Assessment of the analytical sensitivity of ten lateral flow devices against the SARS-CoV-2 omicron variant

10 Antigen test kits evaluated:

- Panbio™ COVID-19 Ag Rapid Test Device
- NowCheck COVID-19 Antigen test
- Roche SARS-CoV-2 Rapid Antigen Test
- STANDARD™ Q COVID-19 Ag Test
- Sunscreen Diagnostics COVID-19 Antigen Rapid Test Cassette
- VivaDiag™ SARS-CoV-2 Ag Rapid Test
- Wantai SARS-CoV-2 Ag Rapid Test
- Testsea SARS-CoV-2 Antigen Test Kit
- InnoScreen COVID-19 Antigen Rapid Test Device
- LYHER Novel Coronavirus Antigen Test Kit

- Both delta and omicron variants showed similar analytical sensitivity among the testing tools evaluated.
- All testing tools were able to detect delta and omicron variants at 6.50 $\log_{10}$ copies / mL (Ct 25.4) and 6.39 $\log_{10}$ copies/mL (Ct 25.8) respectively.
- No testing tools were able to detect delta or omicron at 5.23 $\log_{10}$ copies/mL (Ct 28.8) and 5.33 $\log_{10}$ copies/mL (Ct 28.8) respectively.
- Study was conducted in Australia

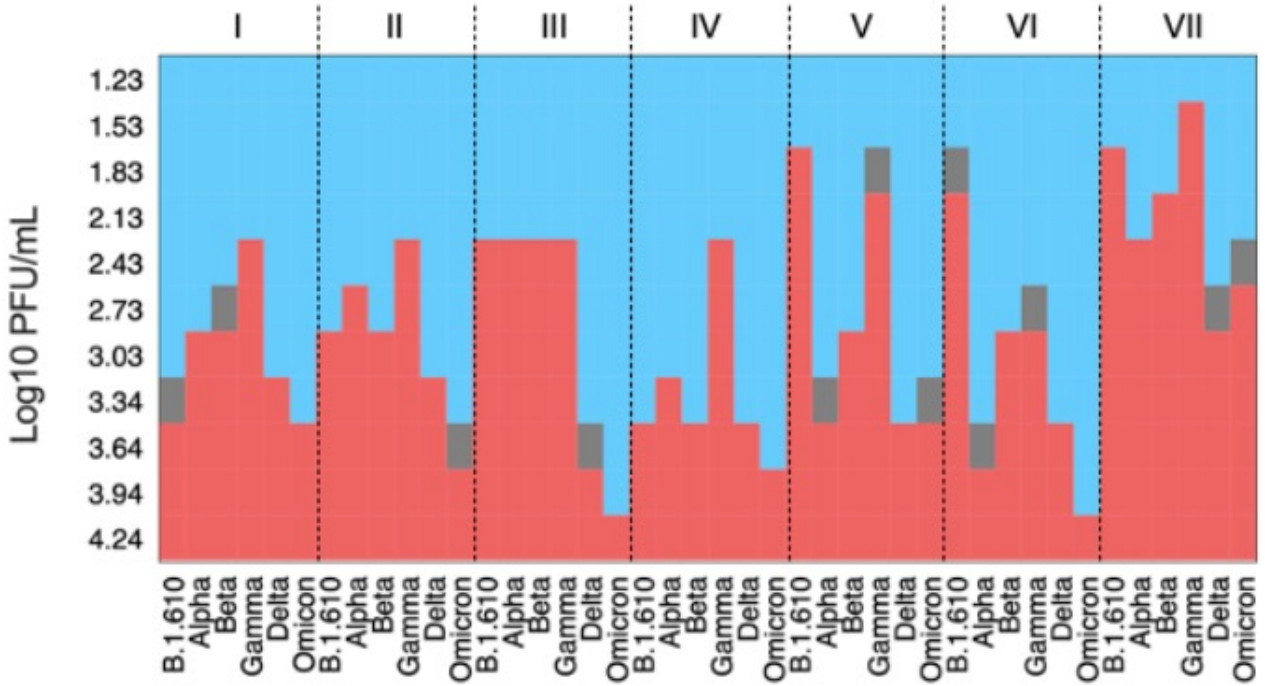
MiOra

Reference: Deerain, J., Druce, J., Tran, T., Batty, M., Yoga, Y., Fennell, M., ... & Williamson, D. A. (2021). Assessment of the analytical sensitivity of ten lateral flow devices against the SARS-CoV-2 omicron variant. Journal of Clinical Microbiology, jcm-02479.

Analytical sensitivity of seven SARS-CoV-2 antigen-detecting rapid tests for Omicron variant

7 Antigen test kits evaluated:

- Panbio™ COVID-19 Ag Rapid Test Device
- STANDARD™ Q COVID-19 Ag Test
- Sure Status
- 2019-nCoV Antigen Test
- Beijing Tigsun Diagnostics Co. Ltd.
- Onsite COVID-19 Ag Rapid Test
- Flowflex



- Study was conducted in Switzerland
- Only 3 of the antigen tests used are WHO-EUL approved: Panbio™, STANDARD™, and Sure Status.
- Analytical sensitivity to detect Omicron was lower than other variants in most of the tests evaluated.
- Flowflex showed highest sensitivity for all variants, with omicron being sensitivity being higher than the delta variant.

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Reference: Bekliz, M., Adea, K., Alvarez, C., Essaidi-Laziosi, M., Escadafal, C., Kaiser, L., & Eckerle, I. (2021). Analytical sensitivity of seven SARS-CoV-2 antigen-detecting rapid tests for Omicron variant. medRxiv.

QUIDEL QuickVue At Home OTC COVID-19 Test Sensitivity and Specificity

Age	QuickVue At-Home OTC COVID-19 Test (N=350)		
	Total #	Total Positive	Prevalence
≤ 5 years	6	0	0%
6 to 21 years	84	9	10.7%
22 to 59 years	249	70	28.1%
≥ 60 years	11	4	36.4%

Limited data from children

Days Post Symptom Onset	QuickVue At-Home OTC COVID-19 Test		
	# Specimens Tested	# Positive Specimens	% Positive
0	32	9	28.1%
1	71	5	7.0%
2	86	21	24.4%
3	49	15	30.6%
4	31	14	45.2%
5	18	5	27.8%
6	9	5	55.6%
>6	10	2	20.0%
Asymptomatic	44	7	15.9%

Test positivity may be affected by the time from the onset of symptoms

Not very sensitive in asymptomatic individuals

Comparison of QuickVue At-Home OTC COVID-19 Test and an authorized EUA Molecular comparator assay with anterior nasal swabs								
Number Tested	True Positive	False Positive	True Negative	False Negative	PPA%	NPA%	PPA 95% CI	NPA 95% CI
350	81	2	251	16	83.5	99.2	74.9 to 89.6	97.2 to 99.8

MiOra

Reference: Quidel Corporation. (2021). QuickVue At-Home OTC COVID-19 Test. https://www.fda.gov/media/147265/download.

BinaxNOW COVID-19 At-Home Antigen Test

Days Since Symptom Onset	Cumulative RT-PCR Positive (+)	Cumulative BinaxNOW COVID-19 Antigen SelfTest Positive (+)	PPA	95% Confidence Interval	
1	12	10	83.3%	51.6%	97.9%
2	34	28	82.4%	65.6%	93.2%
3	50	41	82.0%	68.6%	91.4%
4	63	50	79.4%	67.3%	88.5%
5	78	63	80.8%	70.3%	88.8%
6	90	75	83.3%	74.0%	90.4%
7	117	99	84.6%	76.8%	90.6%
8 to 10	144	118	81.9%	74.7%	87.9%
11 to 14	161	126	78.3%	71.1%	84.4%
All specimens	167	129	77.2%		

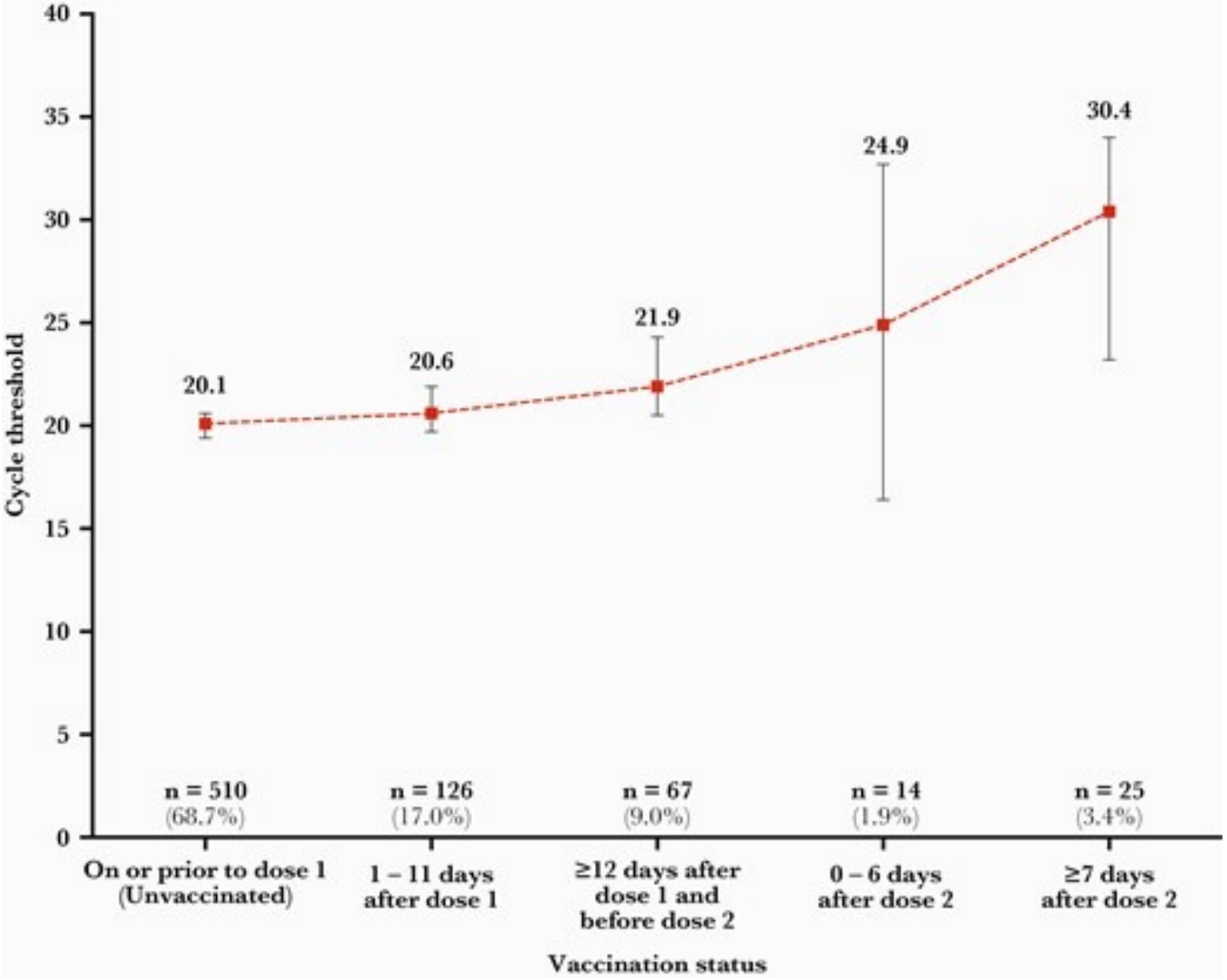
BinaxNOW COVID-19 Ag Card Performance within 7 days of symptom onset against the Comparator Method

BinaxNOW COVID-19 Ag Card	Comparator Method		
	Positive	Negative	Total
Positive	99	5	104
Negative	18	338	356
Total	117	343	460
Positive Agreement: 99/117	84.6% (95% CI: 76.8% - 90.6%)		
Negative Agreement: 338/343	98.5% (95% CI: 96.6% - 99.5%)		

MiOra

Reference: Abbott. (2021). BinaxNOW™ COVID-19 Antigen SelfTEST. https://www.fda.gov/media/147254/download.

COVID-19 Tests may have Lower Sensitivity in Vaccinated Individuals with Breakthrough Infections



- Virus shedding is lower among fully or partially vaccinated (mRNA vaccine) healthcare workers with breakthrough infections (pre-Delta) at UCLA winter of 2020-21 (880 infected among 11930 employees, 30% received at least one dose)
- The data for Delta showed that Ct number was similar between infected vaccinated and unvaccinated but the virus titer dropped faster among vaccinated

MiOra

Reference: Adamson, P. C., Pfeffer, M. A., Arboleda, V. A., Garner, O. B., de St Maurice, A., von Bredow, B., ... & Currier, J. S. (2021). Lower Severe Acute Respiratory Syndrome Coronavirus 2 Viral Shedding Following Coronavirus Disease 2019 Vaccination Among Healthcare Workers in Los Angeles, California. In Open Forum Infectious Diseases (Vol. 8, No. 11, p. ofab526). US: Oxford University Press.