



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		
		Positive	Negative	Total
U.S.	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		
		Positive	Negative	Total
South Korea	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		
		Positive	Negative	Total
Brazil	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%)

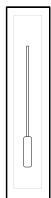
Region	Result	Reference Reagent		
		Positive	Negative	Total
Italy	Positive	29	0	29
	Negative	1	117	118
	Total	30	117	147

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%)

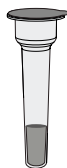
Kit Components



Test Cassette



Sterile Nasal Swab



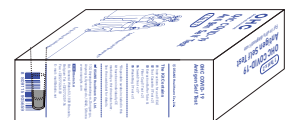
Extraction Buffer Tube



Tube Filter Cap



User Manual Quick Guide



Box (Tube Holder)

Product Specification

Thomas No.	Mfr. No.	Pkg Size	Reaction Time	Sample Type	Storage Temperature
22A00C349	FBE00625	1 Test	15 Min	Nasal Swab	2-30°C / 36-86°F
22A00C350	FBE00608	2 Tests	15 Min	Nasal Swab	2-30°C / 36-86°F
22A00C351	FBE00628	25 Tests	15 Min	Nasal Swab	2-30°C / 36-86°F