



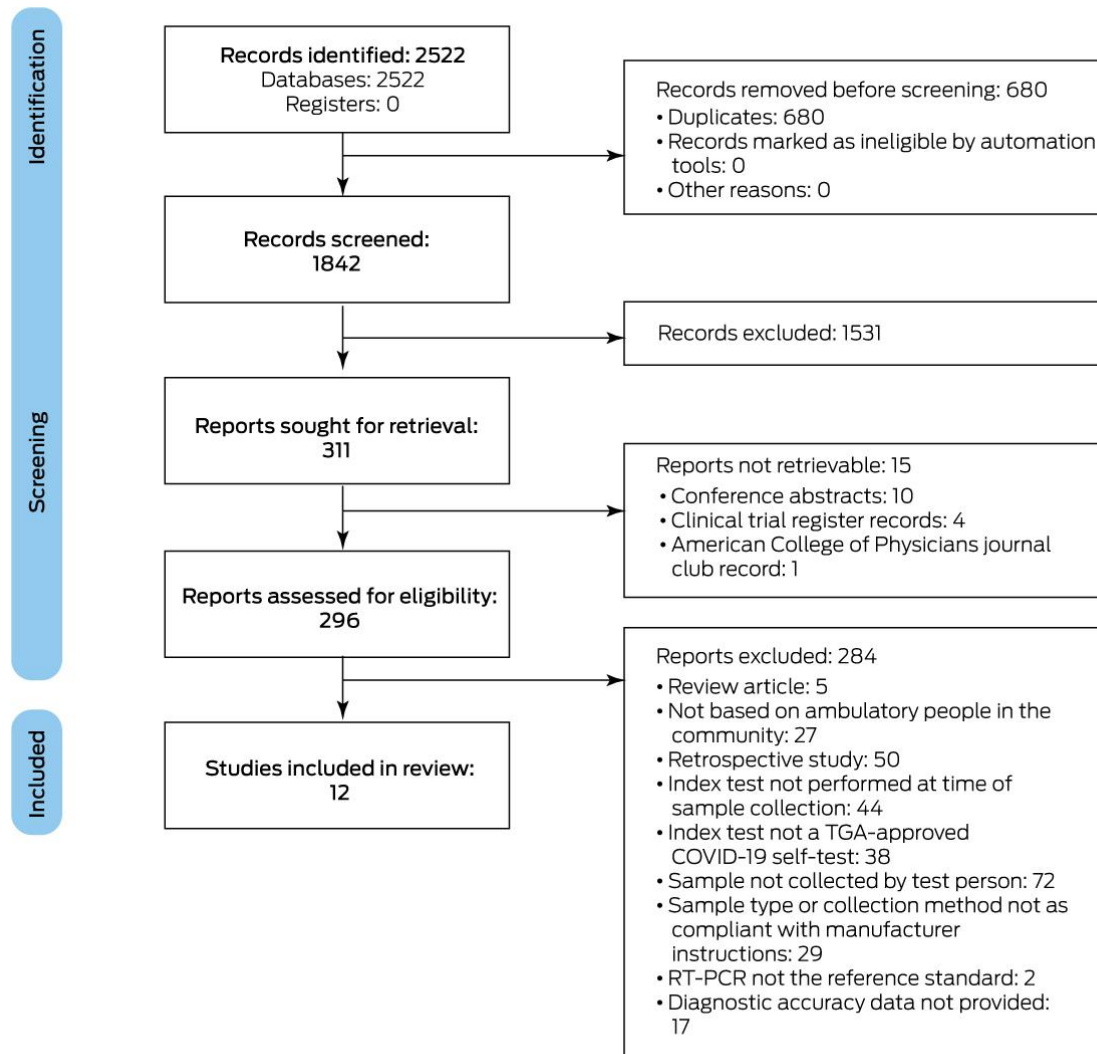
## **Supporting Information**

### **Supplementary methods and results**

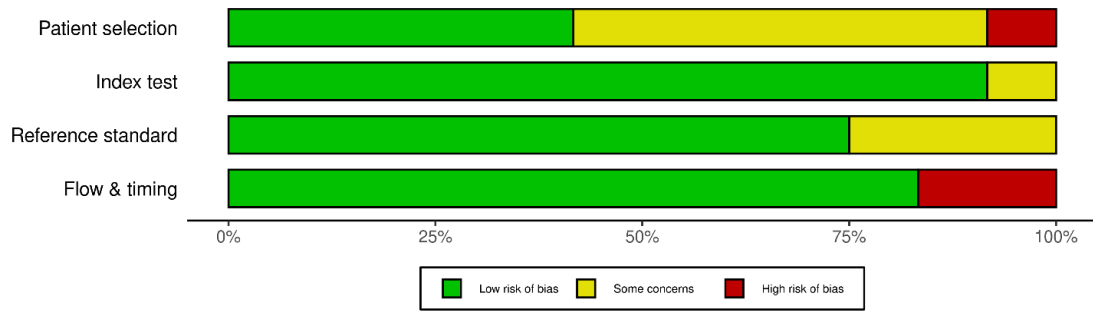
**This appendix was part of the submitted manuscript and has been peer reviewed.  
It is posted as supplied by the authors.**

Appendix to: Bell KJL, Li Y, Medcalf E, Ackermann D. COVID-19 rapid antigen tests approved for self-testing in Australia: published diagnostic test accuracy studies and manufacturer-supplied information. A systematic review. *Med J Aust* 2023; doi: 10.5694/mja2.52151.

**Figure 1. PRISMA flow diagram for our systematic review**



**Figure 2. Risk of bias of the included published studies**

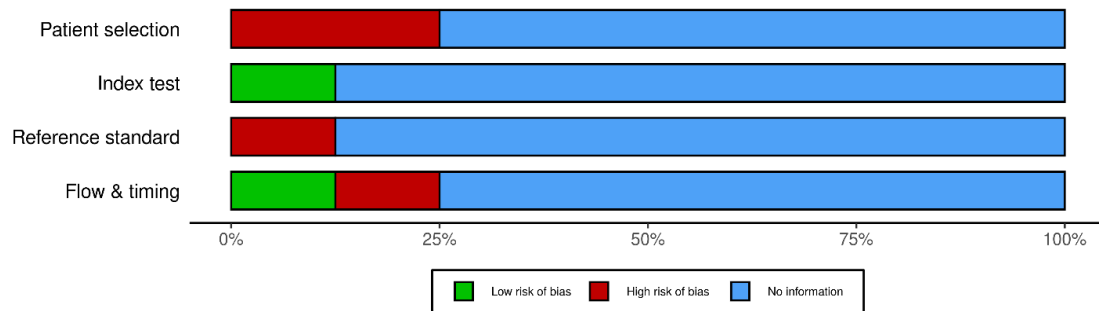


Study	Risk of bias domains			
	D1	D2	D3	D4
Schuit BMJ 2022	+	+	+	+
Venekamp 2023	+	+	+	+
Schuit BMC Med 2022	+	+	+	+
Zwart 2022	+	+	+	+
Klein 2021	-	+	-	+
Landaver-de 2022	X	+	+	+
Stohr 2022	+	+	+	+
Møller 2022	-	-	+	X
Iftner 2022	-	+	+	+
De Meyer 2022	-	+	-	X
Goodall 2022	-	+	-	+
Shah 2021	-	+	+	+

Domains:  
D1: Patient selection.  
D2: Index test.  
D3: Reference standard.  
D4: Flow & timing.

Judgement  
X High  
- Some concerns  
+ Low

**Figure 3. Risk of bias of manufacture supplied studies**



Study	Risk of bias domains			
	D1	D2	D3	D4
All Test COVID-19 Antigen Rapid Test (Oral Fluid)	?	?	?	?
SARS-CoV-2 Antigen Self Test (Roche)	?	+	?	+
Flowflex SARS-CoV-2 Antigen Rapid Test	?	?	?	?
Clungene COVID-19 Antigen Rapid Test	?	?	?	?
Panbio COVID-19 Antigen Self-test	?	?	X	?
V-Chek COVID-19 Antigen Saliva Test	X	?	?	X
Whistling 2019-nCoV Saliva Ag Easy Test	X	?	?	?
MP Biomedicals Rapid SARS-COV-2 Antigen Test Card	?	?	?	?

**Test information:**

- All Test COVID-19 Antigen Rapid Test (Oral fluid): <https://www.tga.gov.au/sites/default/files/covid-19-rapid-antigen-self-tests-are-approved-australia-oral-fluid-01.pdf>
- SARS-CoV-2 Antigen Self Test (Roche): <https://www.tga.gov.au/sites/default/files/covid-19-rapid-antigen-self-tests-are-approved-australia-ifu-352250.pdf>
- Flowflex SARS-CoV-2 Antigen Rapid Test: <https://www.tga.gov.au/sites/default/files/covid-19-rapid-antigen-self-tests-are-approved-australia-ifu-382031-02.pdf>
- MP Biomedicals Rapid SARS-COV-2 Antigen Test Card: <https://www.tga.gov.au/sites/default/files/2022-08/covid-19-rapid-antigen-self-tests-are-approved-australia-ifu-01-373711.pdf>
- Clungene COVID-19 Antigen Rapid Test: <https://www.tga.gov.au/sites/default/files/covid-19-rapid-antigen-self-tests-are-approved-australia-ifu-333341.pdf>
- Panbio COVID-19 Ag Rapid Test Device: <https://www.tga.gov.au/sites/default/files/covid-19-rapid-antigen-self-tests-are-approved-australia-ifu-345192.pdf> <https://www.globalpointofcare.abbott/gb/en/product-details/panbio-covid-19-ag-antigen-test.html>
- BinaxNOW COVID-19 Antigen Card Self-Test: <https://globalpointofcare.eifu.abbott/content/dam/ardx/eifu/iddm/scarborough/IN195150WEB%20v6.0%20BinaxNOW%20COVID-19%20Antigen%20Self%20Test%20Product%20Insert%20-%20English%20US.pdf>
- V-Chek COVID-19 Antigen Saliva Test: <https://www.tga.gov.au/sites/default/files/covid-19-rapid-antigen-self-tests-are-approved-australia-ifu-374065.pdf>
- Whistling 2019-nCoV Saliva Ag EASY TEST: <https://www.ridacom.com/en/products/view/7606> (Removed from TGA website as cancelled by sponsor (ARTG:391125))
- Ecotest COVID-19 Antigen Saliva Test Kit: <https://www.tga.gov.au/sites/default/files/covid-19-rapid-antigen-self-tests-are-approved-australia-ifu-372335.pdf>

**Table 1. Specificity of TGA-approved COVID-19 rapid antigen self-tests in published studies and in manufacturer supplied information**

Author (publication year), country	Rapid antigen test (RAT)	Sample size*	RT-PCR-positive	Specificity reported by study	Specificity reported by manufacturer	Difference (percentage points)
<b>Unsupervised sample collection</b>						
Zwart (2022), <sup>16</sup> Netherlands	Roche SARS-CoV-2 Rapid Antigen Test (oropharyngeal and nasal)	2192	152	99.7%	100%	0.3
Stohr (2022), <sup>17</sup> Netherlands	Roche SARS-CoV-2 Antigen Self-Test (nasal)	1583	192	99.7%	100%	0.3
Møller (2022), <sup>18</sup> Denmark	Panbio COVID-19 Antigen Rapid Test Device (nasal)	388	0	99.7%	99.8%	0.1
Iftner (2022), <sup>19</sup> Germany	Clungene COVID-19 Antigen Rapid Test (nasal, researcher interpretation)	478	0	97.9%	100%	2.1
	Clungene COVID-19 Antigen Rapid Test (nasal, participant interpretation)	476	0	97.9%	100%	2.1
Schuit (2022), <sup>20</sup> Netherlands	All Test COVID-19 Antigen Rapid Test (oral fluid)	2803	182	99.0%	99.3%	0.3
	Roche SARS-CoV-2 Antigen Self-Test (nasal)	2819	180	99.5%	100%	0.5
Schuit (2022), <sup>21</sup> Netherlands	Flowflex SARS-CoV-2 Antigen Rapid Test (nasal)	341	145	98.5%	99.5%	1
	MP Biomedicals Rapid SARS-COV-2 Antigen Test Card (nasal)	581	169	99.3%	100%	0.7
	MP Biomedicals Rapid SARS-COV-2 Antigen Test Card (oropharyngeal and nasal)	255	88	98.2%	100%	1.8
Venekamp (2023), <sup>22</sup> Netherlands	Flowflex SARS-CoV-2 Antigen Rapid Test (nasal)	1229	193	99.8%	99.5%	-0.3
	MP Biomedicals Rapid SARS-COV-2 Antigen Test Card (nasal)	1027	115	99.8%	100%	0.2
<b>Supervised sample collection</b>						
Shah (2021), <sup>23</sup> USA	BinaxNOW COVID-19 Antigen Card Self-Test (nasal)	2110	334	99.6%	99.8% <sup>2</sup>	0.2
Klein (2021), <sup>24</sup> Germany	Panbio COVID-19 Antigen Rapid Test Device (nasopharyngeal)	290	45	99.2%	99.8%	0.6
DeMeyer (2022), <sup>25</sup> Belgium	V-Chek COVID-19 Antigen Saliva Test (oral)	50	13	100%	98.4%	-1.6
	Whistling test 2019-nCoV Saliva Ag Easy Test (oral)	102	55	100%	99.2%	-0.8
Goodall (2022), <sup>26</sup> Canada	Panbio COVID-19 Antigen Rapid Test Device (nasal)	825	62	100%	99.8%	-0.2
Landaverde (2022), <sup>27</sup> USA	BinaxNOW COVID-19 Antigen Card Self-Test <sup>†</sup> (nasal)	209	54	100%	99.8% <sup>2</sup>	-0.2

**Notes:**

1. Sample sizes exclude participants where RAT or RT-PCR result was unclear/inconclusive.
2. Manufacturer reported specificity is for Panbio COVID-19 Antigen Rapid Test Device.
3. TGA: Therapeutic Goods Authority; COVID-19: Coronavirus disease 2019; Self-RAT: rapid antigen self-test; PCR: Polymerase Chain Reaction; SARS-CoV-2: Severe acute respiratory syndrome coronavirus 2.

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