



FDA EUA

OHC COVID-19 Antigen Self Test

OHC COVID-19 Antigen Self Test Detects all Mutations

Variant	Alpha	Beta	Gamma	Delta	Epsilon	Zeta	Eta	Theta	Iota	Kappa	Lambda	Omicron
Lineage	B.1.1.7	B.1.351	P.1	B.1.617.2	B.1.427 + / B.1.429	P.2	B.1.525	P.3	B.1.526	B.1.617.1	C.37	B.1.1.529

The Importance of Self-Testing



Self testing and monitoring both you and your family members for SARS-CoV-2 variants can help protect the community.



Large population testing option with a faster & economical way to test without the need for Doctor's appointment or RT-PCR.



WHO acknowledges self testing as a valid way to conducting COVID-19 testing.

Clinical Performance vs. RT-PCR

A multi-site, Prospective lay-user self-testing clinical performance of OHC COVID-19 Antigen Self test, intended for self-testing of the qualitative detection of SARS-CoV-2 antigens in nasal swab from individuals who are suspected of SARS-CoV-2 within the first 7 days of the onset of symptoms for assessment of sensitivity and specificity in comparison with RT-PCR result.

Region	Result	Reference Reagent		
U.S.		Positive	Negative	Total
	Positive	72	2	74
	Negative	7	137	144
	Total	79	139	218

Positive Percent Agreement= $(72/79) \times 100\% = 91.1\%$ [95% CI: 82.8 to 95.6%]

Negative Percent Agreement= $(137/139) \times 100\% = 98.6\%$ [95% CI: 94.9 to 99.6%]

*At high viral loads (less than a cycle threshold [Ct]-value of 30)

Region	Result	Reference Reagent		
South Korea		Positive	Negative	Total
	Positive	83	0	83
	Negative	7	210	217
	Total	90	210	300

Positive Percent Agreement= $(83/90) \times 100\% = 92.22\%$ [95% CI: 84.8 to 96.2%]

Negative Percent Agreement= $(210/210) \times 100\% = 100\%$ [95% CI: 98.2%-100%]

Region	Result	Reference Reagent		
Brazil		Positive	Negative	Total
	Positive	103	0	103
	Negative	4	133	137
	Total	107	133	240

Positive Percent Agreement= $(103/107) \times 100\% = 96.3\%$ [95% CI: 90.8 to 98.5%]

Negative Percent Agreement= $(133/133) \times 100\% = 100\%$ [95% CI: 97.2 to 100%]

Region	Result	Reference Reagent		
Italy		Positive	Negative	Total
	Positive	29	0	29
	Negative	1	117	118
	Total	30	117	147

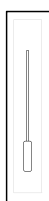
Positive Percent Agreement= $(29/30) \times 100\% = 96.67\%$ [95% CI: 82.8 to 99.9%]

Negative Percent Agreement= $(117/117) \times 100\% = 100\%$ [95% CI: 96.9 to 100%]

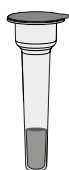
Kit Components



Test Cassette



Sterile Nasal Swab



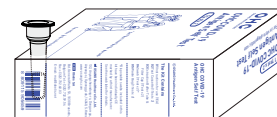
Extraction Buffer Tube



Tube Filter Cap



User Manual Quick Guide



Box (Tube Holder)

Product Specification

Packaging Size	Reaction Time	Sample Type	Storage Temperature
1/2/4/5/25 T Kits	15 Min	Nasal Swab	2-30°C / 36-86°F