

Key

- ✓ **Compliant** with the WHO guidelines (LOD within range 100-1000 TCID₅₀/mL) during TGA validation
- ✘ **Non-compliant** with the WHO guidelines (LOD does not fall within the range 100-1000 TCID₅₀/mL) during TGA validation
- † Where multiple RATs are included under the one (1) ARTG number and have the same product composition, they have only been assessed once in the TGA testing. For example, if a product has a self-test and POCT version, only one was tested.
- * In manufacturer provided evidence, variants that have only been tested with recombinant protein studies.

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, BA.4 and BA.5 Analytical: Delta and Omicron, BA.4 and BA.5	

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) Self-Test	Self-test					Clinical: Delta and Omicron, BA.4 and BA.5 Analytical: Delta and Omicron, BA.4 and BA.5	
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	
345192	Abbott Rapid Diagnostics Pty Ltd	Abbott Rapid Diagnostics Jena GmbH (Germany)	Panbio COVID-19 Antigen Self-test (Nasal)	Self-test	41ADG637 A	✓	✓	✓	✓	Clinical: Omicron, Alpha, Beta and Delta Analytical: Alpha, Beta, Gamma,

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		
									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†					<p>Clinical: Omicron, Alpha, Beta and Delta</p> <p>Analytical: Alpha, Beta, Gamma, Delta, Kappa, Zeta, Theta, Eta and Omicron</p>	
385179	Alpha-Medics Australia Pty Ltd	Qingdao Hightop Biotech Co Ltd (China)	SARS-CoV-2 Antigen Rapid Test	Self-test	COV-1220169	✓	✓	✓	✓	<p>Clinical: Delta, Omicron, BA.4 and BA.5</p> <p>Analytical: Alpha, Beta, Gamma, Delta, Omicron, BA.4 and BA.5</p>

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		
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, BA.4 and BA.5 Analytical: Alpha, Beta, Gamma, Delta, Omicron, BA.4 and BA.5	
386690	Alpha-Medics Australia Pty Ltd	Hangzhou Sejoy Electronics & Instruments Co Ltd	SARS-CoV-2 Antigen Saliva Lolly Test	Self-test	AU20220410	✓	✓	✓	✓	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
396239	Alpha-Medics	Hangzhou Sejoy Electronics &	SARS-CoV-2 Antigen Rapid Test Cassette	Self-test						Clinical: 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		
	Australia Pty Ltd	Instruments Co Ltd (China)							Analytical: Beta, Gamma and Delta	
376310	AM Diagnostics	Hangzhou Alltest Biotech Co Ltd (China)	All Test COVID-19 Antigen Rapid Test (Swab) (INCP-502)	POCT†					Clinical: Omicron Analytical: Alpha*, Beta*, Gamma*, Delta, Omicron, BA.4 and BA.5	
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, Omicron, BA.4 and BA.5	
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	ATNCP211 10008	✓	✓	✓	✓	Clinical: Omicron Analytical: Alpha*, Beta*, Gamma*, Delta, Omicron, BA.4 and BA.5

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		
376310	AM Diagnosti cs	Hangzhou Alltest Biotech Co Ltd (China)	All Test COVID-19 Antigen Rapid Test (Oral Fluid) Self-Test (ICOV-802H)	Self-test	ATCOV211 10029	✓	✓	✓	✓	Clinical: Analytical: Alpha*, Beta*, Gamma*, Delta, Omicron, BA.4 and BA.5
376310	AM Diagnosti cs	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, Omicron, BA.4 and BA.5
333341	APAC Security Pty Ltd	Hangzhou Clongene Biotech Co Ltd (China)	Clungene COVID-19 Antigen Rapid Test	POCT†						Clinical: Delta, Omicron, BA.2, BA.4 and BA.5 Analytical: Alpha, Beta, Gamma, Delta, Omicron, BA.4 and BA.5

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		
333341	APAC Security Pty Ltd	Hangzhou Clongene Biotech Co Ltd (China)	Clungene COVID-19 Antigen Rapid Test (Self - testing)	Self-test	2022020145	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.2, BA.4 and BA.5 Analytical: Alpha, Beta, Gamma, Delta, Omicron, BA.4 and BA.5
346587	Atomo Diagnostics Limited	Access Bio Inc (United States Of America)	Atomo Covid-19 Antigen Test	POCT						Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Delta*, Kappa*, Epsilon*, Lambda* and Omicron
382031	AusDiagnosics Pty Ltd	Acon Biotech (Hangzhou) Co Ltd (China)	Flowflex SARS-CoV-2 Antigen Rapid Test (Self Testing)	Self-test	COV2015250	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.4 and BA.5 Analytical: Alpha*, Beta*, Gamma*,

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		
									Kappa*, Eta*, Mu*, Epsilon*, Iota*, Lambda*, Zeta*, Theta*, Delta, Omicron, BA.4 and BA.5	
385653	Australia Biotech Pty Ltd	Guangzhou Wondfo Biotech Co Ltd (China)	Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)	Self-test	W6342033 1	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.4 and BA.5 Analytical: Alpha, Beta, Delta, Omicron, BA.4 and BA.5
375418	Australia Health Products Central Pty Ltd	Hangzhou Testsea Biotechnology Co Ltd (China)	Cellife Covid-19 Antigen Test Cassette	POCT	TL1L14	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.4, BA.5 Analytical: Alpha*, Beta*, Gamma*, Kappa*, Mu*, Lambda*, Iota*, Epsilon*, Eta*,

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		
									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, BA.4, BA.5 Analytical: 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	✓	✓	✓	✓	Clinical: Delta Analytical: Alpha, Beta, Gamma, Kappa, Iota, 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		
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 and BA.5	
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) Company Pty Ltd	Innovita (Tangshan) Biological Technology Co Ltd (China)	2019 nCoV Ag Test (Latex Chromatography Assay) - Self- test	Self-test					Clinical: Delta, and Omicron Analytical: Delta, Beta , Omicron, BA.4 and BA.5	
387550	BGI Health (AU)	Innovita (Tangshan) Biological	2019 nCoV Ag Test (Latex Chromatography Assay) - POCT	POCT					Clinical: Delta, Beta 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		
	Company Pty Ltd	Technology Co Ltd (China)							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, BA.1 Analytical: Alpha, Kappa, Delta, Omicron	
345219	Bioelect Pty Ltd	SD Biosensor Inc (Korea - Republic of)	STANDARD™ Q COVID-19 Ag Test	POCT	58327KAA C1	✓	✓	✓	✓	Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Delta, Kappa*, Epsilon*, Iota*, Lambda*, Zeta*, Delta and Omicron, BA.4 and BA.5
345219	Bioelect Pty Ltd	SD Biosensor Inc (Korea - Republic of)	STANDARD™ Q COVID-19 Ag Test Nasal swab	POCT†						Clinical: 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: Delta and Omicron, BA.4 and BA.5
374065	Cole Workwear PL	Guangzhou Decheng Biotechnology Co Ltd (China)	2019-nCoV Ag Saliva Rapid Test Card	POCT	05821068C	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.1, BA.2, BA.4, BA.5 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, BA.1, BA.2, BA.4, BA.5 Analytical: Beta*, Gamma*, Epsilon*, Alpha, Kappa, Delta and Omicron
374574	Compliance	Hangzhou Alltest Biotech Co Ltd	SARS-CoV-2 Antigen Rapid Test INCP-502-N	POCT	ATNCP211 10034	✓	✓	✓	✓	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		
	Management Solutions								Analytical: Alpha, Beta, Gamma, Delta, Omicron, BA.4, BA.5	
374574	Compliance Management Solutions	Hangzhou Alltest Biotech Co Ltd	COVID-19 Antigen Rapid Test (Oral Fluid) ICOV-802	POCT					Clinical: Delta, Omicron, BA.5 Analytical: Alpha, Beta, Gamma, Delta, Omicron, BA.4, BA.5	
374574	Compliance Management Solutions	Hangzhou AllTest Biotech Co.,Ltd	JusChek COVID-19 Antigen Rapid Test (Oral Fluid) ICOV-802H	Self-test					Clinical: Delta, Omicron, BA.5 Analytical: Alpha, Beta, Gamma, Delta, Omicron, BA.4, BA.5	
374574	Compliance Management	Hangzhou AllTest Biotech Co.,Ltd	JusChek SARS-CoV-2 Antigen Rapid Test (Nasal Swab) INCP-502H	Self-test†					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		
	ent Solutions								Analytical: Alpha, Beta, Gamma, Delta, Omicron, BA.4, BA.5	
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, BA.4, BA.5	
374574	Compliance Management Solutions	Hangzhou Alltest Biotech Co Ltd	JusChek COVID-19 Antigen Rapid Test ICOV-802 (Oral Fluid)	POCT					Clinical: Delta, Omicron, BA.5 Analytical: Alpha, Beta, Gamma, Delta, Omicron, BA.4, BA.5	
374574	Compliance Management	Hangzhou AllTest Biotech Co.,Ltd	Beright SARS-CoV-2 Antigen Rapid Test INCP-502-N	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		
	ent Solutions								Analytical: Alpha, Beta, Gamma, Delta, Omicron, BA.4, BA.5	
374574	Compliance Management Solutions	Hangzhou AllTest Biotech Co.,Ltd	Beright COVID-19 Antigen Rapid Test ICOV-802 (Oral Fluid)	POCT					Clinical: Delta, Omicron, BA.5 Analytical: Alpha, Beta, Gamma, Delta, Omicron, BA.4, BA.5	
384660	Dexcon Pty Ltd	Hangzhou Realy Tech Co Ltd (China)	Novel coronavirus (SARS-Cov-2) Antigen Rapid tests device (nasal swab)	Self-test	202203079	✓	✓	✓	✓	Clinical: Alpha, Beta, Gamma, Delta, Epsilon and Omicron Analytical: Alpha, Beta, Gamma, Delta, Epsilon, Omicron, BA4 and BA5

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		
399643	Dian Biotech Pty Ltd	Hangzhou Testsea Biotechnology Co Ltd (China)	SARS-COV-2 RAPID ANTIGEN TEST KIT RAT-01 (SELF-TEST)	Self-test					Clinical: Delta and Omicron Analytical: Delta 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	
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 Omicron, BA4 and BA5	

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

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		
372335	Emergence Technology Pty Ltd	Assure Tech (Hangzhou) Co Ltd (China)	Ecotest COVID-19 Antigen Nasal Test Kit	POCT†					Clinical: Delta, Omicron and BA.5 Analytical: XBB, BA.4, BA.5, 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	I2109083	✓	✓	✓	✓	Clinical: Delta, Omicron and BA.5 Analytical: XBB, BA.4, BA.5, Omicron, Delta, Alpha, Beta, and Gamma
					E2022060106	✓	✓	✓	✓	
375754	Emergo Asia Pacific Pty Ltd T/a	Guangzhou Wondfo Biotech Co Ltd (China)	2019-nCoV Antigen Test (Lateral Flow Method)	POCT	W19611112	✓	✓	✓	✓	Clinical: Delta, Omicron, and BA.5 Analytical: Alpha*, Beta*, Gamma*, Kappa*, Delta and

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		
	Emergo Australia								Omicron, BA.4 and BA.5	
374693	Eurofins Technologies Australia Pty Ltd	Hangzhou Alltest Biotech Co Ltd (China)	SARS-CoV-2 Antigen Rapid Test (Swab)	POCT	NCP21030 025	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.5 Analytical: BA.5, BA.4, 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, BA.5 Analytical: BA.5, BA.4, Alpha*, Beta*, Gamma*, Delta and Omicron
396675	Fortun8 International Trading	Hangzhou Clongene Biotech Co Ltd (China)	CLUNGENE COVID-19 Antigen Rapid Test (For self-testing)	Self-test						Clinical: 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		
	Co Pty Limited								Analytical: 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					Clinical: Delta, Omicron, BA.4 Analytical: Alpha*, Beta*, Gamma*, Kappa*, Epsilon*, Eta*, Iota*, Lambda*, Mu*, Delta, Omicron, BA.4, BA.5, BA.2.75	
399559	HA TECH PTY LTD	HA TECH PTY LTD (Australia)	GENEDIAN COVID-19 Antigen Test Cassette - Self Testing	Self-test					Clinical: Omicron Analytical: Omicron	
365551	Haemokinesis Pty Ltd	RapiGEN Inc (Korea - Republic of)	BIOCREDIT COVID-19 Ag	POCT	H073A040 D	✓	✗	✓	✓	Clinical: Delta, Omicron, BA.5 Analytical: Kappa*, 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		
Cancelled by sponsor										Eta*, Lambda*, Alpha, Beta, Gamma, Delta, Omicron, Zeta,
335597 Cancelled by sponsor	Haemokinesis Pty Ltd	PCL Inc (Korea - Republic of)	PCL COVID19 Rapid FIA	POCT	COV05-2005K-101	✓	✗	✓	✓	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	405-07002-2111025	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.4, BA.5 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: Omicron, BA.4 and BA.5 Analytical: Alpha*, Beta*, Gamma*,

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		
										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						Clinical: Omicron, BA.4 and BA.5 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	YPSA211002	✓	✓	✓	✓	Clinical: Omicron, BA.4 and BA.5 Analytical: Alpha*, Beta*, Gamma*, Delta*, Lambda*, Omicron*
345031	Hough Pharma Pty Ltd	BIOHIT HealthCare (Hefei) Co Ltd	Hough Covid-19 Home Test	Self-test	SA211004	✓	✓	✓	✘	Clinical: Omicron, BA.4 and BA.5
					SA220212	✓	✓	✓	✓	Analytical: Alpha*, Beta*, Gamma*,

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		
									Delta*, Lambda*, Omicron*	
336146	Innovation Scientific Pty Ltd	Innovation Scientific Pty Ltd	InnoScreen COVID-19 Antigen Rapid Test Device	POCT	SR2021100080	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.2 and BA.5 Analytical: Alpha*, Beta*, Gamma*, Delta, Kappa*, Epsilon*, Iota*, Lambda*, Zeta*, Delta, Omicron, BA.4 and BA.5
336146	Innovation Scientific Pty Ltd	Innovation Scientific Pty Ltd (Australia)	InnoScreen COVID-19 Antigen Rapid Test Device (Self Test)	Self-test	SR2021100079	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.2 and BA.5 Analytical: Alpha*, Beta*, Gamma*, Delta, Kappa*, Epsilon*, Iota*, Lambda*, Zeta*,

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		
									Delta, Omicron, BA.4 and BA.5	
385429	Jamach Pty Ltd	Hangzhou Testsea Biotechnology Co Ltd (China)	Jamach COVID-19 Antigen Test Cassette	Self-test	TL2D01	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.4 and BA.5 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	1901D005 GEN	✓	✓	✓	✓	Clinical: Analytical: Gamma*, Alpha, Beta, 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		
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
332961	MD Solutions Australia Pty Ltd	CTK Biotech Inc (United States Of America)	Aria and OnSite Covid-19 Rapid AG Test	POCT	F0415S2D0 0D	✓	✓	✓	✓	Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Delta, Omicron
332961	MD Solutions Australia Pty Ltd	CTK Biotech Inc	OnSite COVID-19 Ag Self Test	Self-test†						Clinical: Delta, 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		
383823	MD Solutions Australasia Pty Ltd	Philosys Co Ltd (Korea - Republic of)	Gmate COVID-19 Ag Saliva	Self-test						Clinical: Omicron Analytical: Alpha, Beta, Delta, Omicron BA.1, BA.2
374063 Cancelled by TGA	Medi-Stats ANZ Pty Ltd	Empowered Diagnostics LLC (United States Of America)	CovClear COVID-19 Antigen Test	POCT	02-299-2021	×	×	✓	✓	Clinical: Analytical: Delta
333344	Medsupply Australia Pty Ltd	HANGZHOU BIOTEST BIOTECHNO LTD (China)	COVID-19 Antigen Rapid Test Cassette	POCT	COVN2111 010-S	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.4, BA.5 Analytical: Alpha, Beta, Gamma, Delta, Omicron, BA.4, BA.5

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		
333344	Medsupply Australia Pty Ltd	HANGZHOU BIOTEST BIOTECH CO LTD	RightSign COVID-19 Antigen Rapid Test Cassette	Self-test†					Clinical: Delta, Omicron, BA.4, BA.5 Analytical: Alpha, Beta, Gamma, Delta, Omicron, BA.4, BA.5	
373711	MP Biomedicals Australasia Pty Ltd	MP Biomedicals Asia Pacific	Rapid SARS-CoV-2 Antigen Test Card	POCT	8AL10-020	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.2-like, BA.5-like. Analytical: Alpha*, Beta*, Gamma*, Epsilon*, Iota*, Kappa*, Theta*, Eta*, Zeta*, Delta, Omicron, BA.4 and BA.5

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		
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, BA.2-like, BA.5-like. Analytical: Alpha*, Beta*, Gamma*, Epsilon*, Iota*, Kappa*, Theta*, Eta*, Zeta*, Delta, Omicron, BA.4 and BA.5
349933	Nature's Family Australia Pty Ltd	GenBody Inc (Korea - Republic of)	GenBody COVID-19 Ag	POCT	FMFA25211	✓	✓	✓	✓	Clinical: Delta, Omicron Analytical: Alpha, Beta, Gamma, Delta, Epsilon, Eta, Iota, Zeta, Omicron
383887	Nature's Family	GenBody Inc	Covid-19 Ag Home Test	Self-test	FXFGS27221	✓	✓	✓	✓	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		
	Australia Pty Ltd								Analytical: Alpha, Beta, Gamma, Delta, Omicron	
386305	Nuex Medical Melbourne	Hangzhou Testsea Biotechnology Co Ltd	COVID-19 Antigen Test Cassette - Self Test	Self-test					Clinical: Delta, Omicron, BA.4 and BA.5 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*	

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		
382250	Orvato Healthcare Pty Ltd (formerly Medco Solutions)	Acon Biotech (Hangzhou) Co Ltd (China)	Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	Self-test	COV2015130	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.4 and BA.5 Analytical: Alpha*, Beta*, Gamma*, Epsilon*, Mu*, Zeta*, Eta*, Theta*, Iota*, Lambda*, Kappa*, Delta, Omicron, BA.4 and BA.5
					COV2015087	✓	✓	✓	✓	
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)	Self-test						Clinical: Delta, Omicron, BA.4, BA.5 Analytical: Alpha, Beta, Gamma, Delta, Kappa, Epsilon, Iota, Omicron, BA.4, BA.5

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		
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, BA.4, BA.5 Analytical: Alpha, Beta, Gamma, Delta, Kappa, Epsilon, Iota, Omicron, BA.4, BA.5	
342512	Pantonic Health Pty Ltd	Access Bio Inc	CareStart™ COVID-19 Antigen test kit	POCT	CM21J05	✓	✓	✓	✓	Clinical: Omicron, BA.4 and BA.5 Analytical: Alpha*, Beta*, Delta*, Kappa*, Epsilon*, Lambda*, Omicron, BA.4 and BA.5

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		
342512	Pantonic Pty Ltd	Access Bio Inc (United States Of America)	CareStart COVID-19 Antigen Home Test	Self-test	CM21J01	✓	✓	✓	✓	Clinical: Omicron, BA.4 and BA.5 Analytical: Alpha*, Beta*, Delta*, Kappa*, Epsilon*, Lambda*, Omicron, BA.4 and BA.5
373151	Pharma Soul Pty Ltd	Hangzhou Testsea Biotechnology Co Ltd (China)	Testsea SARS-CoV-2 Antigen Test Kit	POCT	TL1103	✓	✓	✓	✓	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

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, 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, BA.4 and BA.5 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	✓	✓	✓	✓	Clinical: Omicron, BA.5 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	TL2B97	✓	✓	✓	✓	Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*,

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		
									Omicron*, Kappa*, Mu*, Epsilon*, Eta*, Iota*, Theta*, Zeta*, Delta	
399270	PROTEK NANO PTY LTD	Getein Biotech Inc (China)	SARS-CoV-2/Influenza A/B Antigen Rapid Test Kit (POCT)	POCT COMBO					Clinical: Delta and Omicron Analytical: Delta and Omicron Influenza: Influenza A (H1N1, H3N2), Influenza B (Victoria, Yamagata)	
399270	PROTEK NANO PTY LTD	Getein Biotech Inc (China)	SARS-CoV-2/Influenza A/B Antigen Rapid Self-Test Kit	Self-test COMBO					Clinical: Delta and Omicron Analytical: Delta and Omicron Influenza: Influenza A (H1N1,	

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		
									H3N2), Influenza B (Victoria, Yamagata)	
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 and BA.5 Analytical: Alpha*, Beta*, Gamma*, Kappa*, Epsilon*, Iota*, Lambda*, Zeta*, Delta, Omicron, BA.4 and BA.5
352250	Roche Diagnostics	SD Biosensor Inc	SARS-CoV-2 Rapid Antigen Test Nasal	POCT†						Clinical: Delta, Omicron and BA.5

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		
	Australia Pty Limited									Analytical: Alpha*, Beta*, Gamma*, Kappa*, Epsilon*, Iota*, Lambda*, Zeta*, Delta, Omicron, BA.4 and BA.5
352250	Roche Diagnostics Australia Pty Limited	SD Biosensor Inc	SARS-CoV-2 Antigen Self Test Nasal	Self-test	QC038105 2I	✓	✓	✓	✓	Clinical: Delta, Omicron and BA.5 Analytical: Alpha*, Beta*, Gamma*, Kappa*, Epsilon*, Iota*, Lambda*, Zeta*, Delta, Omicron, BA.4 and BA.5
336661 Cancelled	Roche Diagnostics Australia	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		
	Pty Limited									
387390	Safe Interact Pty Ltd	Meril Diagnostics Pvt Ltd (India)	COVIFIND COVID-19 Antigen Self-Test	Self-test						Clinical: Delta, Omicron, BA.4 and BA.5 Analytical: Delta, Omicron, BA.4 and BA.5
334501	Solasta Life Pty Ltd	Hangzhou Realy Tech Co Ltd	Novel Coronavirus (SARS-CoV-2) Antigen rapid test	POCT	202110071	✓	✓	✓	✓	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*,

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		
									Epsilon*, 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, BA.4 and BA.5 Analytical: Alpha*, Beta*, Gamma*, Epsilon*, Delta, Omicron, BA.4 and BA.5	
395590	Sonictec Pty Ltd	Hangzhou Fanttest Biotech Co Ltd (China)	Fanttest: Covid-19/Influenza A&B Antigen Test Kit	Self-test COMBO					Clinical: Delta, Omicron, BA.4 and BA.5 Analytical: Gamma, Delta, Omicron, BA.4 and BA.5 Influenza: Influenza A (H1N1, H3N2), Influenza B	

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		
									(Victoria, Yamagata)	
348890	Stonestar Wholesale Pty Ltd	VivaChek Biotech (Hangzhou) Co Ltd (China)	VivaDiag™ SARS-CoV-2 Ag Rapid Test	POCT	SE2106178	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.4 and BA.5 Analytical: Alpha*, Beta*, Gamma*, and Epsilon*, Delta, Omicron, BA.4 and BA.5
348890	Stonestar Wholesale Pty Ltd	VivaChek Biotech (Hangzhou) Co Ltd (China)	VivaDiag Pro SARS-CoV-2 Ag rapid test	Self-test	SE2104012	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.4 and BA.5 Analytical: Alpha*, Beta*, Gamma*, Epsilon*, Delta, Omicron, BA.4 and BA.5

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		
347092	SureScreen Australia Pty Limited	BTNX Inc (Canada)	Rapid Response™ COVID-19 Antigen Rapid Test Device	POCT	I2108208	✓	✓	✓	✓	Clinical: Omicron, BA.4, BA.5 Analytical: Alpha*, Beta*, Gamma*, Delta, Omicron, BA.4, BA.5
347092	SureScreen Australia Pty Limited	BTNX Inc (Canada)	Rapid Response COVID-19 Antigen Rapid Test Cassette - At Home	Self-test†						Clinical: Omicron, BA.4, BA.5 Analytical: Alpha*, Beta*, Gamma*, Delta, Omicron, BA.4, BA.5
387662	SureScreen Australia Pty Limited	SureScreen Diagnostics Ltd (United Kingdom)	SARS-CoV-2 Antigen Rapid test Cassette (Nasal Swab) (Gold)	Self-test						Clinical: BA.4, BA.5 Analytical: Delta, Omicron, BA.4, BA.5

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		
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: BA.4, BA.5 Analytical: Delta, Omicron, BA.4, BA.5	
387662	SureScreen Australia Pty Limited	SureScreen Diagnostics Ltd (United Kingdom)	SARS-CoV-2 Antigen Rapid test Cassette (Nasal Swab) (Gold)	POCT					Clinical: BA.4, BA.5 Analytical: Delta, Omicron, BA.4, BA.5	
387662	SureScreen Australia Pty Limited	SureScreen Diagnostics Ltd (United Kingdom)	SARS-CoV-2 Antigen Rapid Test Cassette (Rhino Swabs)	POCT					Clinical: BA.4, BA.5 Analytical: Delta, Omicron, BA.4, BA.5	

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	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.4 and BA.5 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, BA.4, BA.5

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: Delta, Omicron, BA.4, BA.5 Influenza: Influenza A (H1N1, H3N2), Influenza B (Victoria, Yamagata)	
396552	Touch Biotechnology Pty Ltd	Hangzhou Realy Tech Co Ltd (China)	Realy Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device	Self-test					Clinical: Delta and Omicron Analytical: Gamma, Delta and Omicron	
388031	VITRYL AUS PTY LTD	Labnovation Technologies Inc (China)	SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography)	Self-test					Clinical: Delta, Omicron, BA.4 and BA.5 Analytical: Delta Omicron, BA.4 and BA.5	

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		
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, BA.4 and BA.5 Analytical: Alpha, Beta, Gamma, Delta, Omicron, BA.4 and BA.5	