ULTRA

COVID-19 Ag

ULTRA COVID-19 Ag Test

bestbiondx
smarter diagnostics

Cat. No : RK081-25

CE IVD

ULTRA COVID-19 Ag Test is a rapid immunochromatograpic assay for the qualitative detection of specific antigens to SARS-CoV-2 present in human nasopharynx.

Benefits

- SARS-CoV-2 nucleocapsid protein detection
- Testing time 15 – 30 minutes
- 93.47% sensitivity, 100% specificity
- 25 tests per kits
- 24 months shelf-life
- 2-30°C storage temperature

Test date: 2022.01.19

ULTRA COVID-19 Ag Test can detect SARS-CoV-2 variants

ULTRA COVID-19 Ag Test is not affected by
Alpha, Beta, Gamma, Delta, Kappa, Epsilon, Iota, Lambda, Zeta, Mu, Omicron, SARS-CoV-2 variants

There was no effect on sensitivity as a result of evaluation for 42 strains of SARS-CoV-2 variants.

1. In-silico analysis of 42 variants result (experimentation performed by computer)

#	Pango lineage	GISAID ACCESSION ID. EPI_ISL	Dominant Mutation site (amio acid number)	Result (P or N)
2-1	B	402125	N/A (as standard)	N/A
2-2	A.23.1	925892	202	N
2-3	AT.1	2385327	67, 203	N
2-4	AT.1	1259283	203, 2	N
2-5	B.1.1.7	835226	3, 203, 2 235	N
2-6	B.1.351	660190	205	N
2-7	B.1.427	1060793	205	N
2-8	B.1.429	1771435	205, 2	N
2-9	B.1.429	1194304	205	N
2-10	B.1.525	2432518	2, 12,	N
2-11	B.1.526.1	2204920	205, 2	N
2-12	B.1.526.2	1080752	13, 202	N
2-13	B.1.526	1227165	199, 234	N
2-14	B.1.616	1239370	325	P
2-15	B.1.617.1	1360306	203, 277	N
2-16	B.1.617.2	1508996	63, 20	N
2-17	B.1.617.3	1704494	67, 2	N
2-18	B.1.621	1582980	2	N
2-19	C.36	1936140	203, 204, 212	N
2-20	C.37	1111296	13, 203, 204, 214, 366	N
2-21	P.1	792680	80, 203, 204	N
2-22	P.2	1182578	119, 203, 204, 234	N
2-23	P.3	1213573	203, 204	N
2-24	B.1.617.1	1789542	203, 377, 385	N
2-25	B.1.617.1	1620161	3, 203, 377	N
2-26	B.1.617.1	1545312	203, 204	N
2-27	B.1.617.1	1823120	203, 236, 377	N
2-28	B.1.617.1	1904467	3, 13, 203, 243, 377	N
2-29	B.1.617.1	1660436	3, 63, 203, 377	N
2-30	B.1.617.1	1913208	30, 203, 377	N
2-31	B.1.617.1	1969991	203, 310, 377	P
2-32	B.1.617.1	1970310	63, 203, 377. 385	N
2-33	B.1.617.1	1660458	63, 203, 377	N
2-34	B.1.617.2	1807318	63, 203, 204, 205, 206, 207, 208, 377, 385	N
2-35	B.1.617.2	1913205	63, 203, 215, 377	N
2-36	AY.1	3244751	63, 203, 215, 377	N
2-37	AY.1	2123565	63,203,377	N
2-38	AY.1	2192221	63, 203, 215, 377	N
2-39	AY.1	2920875	63, 203, 215, 377	N
2-40	B.1.621	3477571	205	N
2-41	C.1.2	2695610	13, 204, 384, 203	N
2-42	B.1.1.529	6640917	13, 31(deletion), 32(deletion), 33(deletion), 203, 204	N

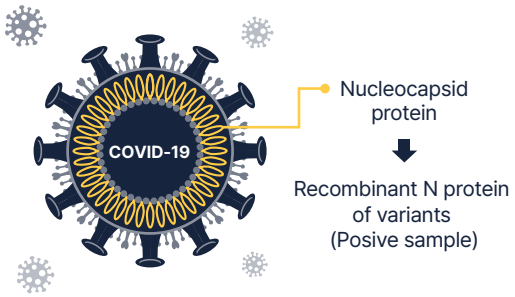
In-silico

* N: A change in performance is unlikely (Result of in-silico analysis-Mutation site is not located in the epitope region.)
P: There is a possibility of a change in performance (Result of in-silico analysis-Mutation site is located in the epitope region.)

Result: 2 out of 42 variants were "P", affecting performance

2. Recombinant protein spiked specimen

Since ULTRA COVID-19 Ag Test targets nucleocapsid protein(N protein), recombinant N protein of variants were synthesized and used as positive specimen.



Result: No performance affect for the ALL variants

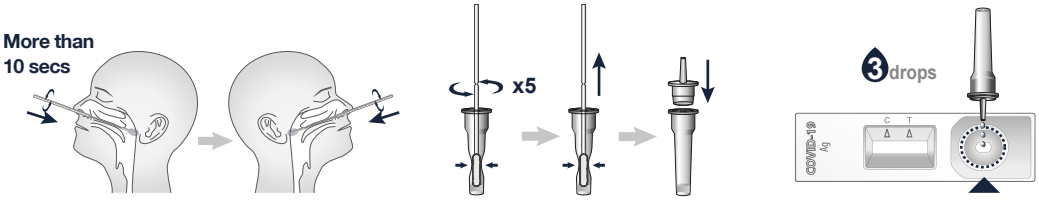
As a result of in-silico analysis of 42 variants, the mutation sites of 2 variants corresponded to the epitope region. However, it was confirmed that the 2 variants did not affect the sensitivity of ULTRA COVID-19 Ag Test through the test for analytical sensitivity. (Recombinant protein spiked specimen test)

source: Internal evaluation

SD BIOSENSOR

ULTRA COVID-19 Ag

Test Procedure



1 **Collect the specimen** from left and right nostrils of nasopharyngeal swab

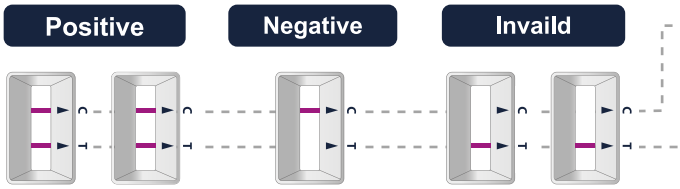
2 **Mix the specimen** with extraction buffer

3 **Apply the specimen** apply 3 drops of extracted specimen.

4 **Read in 15-30 minutes**

! Do not read after 30 mins

Interpretation of Test Results



"C" Control Line

A purple colored band will appear in the top section of the result window to show that the test is working properly.

"T" Test Line

Even if the control line/test line is faint, or the test line isn't uniform, the test should be considered to be performed properly and the test result should be interpreted as a positive result.

- Positive results should be considered in conjunction with the clinical history and other data available.
- Symptomatic individuals who test negative with this test kit should be definitely tested sequentially be RT-PCR to rule out COVID-19 infection.

Performance Characteristics

Limit of Detection (LoD)

- ULTRA COVID-19 Ag Test uses new raw materials to improve performance
- ULTRA COVID-19 Ag Test outperforms other COVID-19 antigen rapid tests at least **8x better**
- The LoD of ULTRA COVID-19 Ag Test is **6.17x10 $TCID_{50}$/ml (RNA Copies 3,604)**

SARS-CoV-2 variant	LoD Titer ($TCID_{50}$/ml)	RNA copies/reaction
Cultured virus SARS-CoV-2 (2019-nCOV) NCCP 43326/2020/Korea	6.17x10	3,604

Clinical evaluation

- Single site, prospective, randomized, single blinded study conducted in India
- Total 540 nasopharyngeal swab specimen were tested
- ULTRA COVID-19 Ag Test shows **93.47% sensitivity** and **100% specificity**

Sensitivity & Specificity of the ULTRA COVID-19 Ag Test compared to RT-PCR

Reference Test		RT-PCR		
		Positive	Negative	Total
ULTRA COVID-19 Ag Test	Positive	43	0	43
	Negative	3	494	497
	Total	46	494	540
Sensitivity		**93.47%** (43/46) [95% CI: 82.10% - 98.63%]		
Specificity		**100%** (494/494) [95% CI: 99.26% - 100%]		

Performance according to days of symptom onset

Based on days of symptom onset	Sensitivity	Specificity
0-3 days	**100%** (19/19) [95% CI: 82.35%-100%]	**100%** (17/17) [95% CI: 80.49%-100%]
4-7 days	**100%** (14/14) [95% CI: 76.84%-100%]	**100%** (31/31) [95% CI: 76.84%-100%]
> 7 days	**81.8%** (9/11) [95% CI: 48.22%-97.72%]	**83.33%** (10/12) [95% CI: 51.59%-97.91%]
Asymptomatic	**100%** (1/1) [95% CI: 2.50%-100%]	**99.77%** (434/435) [95% CI: 98.73%-99.99%]

source: Internal evaluation

bestbion dx GmbH
Horbeller Str. 33
50858 Köln
Deutschland

Telefon: +49 2234 98795 – 0
Telefax: +49 2234 98795 – 29
Email: service@bestbion.com
Internet: www.bestbion.com

bestbion dx
smarter diagnostics

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