltd	Hangzhou Realy Tech Co Ltd	Novel Coronavirus (SARS-CoV-2) Antigen rapid test	POCT					<b>Clinical:</b> Delta <b>Analytical:</b> 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					<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> Alpha*, Beta*, Gamma*, Epsilon*, Delta, Omicron	
384537	Sonictec Pty Ltd	Hangzhou Realy Tech Co Ltd (China)	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device	Self-test					<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> Alpha*, Beta*, Gamma*, Epsilon*, Delta, Omicron	
348890	Stonestar Wholesale Pty Ltd	VivaChek Biotech	VivaDiag™ SARS-CoV-2 Ag Rapid Test	POCT					<b>Clinical:</b> 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		
		(Hangzhou) Co Ltd (China)								<b>Analytical:</b> 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						<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> 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	✓	✓	✓	✓	<b>Clinical:</b> Omicron <b>Analytical:</b> Alpha*, Beta*, Gamma*, Delta, Omicron
387662	SureScreen Australia Pty Limited	SureScreen Diagnostics Ltd (United Kingdom)	SARS-CoV-2 Antigen Rapid test Cassette (Nasal Swab) (Gold)	Self-test						<b>Clinical:</b> <b>Analytical:</b> Delta
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						<b>Clinical:</b> <b>Analytical:</b> Delta
345191	Suretest	Beijing Wantai Biologicalpharm	Wantai SARS-CoV-2 Ag Rapid Test (Colloidal Gold)	POCT	JNA202110801	✓	✓	✓	✓	<b>Clinical:</b> <b>Analytical:</b> *Delta and *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		
		acy Enterprise Co Ltd								
385370	Talbot Medical Pty Ltd	Maccura Biotechnology Co Ltd (China)	Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Assay Kit	Self-test					<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> Delta, Omicron	
388031	VITRYL AUS PTY LTD	Labnovation Technologies Inc (China)	SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography)	Self-test					<b>Clinical:</b> Delta, and Omicron <b>Analytical:</b> 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					<b>Clinical:</b> Delta, Omicron <b>Analytical:</b> Alpha, Beta, Gamma, Delta, and Omicron	