

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	TGA testing Batch number	TGA testing Wild type analytical sensitivity	TGA testing Delta analytical sensitivity	TGA testing Omicron analytical sensitivity	TGA testing Device quality	Manufacturer provided evidence
374507	2San Pty Ltd	Hangzhou Laihe Biotech Co Ltd (China)	LYHER Novel Coronavirus (Covid-19) Antigen Test Kit (Colloidal Gold) (POCT)	2104052	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.4, BA.5 Analytical: Delta, Omicron, BA.4, BA.5
374507	2San Pty Ltd	Hangzhou Laihe Biotech Co Ltd (China)	LYHER Novel Coronavirus (Covid-19) Antigen Test Kit (colloidal Gold) Self-Test (Self-test)	2104055	Testing could not be completed for this batch due to false positive results for known	Testing could not be completed for this batch due to false positive results for known	Testing could not be completed for this batch due to false positive results for known		Clinical: Delta, Omicron, BA.4, BA.5 Analytical: Delta, Omicron, BA.4, BA.5

ARTG	Sponsor	Manufacturer	Test Kit name	TGA testing Batch number	TGA testing Wild type analytical sensitivity	TGA testing Delta analytical sensitivity	TGA testing Omicron analytical sensitivity	TGA testing Device quality	Manufacturer provided evidence
					<i>negative samples</i>	<i>negative samples</i>	<i>negative samples</i>		
				2202038	✓	✓	✓	✓	
345192	Abbott Rapid Diagnostics Pty Ltd	Abbott Rapid Diagnostics Jena GmbH (Germany)	Panbio™ COVID-19 Ag Rapid Test Device (Nasopharyngeal) (POCT)	41ADG561A Sub: A	✓	✓	✓	✓	Clinical: Delta, Omicron, Alpha, Beta Analytical: Alpha, Beta, Gamma, Delta, Kappa, Zeta, Theta, Eta, Omicron
345192	Abbott Rapid Diagnostics Pty Ltd	Abbott Rapid Diagnostics Jena GmbH (Germany)	Panbio COVID-19 Antigen Self-test (Nasal) (Self-test) † Panbio COVID-19 Ag Rapid Test Device (Nasal) (POCT)	41ADG637A	✓	✓	✓	✓	Clinical: Omicron, Alpha, Beta, Delta Analytical: Alpha, Beta, Gamma, Delta, Kappa, Zeta, Theta, Eta, Omicron
385179	Alpha- Medics Australia Pty Ltd	Qingdao Hightop Biotech Co Ltd (China)	SARS-CoV-2 Antigen Rapid Test (Self-test) † SARS-CoV-2 Antigen Rapid Test (without software) (Self-test)	COV-1220169	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.4, BA.5 Analytical: Alpha, Beta, Gamma, Delta, Omicron, BA.4, BA.5

ARTG	Sponsor	Manufacturer	Test Kit name	TGA testing Batch number	TGA testing Wild type analytical sensitivity	TGA testing Delta analytical sensitivity	TGA testing Omicron analytical sensitivity	TGA testing Device quality	Manufacturer provided evidence
386690	Alpha-Medics Australia Pty Ltd	Hangzhou Sejoy Electronics & Instruments Co Ltd (China)	SARS-CoV-2 Antigen Saliva Lolly Test (Self-test) † SARS-CoV-2 Antigen Saliva Lolly Test (without software) (Self-test)	AU20220410	✓	✓	✓	✓	Clinical: Omicron Analytical: Beta, Gamma, Delta, Omicron
396239	Alpha-Medics Australia Pty Ltd	Hangzhou Sejoy Electronics & Instruments Co Ltd (China)	SARS-CoV-2 Antigen Rapid Test Cassette (Self-test)	COVG221010	✓	✓	✓	✓	Clinical: Omicron Analytical: Beta, Gamma, Delta
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) † All Test COVID-19 Antigen Rapid Test (Swab) (INCP-502) (POCT)	ATNCP21110008	✓	✓	✓	✓	Clinical: Omicron and BA.5 Analytical: Alpha*, Beta*, Gamma*, Delta, Omicron, BA.4, BA.5
376310	AM Diagnostics	Hangzhou Alltest Biotech Co Ltd (China)	All Test COVID-19 Antigen Rapid Test (Oral)	ATCOV21110029	✓	✓	✓	✓	Clinical: BA.5

ARTG	Sponsor	Manufacturer	Test Kit name	TGA testing Batch number	TGA testing Wild type analytical sensitivity	TGA testing Delta analytical sensitivity	TGA testing Omicron analytical sensitivity	TGA testing Device quality	Manufacturer provided evidence
			Fluid) Self-Test (ICOV-802H) (Self-test) † All Test COVID-19 Antigen Rapid Test (Oral fluid) (ICOV-802) (POCT) † My Covid Test Antigen Rapid Test (Oral Fluid) Self-Test (ICOV-802H) (Self-test)						Analytical: Alpha*, Beta*, Gamma*, Delta, Omicron, BA.4, BA.5
333341	APAC Security Pty Ltd	Hangzhou Clongene Biotech Co Ltd (China)	Clungene COVID-19 Antigen Rapid Test (Self - testing) (Self-test) † Clungene COVID-19 Antigen Rapid Test (POCT)	2022020145	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.2, BA.4, BA.5 Analytical: Alpha, Beta, Gamma, Delta, Omicron, BA.4, BA.5
346587	Atomo Diagnostics Limited	Access Bio Inc (United States Of America)	Atomo Covid-19 Antigen Test (POCT)	CH21K02	✓	×	✓	✓	Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Delta* Kappa*,

ARTG	Sponsor	Manufacturer	Test Kit name	TGA testing Batch number	TGA testing Wild type analytical sensitivity	TGA testing Delta analytical sensitivity	TGA testing Omicron analytical sensitivity	TGA testing Device quality	Manufacturer provided evidence
Cancelled by Sponsor				CH22B04	✓	✓	✓	✓	Epsilon*, Lambda*, Omicron
382031	AusDiagnos tics 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, BA.5 Analytical: Alpha*, Beta*, Gamma*, Kappa*, Eta*, Mu*, Epsilon*, Iota*, Lambda*, Zeta*, Theta*, Delta, Omicron, BA.4, BA.5
385653	Australia Biotech Pty Ltd	Guangzhou Wondfo Biotech Co Ltd (China)	Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) (Self-test)	W63420331	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.4, BA.5 Analytical: Alpha, Beta, Delta, Omicron, BA.4, BA.5
375418	Australia Health Products Central Pty Ltd	Hangzhou Testsea Biotechnology Co Ltd (China)	Cellife Covid-19 Antigen Test Cassette (POCT) † Cellife Covid-19 Antigen Test Cassette for Self (Self-test)	TL1L14	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.4, BA.5 Analytical: Alpha*, Beta*, Gamma*, Kappa*, Mu*, Lambda*, Iota*, Epsilon*, Eta*, Theta*,

ARTG	Sponsor	Manufacturer	Test Kit name	TGA testing Batch number	TGA testing Wild type analytical sensitivity	TGA testing Delta analytical sensitivity	TGA testing Omicron analytical sensitivity	TGA testing Device quality	Manufacturer provided evidence
									Zeta*, Delta, Omicron, BA.2, BA.4, BA.5
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, 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) † SARS-CoV-2 Virus Antigen Detection Kit (Colloidal Gold Method) (POCT)	3121202209001	✓	✓	✓	✓	Clinical: Delta, Omicron Analytical: Delta, BA.4, BA.5
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)	20220302	✓	✓	✓	✓	Clinical: Delta, Beta, Omicron Analytical: Delta, Beta, Omicron, BA.4, BA.5

ARTG	Sponsor	Manufacturer	Test Kit name	TGA testing Batch number	TGA testing Wild type analytical sensitivity	TGA testing Delta analytical sensitivity	TGA testing Omicron analytical sensitivity	TGA testing Device quality	Manufacturer provided evidence
387550	BGI Health (AU) Company Pty Ltd	Innovita (Tangshan) Biological Technology Co Ltd (China)	2019 nCoV Ag Test (Latex Chromatography Assay) – POCT (POCT)	20220301	✓	✓	✓	✓	Clinical: Delta, Beta, Omicron Analytical: Delta, Beta, Omicron, BA.4, BA.5
387020	Big Start Pty Ltd	Guangzhou Decheng Biotechnology Co Ltd (China)	2019-nCoV Ag Rapid Test Kit (Self-test)	068220601	✓	✓	✓	✓	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)	58327KAAC1	✓	✓	✓	✓	Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Delta, Kappa*, Epsilon*, Iota*, Lambda*, Zeta*, Delta, Omicron, BA.4, BA.5
			† STANDARD™ Q COVID-19 Ag Test Nasal swab (POCT)						Clinical: Omicron Analytical: Delta, Omicron, BA.4, BA.5

ARTG	Sponsor	Manufacturer	Test Kit name	TGA testing Batch number	TGA testing Wild type analytical sensitivity	TGA testing Delta analytical sensitivity	TGA testing Omicron analytical sensitivity	TGA testing Device quality	Manufacturer provided evidence
374065	Cole Workwear PL	Guangzhou Decheng Biotechnology Co Ltd (China)	2019-nCoV Ag Saliva Rapid Test Card (POCT) † V-Chek COVID-19 Antigen Saliva Test	05821068C	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.1, BA.2, BA.4, BA.5 Analytical: Beta*, Gamma*, Epsilon*, Alpha, Kappa, Delta, Omicron, BA.4, BA.5
374574	Compliance Managemen t Solutions	Hangzhou Alltest Biotech Co Ltd (China)	SARS-CoV-2 Antigen Rapid Test INCP-502-N (POCT) † JusChek SARS-CoV-2 Antigen Rapid Test (Nasal Swab) INCP- 502H (Self-test) † JusChek SARS-CoV-2 Antigen Rapid Test INCP-502-N (POCT) † Beright SARS-CoV-2 Antigen Rapid Test INCP-502-N (POCT)	ATNCP21110034	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.5 Analytical: Alpha, Beta, Gamma, Delta, Omicron, BA.4, BA.5
374574				ATCOV21110060	✓	✓	✓	✗	Clinical: Delta, Omicron, BA.5

ARTG	Sponsor	Manufacturer	Test Kit name	TGA testing Batch number	TGA testing Wild type analytical sensitivity	TGA testing Delta analytical sensitivity	TGA testing Omicron analytical sensitivity	TGA testing Device quality	Manufacturer provided evidence
	Compliance Managemen t Solutions	Hangzhou Alltest Biotech Co Ltd (China)	COVID-19 Antigen Rapid Test (Oral Fluid) ICOV- 802 (POCT)					>5% invalid results that required repeat testing	Analytical: Alpha, Beta, Gamma, Delta, Omicron, BA.4, BA.5
			† JusChek COVID-19 Antigen Rapid Test (Oral Fluid) ICOV-802H (Self- test) † JusChek COVID-19 Antigen Rapid Test ICOV-802 (Oral Fluid) (POCT) † Beright COVID-19 Antigen Rapid Test ICOV-802 (Oral Fluid) (POCT)	ATCOV2209405-S	✓	✓	✓	✓	
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, Omicron, BA4, BA5 Analytical: Alpha, Beta, Gamma, Delta, Epsilon, Omicron, BA4, BA5

ARTG	Sponsor	Manufacturer	Test Kit name	TGA testing Batch number	TGA testing Wild type analytical sensitivity	TGA testing Delta analytical sensitivity	TGA testing Omicron analytical sensitivity	TGA testing Device quality	Manufacturer provided evidence
382615	Doncaster Australia Pty Ltd	Hangzhou Realy Tech Co Ltd (China)	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) (Self-test) † Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) (POCT)	202201179	✓	✓	✓	✓	Clinical: Delta, Omicron, BA4, BA5 Analytical: Alpha, Beta, Gamma, Delta, Epsilon Omicron, BA4, BA5
346643 Cancelled by sponsor	Emergence Technology Pty Ltd	Assure Tech (Hangzhou) Co Ltd (China)	COVID-19 Antigen Rapid Test Device (POCT)	I2011094	Testing could not be completed for this batch due to false positive results for negative controls	Testing could not be completed for this batch due to false positive results for negative controls	Testing could not be completed for this batch due to false positive results for negative controls		Clinical: Analytical: Delta*, Kappa*, Alpha*, Beta*, Gamma*, Omicron
372335	Emergence Technology Pty Ltd	Assure Tech (Hangzhou) Co Ltd (China)	Ecotest COVID-19 Antigen Saliva Test kit (COV-S35Pen) (Self-test)	I2110184	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.5 Analytical: XBB, BA.4, BA.5, Omicron, Delta, Alpha, Beta, Gamma

ARTG	Sponsor	Manufacturer	Test Kit name	TGA testing Batch number	TGA testing Wild type analytical sensitivity	TGA testing Delta analytical sensitivity	TGA testing Omicron analytical sensitivity	TGA testing Device quality	Manufacturer provided evidence
			† Ecotest COVID-19 Antigen Saliva Test Kit (POCT)						
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, BA.5 Analytical: XBB, BA.4, BA.5, Omicron, Delta, Alpha, Beta, Gamma
			† Ecotest COVID-19 Antigen Nasal Test Kit (POCT)	E2022060106	✓	✓	✓	✓	
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	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.5 Analytical: Alpha*, Beta*, Gamma*, Kappa*, Delta, Omicron, BA.4, BA.5
374693	Eurofins Technologies Australia Pty Ltd	Hangzhou Alltest Biotech Co Ltd (China)	SARS-CoV-2 Antigen Rapid Test (Swab) (POCT) † GSD NovaGen SARS CoV-2 Ag Rapid Test	NCP21030025	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.5 Analytical: BA.5, BA.4, Alpha*, Beta*, Gamma*, Delta, Omicron

ARTG	Sponsor	Manufacturer	Test Kit name	TGA testing Batch number	TGA testing Wild type analytical sensitivity	TGA testing Delta analytical sensitivity	TGA testing Omicron analytical sensitivity	TGA testing Device quality	Manufacturer provided evidence
			(Nasal swab) Self-testing (Self-test)						
396675	Fortun8 International Trading Co Pty Limited	Hangzhou Clongene Biotech Co Ltd (China)	CLUNGENE COVID-19 Antigen Rapid Test (For self-testing) (Self-test)	2022100028	✓	✓	✓	✓	Clinical: Delta, Omicron Analytical: Alpha, Beta, Gamma, Delta, Omicron
384538	Gardian Technologies Pty Ltd	Jiangsu Medomics Medical Technology Co Ltd (China)	Gardian T3 COVID-19-SARS-CoV-2 Antigen Saliva (Self-test)	20220323	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.4 Analytical: Alpha*, Beta*, Gamma*, Kappa*, Epsilon*, Eta*, Iota*, Lambda*, Mu*, Delta, Omicron, BA.4, BA.5, BA.2.75
365551 Cancelled by sponsor	Haemokinesis Pty Ltd	RapiGEN Inc (Korea - Republic of)	BIOCREDIT COVID-19 Ag (POCT)	H073A040D	✓	✗	✓	✓	Clinical: Delta, Omicron, BA.5 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)	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, Omicron, BA.5
345031	Hough Pharma Pty Ltd	BIOHIT HealthCare (Hefei) Co Ltd (China)	SARS-CoV-2 Antigen Rapid Test Kit: Point of care testing (POCT)	SA211208	<i>Testing could not be completed for this batch due to false positive results for negative controls</i>	<i>Testing could not be completed for this batch due to false positive results for negative controls</i>	<i>Testing could not be completed for this batch due to false positive results for negative controls</i>		Clinical: Omicron, BA.4, BA.5 Analytical: Alpha*, Beta*, Gamma*, Delta*, Lambda*, Omicron*
				SA220101	✓	✓	✓	✓	

ARTG	Sponsor	Manufacturer	Test Kit name	TGA testing Batch number	TGA testing Wild type analytical sensitivity	TGA testing Delta analytical sensitivity	TGA testing Omicron analytical sensitivity	TGA testing Device quality	Manufacturer provided evidence
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, 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	<i>Testing could not be completed due to faulty test kit components (UV torches)</i>	<i>Testing could not be completed due to faulty test kit components (UV torches)</i>	<i>Testing could not be completed due to faulty test kit components (UV torches)</i>	✖	Clinical: Omicron, BA.4, BA.5 Analytical: Alpha*, Beta*, Gamma*, Delta*, Lambda*, Omicron*
				SA220212	✓	✓	✓	✓	
336146	Innovation Scientific Pty Ltd	Innovation Scientific Pty Ltd (Australia)	InnoScreen COVID-19 Antigen Rapid Test Device (POCT)	SR2021100080	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.2, BA.4, BA.5 Analytical: Alpha*, Beta*, Gamma*, Delta, Kappa*, Epsilon*, Iota*, Lambda*, Zeta*, Delta, Omicron, BA.4, BA.5

ARTG	Sponsor	Manufacturer	Test Kit name	TGA testing Batch number	TGA testing Wild type analytical sensitivity	TGA testing Delta analytical sensitivity	TGA testing Omicron analytical sensitivity	TGA testing Device quality	Manufacturer provided evidence
336146	Innovation Scientific Pty Ltd	Innovation Scientific Pty Ltd (Australia)	InnoScreen COVID-19 Antigen Rapid Test Device (Self-test)	SR2021100079	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.2, BA.4, BA.5 Analytical: Alpha*, Beta*, Gamma*, Delta, Kappa*, Epsilon*, Iota*, Lambda*, Zeta*, Delta, Omicron, BA.4, 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, BA.5 Analytical: Alpha*, Beta*, Gamma*, Kappa*, Mu*, Lambda*, Epsilon*, Eta*, Zeta*, Iota*, Theta*, Delta, Omicron
343293 Cancelled by Sponsor	Life Bioscience Pty Ltd	BioNote Inc (Korea - Republic of)	NowCheck COVID-19 Antigen Test (POCT)	1901D005GEN	✓	✓	✓	✓	Clinical: Analytical: Gamma*, Alpha, Beta, Delta, Omicron
385275	LRY Group of	Jiangsu Well Biotech Co Ltd (China)	Orawell COVID-19 Ag Rapid Saliva Test (SELF-TEST KIT) (Self-test)	202112021	Testing could not be completed for this	Testing could not be completed for this	Testing could not be completed for this		Clinical: Delta Analytical: *Kappa, *Epsilon, *Lambda,

ARTG	Sponsor	Manufacturer	Test Kit name	TGA testing Batch number	TGA testing Wild type analytical sensitivity	TGA testing Delta analytical sensitivity	TGA testing Omicron analytical sensitivity	TGA testing Device quality	Manufacturer provided evidence
	Companies Pty Ltd				<i>batch due to false positive results for negative controls</i>	<i>batch due to false positive results for negative controls</i>	<i>batch due to false positive results for negative controls</i>		Alpha, Beta, Gamma, Delta
				202210101	✓	✓	✓	✓	
332961	MD Solutions Australasia Pty Ltd	CTK Biotech Inc (United States Of America)	Aria and OnSite Covid- 19 Rapid AG Test (POCT) † OnSite COVID-19 Ag Self Test (Self-test)	F0415S2D00D	✓	✓	✓	✓	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)	CS10VEDO	✓	✓	✓	✓	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

ARTG	Sponsor	Manufacturer	Test Kit name	TGA testing Batch number	TGA testing Wild type analytical sensitivity	TGA testing Delta analytical sensitivity	TGA testing Omicron analytical sensitivity	TGA testing Device quality	Manufacturer provided evidence
333344	Medsupply Australia Pty Ltd	HANGZHOU BIOTEST BIOTECH NO LTD (China)	COVID-19 Antigen Rapid Test Cassette (POCT) † RightSign COVID-19 Antigen Rapid Test Cassette (Self-test)	COVN2111010-S	✓	✓	✓	✓	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 Pte Ltd (Singapore)	Rapid SARS-CoV-2 Antigen Test Card (POCT) † Rapid SARS-COV-2 Antigen Test Card Self-test (without pre-filled extraction tube) (Self-test) † Rapid SARS-CoV-2 Antigen Test Card (with pre-filled extraction tube) (POCT) † Rapid SARS-COV-2 Antigen Test Card Self-test (with pre-filled extraction tube) (Self-test)	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, BA.5

ARTG	Sponsor	Manufacturer	Test Kit name	TGA testing Batch number	TGA testing Wild type analytical sensitivity	TGA testing Delta analytical sensitivity	TGA testing Omicron analytical sensitivity	TGA testing Device quality	Manufacturer provided evidence
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 Australia Pty Ltd	GenBody Inc (Korea – Republic of)	Covid-19 Ag Home Test (Self-test)	FXFGS27221	✓	✓	✓	✓	Clinical: Delta, Omicron Analytical: Alpha, Beta, Gamma, Delta, Omicron
386305	Nuex Medical Melbourne	Hangzhou Testsea Biotechnology Co Ltd (China)	COVID-19 Antigen Test Cassette - Self Test (Self-test)	TL2F20	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.4, BA.5 Analytical: Alpha*, Beta*, Gamma*, Kappa*, Mu*, Lambda*, Delta, Omicron
382250	Orvato Healthcare Pty Ltd (formerly	Acon Biotech (Hangzhou) Co Ltd (China)	Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing) (Self-test)	COV2015130	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.4, BA.5

ARTG	Sponsor	Manufacturer	Test Kit name	TGA testing Batch number	TGA testing Wild type analytical sensitivity	TGA testing Delta analytical sensitivity	TGA testing Omicron analytical sensitivity	TGA testing Device quality	Manufacturer provided evidence
	Medco Solutions)			COV2015087	✓	✓	✓	✓	Analytical: Alpha*, Beta*, Gamma*, Epsilon*, Mu*, Zeta*, Eta*, Theta*, Iota*, Lambda*, Kappa*, Delta, Omicron, BA.4 and BA.5
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) † SARS-CoV-2 antigen Test Kit (LFIA) (Self-test)	2021122601 (Type I)	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.4, BA.5 Analytical: Alpha, Beta, Gamma, Delta, Kappa, Epsilon, Iota, Omicron, BA.4, BA.5
				2021122601 (Type II)	✓	✓	✓	✓	
				2021122601 (Type III)	✓	✓	✓	✓	
342512	Pantonic Health Pty Ltd	Access Bio Inc (United States of America)	CareStart™ COVID-19 Antigen test kit (POCT)	CM21J05	✓	✓	✓	✓	Clinical: Omicron, BA.4, BA.5 Analytical: Alpha*, Beta*, Delta*, Kappa*, Epsilon*, Lambda*, Omicron, BA.4, BA.5

ARTG	Sponsor	Manufacturer	Test Kit name	TGA testing Batch number	TGA testing Wild type analytical sensitivity	TGA testing Delta analytical sensitivity	TGA testing Omicron analytical sensitivity	TGA testing Device quality	Manufacturer provided evidence
342512	Pantonic Pty Ltd	Access Bio Inc (United States Of America)	CareStart COVID-19 Antigen Home Test (Self-test)	CM21J01	✓	✓	✓	✓	Clinical: Omicron, BA.4, BA.5 Analytical: Alpha*, Beta*, Delta*, Kappa*, Epsilon*, Lambda*, Omicron, BA.4, BA.5
373151	Pharma Soul Pty Ltd	Hangzhou Testsea Biotechnology Co Ltd (China)	Testsea SARS-CoV-2 Antigen Test Kit (POCT) † TESTSEALABS COVID-19 Antigen Test Cassette (Self-test)	TL1I03	✓	✓	✓	✓	Clinical: Delta, Omicron Analytical: Delta, Omicron
374627	Pharma Soul Pty Ltd	iXensor Co Ltd (Taiwan)	PixoTest® COVID-19 AG Test Kit (POCT)	I21I28D	Testing could not be completed for this batch due to absence of controls	Testing could not be completed for this batch due to absence of controls	Testing could not be completed for this batch due to absence of controls		Clinical: 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)	TL2C0E	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.4, BA.5

ARTG	Sponsor	Manufacturer	Test Kit name	TGA testing Batch number	TGA testing Wild type analytical sensitivity	TGA testing Delta analytical sensitivity	TGA testing Omicron analytical sensitivity	TGA testing Device quality	Manufacturer provided evidence
									Analytical: Alpha, Beta, Gamma, Delta, Omicron, BA.4, BA.5
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*, 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*, Omicron*, Kappa*, Mu*, Epsilon*, Eta*, Iota*, Theta*, Zeta*, Delta
395414	Rapant Pty Ltd	Hangzhou Realy Tech Co Ltd (China)	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab) (Self-test)	202210005	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.4, BA.5 Analytical: Delta, Omicron, BA.4, BA.5
352250	Roche Diagnostics	SD Biosensor Inc (Korea – Republic of)	SARS-CoV-2 Rapid Antigen Test Nasal (POCT)	QC03910831 / Sub: I-2	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.5

ARTG	Sponsor	Manufacturer	Test Kit name	TGA testing Batch number	TGA testing Wild type analytical sensitivity	TGA testing Delta analytical sensitivity	TGA testing Omicron analytical sensitivity	TGA testing Device quality	Manufacturer provided evidence
	Australia Pty Limited		† SARS-CoV-2 Rapid Antigen Test (POCT)						Analytical: Alpha*, Beta*, Gamma*, Kappa*, Epsilon*, Iota*, Lambda*, Zeta*, Delta, Omicron, BA.4, BA.5
352250	Roche Diagnostics Australia Pty Limited	SD Biosensor Inc (Korea – Republic of)	SARS-CoV-2 Antigen Self Test Nasal (Self-test)	QC0381052I	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.5 Analytical: Alpha*, Beta*, Gamma*, Kappa*, Epsilon*, Iota*, Lambda*, Zeta*, Delta, Omicron, BA.4, BA.5
387390	Safe Interact Pty Ltd	Meril Diagnostics Pvt Ltd (India)	COVIFIND COVID-19 Antigen Self-Test (Self- test)	MIC10220066	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.4, BA.5 Analytical: Delta, Omicron, BA.4, BA.5
334501	Solasta Life Pty Ltd	Hangzhou Realy Tech Co Ltd (China)	Novel Coronavirus (SARS-CoV-2) Antigen rapid test (POCT) † Novel Coronavirus (SARS-Cov-2) Antigen	202110071	✓	✓	✓	✓	Clinical: Delta, Omicron Analytical: Alpha*, Beta*, Gamma*, Epsilon*, Delta, Omicron

ARTG	Sponsor	Manufacturer	Test Kit name	TGA testing Batch number	TGA testing Wild type analytical sensitivity	TGA testing Delta analytical sensitivity	TGA testing Omicron analytical sensitivity	TGA testing Device quality	Manufacturer provided evidence
			Rapid Test Device (nasal swab) (Self-test)						
384537	Sonictec Pty Ltd	Hangzhou Realy Tech Co Ltd (China)	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (Self-test)	202206037	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.4, BA.5 Analytical: Alpha*, Beta*, Gamma*, Epsilon*, Delta, Omicron, BA.4, BA.5
395590	Sonictec Pty Ltd	Hangzhou Fanttest Biotech Co Ltd (China)	Fanttest: Covid-19/Influenza A&B Antigen Test Kit (Self-test COMBO)	I2210001	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.4, BA.5 Analytical: Gamma, Delta, Omicron, BA.4, BA.5
				I2210002	✓	✓	✓	✓	Influenza: Influenza A (H1N1, H3N2), Influenza B (Victoria, Yamagata)
				I2210003	✓	✓	✓	✓	
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, BA.5 Analytical: Alpha*, Beta*, Gamma*,

ARTG	Sponsor	Manufacturer	Test Kit name	TGA testing Batch number	TGA testing Wild type analytical sensitivity	TGA testing Delta analytical sensitivity	TGA testing Omicron analytical sensitivity	TGA testing Device quality	Manufacturer provided evidence
									Epsilon*, Delta, Omicron, BA.4, 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, BA.5 Analytical: Alpha*, Beta*, Gamma*, Epsilon*, Delta, Omicron, BA.4, BA.5
347092	SureScreen Australia Pty Limited	BTNX Inc (Canada)	Rapid Response™ COVID-19 Antigen Rapid Test Device (POCT) † Rapid Response COVID-19 Antigen Rapid Test Cassette - At Home (Self-test) † Surescreen Diagnostics COVID-19 Antigen Rapid Test (POCT)	I2108208	✓	✓	✓	✓	Clinical: Omicron, BA.4, BA.5 Analytical: Alpha*, Beta*, Gamma*, Delta, Omicron, BA.4, BA.5
387662	SureScreen Australia Pty Limited	SureScreen Diagnostics Ltd	SARS-CoV-2 Antigen Rapid test Cassette	COVN22030033	✓	✓	✓	✓	Clinical: BA.4, BA.5

ARTG	Sponsor	Manufacturer	Test Kit name	TGA testing Batch number	TGA testing Wild type analytical sensitivity	TGA testing Delta analytical sensitivity	TGA testing Omicron analytical sensitivity	TGA testing Device quality	Manufacturer provided evidence
		(United Kingdom)	(Nasal Swab) (Gold) (Self-test) † SARS-CoV-2 Antigen Rapid test Cassette (Nasal Swab) (Gold) (POCT)						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) with RhinoSwab Junior (Self-test) † SARS-CoV-2 Antigen Rapid Test Cassette (Rhino Swabs) (POCT)	COVN22030033 (Rhino swab)	✓	✓	✓	✓	Clinical: BA.4, BA.5 Analytical: Delta, Omicron, BA.4, BA.5
345191	Suretest	Beijing Wantai Biologicalpharmacy Enterprise Co Ltd	Wantai SARS-CoV-2 Ag Rapid Test (Colloidal Gold) (POCT)	JNA202110801	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.4, BA.5 Analytical: Delta*, Omicron*
385370	Talbot Medical Pty Ltd	Maccura Biotechnology Co Ltd (China)	Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-	0322082	✓	✓	✓	✓	Clinical: Delta Analytical: Delta

ARTG	Sponsor	Manufacturer	Test Kit name	TGA testing Batch number	TGA testing Wild type analytical sensitivity	TGA testing Delta analytical sensitivity	TGA testing Omicron analytical sensitivity	TGA testing Device quality	Manufacturer provided evidence
			CoV-2) Antigen Assay Kit (Self-test)						
395591	Touch Biotechnology Pty Ltd	Vitrosens Biyoteknoloji LTD STI (Turkey)	TouchBio SARS-CoV-2 & FLU A/B Antigen Combo Test (nasal) (Self-test COMBO)	ST1022091401	✓	✓	✓	✓	Clinical: Alpha, Beta, Delta, Eta, Omicron, BA.4, BA.5 Analytical: Delta, Omicron, BA.4, BA.5 Influenza: Influenza A (H1N1, H3N2), Influenza B (Victoria, Yamagata)
396552 Cancelled by sponsor	Touch Biotechnology Pty Ltd	Hangzhou Realy Tech Co Ltd (China)	Realy Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (Self-test)	202201163	Testing could not be completed for this batch due to false positive results for negative controls	Testing could not be completed for this batch due to false positive results for negative controls	Testing could not be completed for this batch due to false positive results for negative controls		Clinical: Delta, Omicron Analytical: Gamma, Delta, Omicron

ARTG	Sponsor	Manufacturer	Test Kit name	TGA testing Batch number	TGA testing Wild type analytical sensitivity	TGA testing Delta analytical sensitivity	TGA testing Omicron analytical sensitivity	TGA testing Device quality	Manufacturer provided evidence
388031	VITRYL AUS PTY LTD	Labnovation Technologies Inc (China)	SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatograp hy) (Self-test)	20220511C	✓	✓	✓	✓	Clinical: Delta, Omicron, BA.4, BA.5 Analytical: Delta, Omicron, BA.4, BA.5
				20220511B	✓	✓	✓	✓	
377136	Well Biotech Pty Ltd	Jiangsu Well Biotech Co Ltd (China)	Orawell COVID-19 Ag Rapid Saliva Test Device (Self-test)	202111081	<i>Testing could not be completed for this batch due to false positive results for negative controls</i>	<i>Testing could not be completed for this batch due to false positive results for negative controls</i>	<i>Testing could not be completed for this batch due to false positive results for negative controls</i>		Clinical: Delta, Omicron, BA.4, BA.5 Analytical: Alpha, Beta, Gamma, Delta, Omicron, BA.4, BA.5
				20220517	✓	✓	✓	✓	