



**OHC**  
OSANG HEALTHCARE



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>B.1.1.529</b>

### 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%)

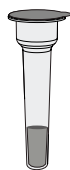
### Kit Components



Test Cassette



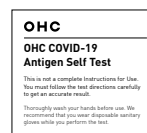
Sterile Nasal Swab



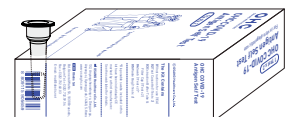
Extraction Buffer Tube



Tube Filter Cap



User Manual Quick Guide



Box (Tube Holder)

### Product Specification

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





## Attachments and Documentation

- FDA EUA Letter
- Package Insert
- Health Care Provider Fact Sheet
- Health Care Provider Instructions
- Patient Fact Sheet

## Ordering Process

Call (512) 651-1977 or email [sales@nhd.llc](mailto:sales@nhd.llc) for market pricing.

Request a purchase order form online at [www.nhdmedical.com](http://www.nhdmedical.com) or from your sales representative.

**PLEASE NOTE:** Due to the ongoing and rapidly changing pandemic conditions, pricing is variable and delivery times cannot be guaranteed by FedEx or UPS. We appreciate your business and strive to provide the most reliable product inventory and order processing.



Call 512-651-1977 | Email [sales@nhd.llc](mailto:sales@nhd.llc) | Visit [www.NHDmedical.com](http://www.NHDmedical.com)  
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