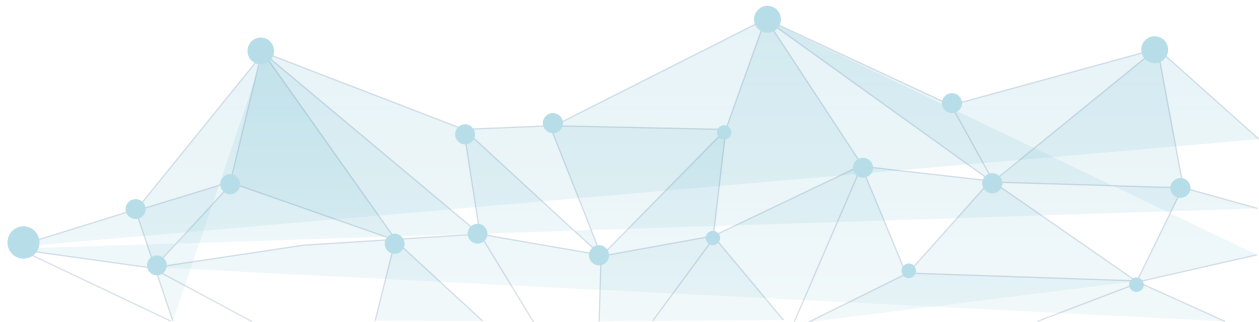


AllCheck COVID19 Ag



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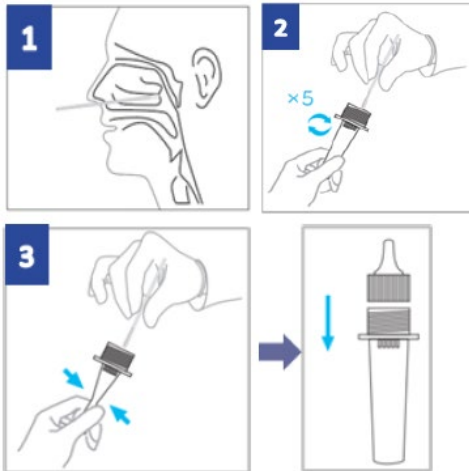
AllCheck COVID19 Ag



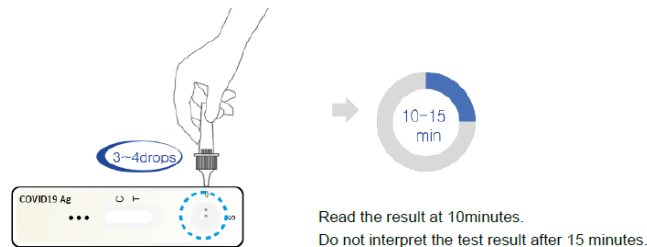
○ AllCheck COVID19 Ag Test is a rapid chromatographic immunoassay for the qualitative detection of specific SARS-CoV-2 antigens present in human nasopharynx and nasal cavity

○ Test procedure

1. Collection of specimen



2. Test



3. Result interpretation

[Negative]



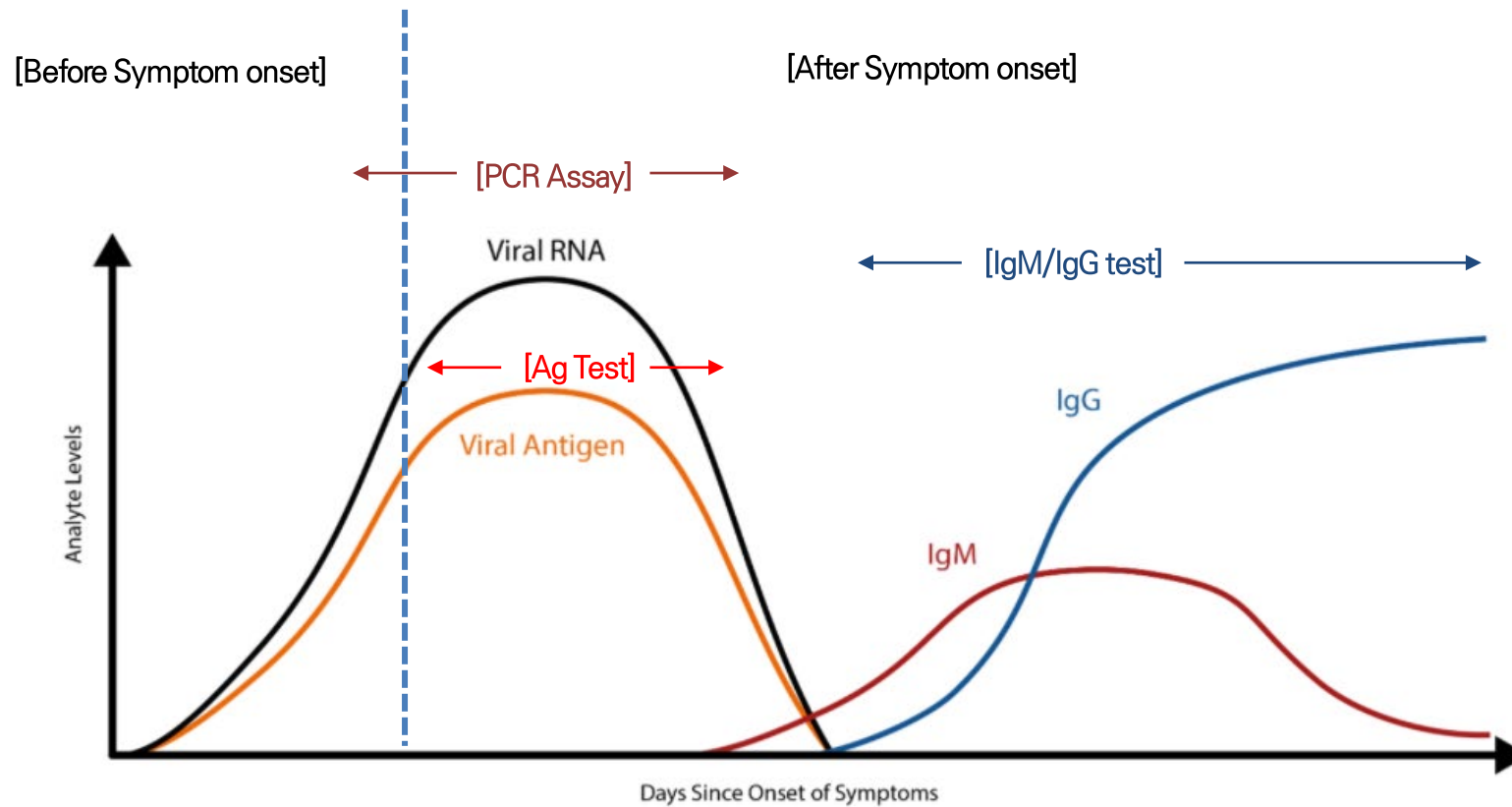
[Positive]



[Invalid]



Diagnostics of SARS-CoV-2



RT-PCR assay can detect SARS-CoV-2 RNA with high sensitivity but require specialized biocontainment laboratories, operated by highly trained technicians

Antigen and antibody test can provide rapid results and are easy to use.

Clinical Evaluation



100 nasopharyngeal swab specimen samples (40 Positives and 60 Negatives) were collected from individuals who tested with a RT-PCR method for SARS-CoV-2 infection.

Clinical performance Result		RT-PCR method		Total
		Positive	Negative	
AllCheck COVID19 Ag	Positive	39	0	39
	Negative	1	60	61
Total		40	60	100

Sensitivity: 97.5%(95% CI: 97.12~99.56%), Specificity: 100%(95% CI: 93.98~100%)

The Limit of Detection (LoD) of the AllCheck COVID19 Ag was determined using limiting dilutions of heat-inactivated SARS-CoV-2, isolate USA-WA1/2020. The LoD is 2.5×10^2 TCID₅₀/ml.

Comparison of Ag tests



AllCheck COVID19 Ag has higher performance than other products

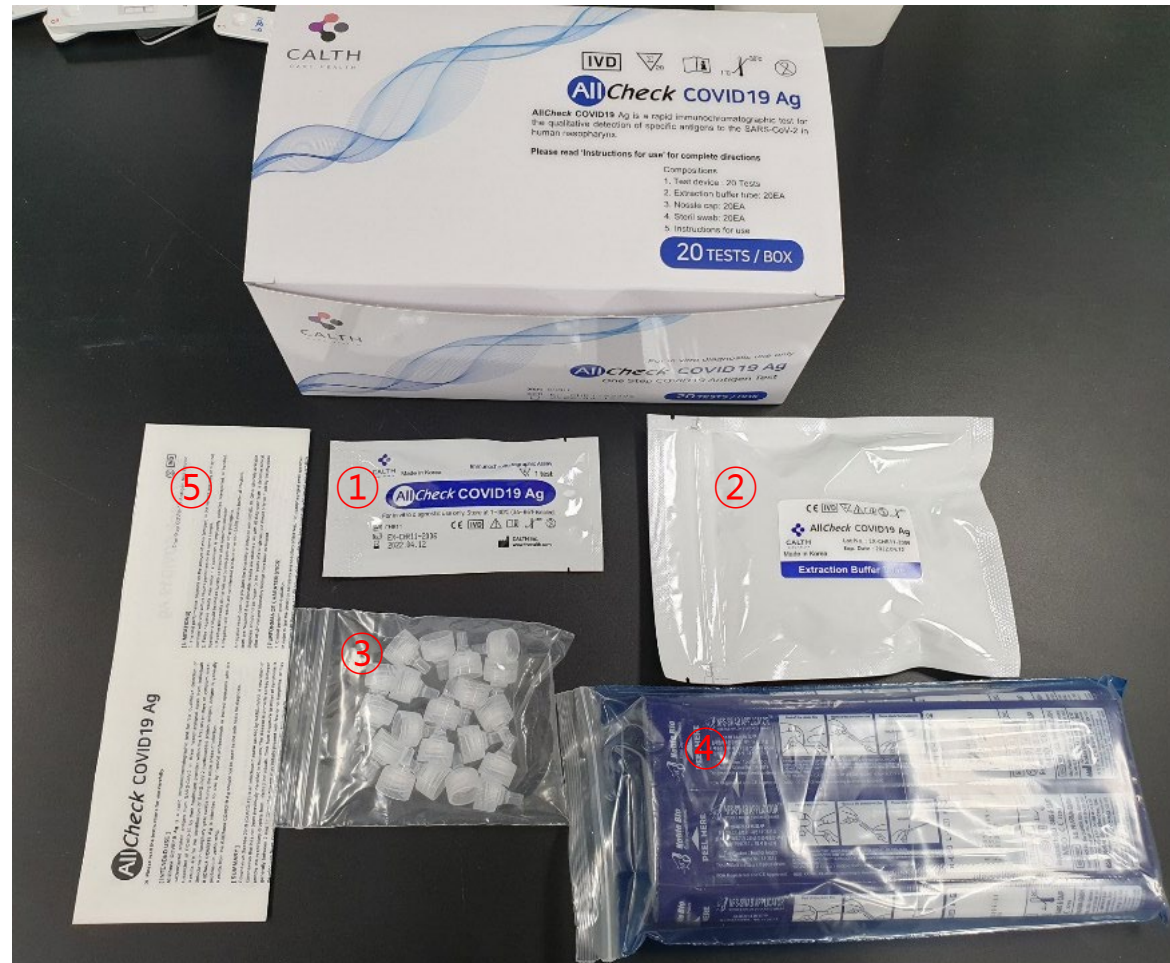
No.	Specimen ID	Ct value	AllCheck	A	C	D
1	20GDV123159	15.1	+++	Neg	Neg	+++
2	20GDV123168	16.6	+++	+	+	++
3	20GDV123212	16.9	+++	Neg	+	++
4	20GDV123264	20.8	++	+	+	++
5	20GDV123281	20.9	+++	+	+	+++
6	20GDV123282	21	+	Neg	Neg	+
7	20GDV123275	21.8	++	Neg	Neg	+
8	20GDV123178	22.1	+	Neg	Neg	+
9	20GDV123277	22.9	+	Neg	Neg	Neg
10	20GDV123214	23.2	+	Neg	Neg	+
11	20GDV123170	23.4	Neg		Neg	Neg
12	20GDV123137	24	+	Neg	Neg	Neg
13	20GDV123166	25.3	+		Neg	+
14	20GDV123087	26.2	+		Neg	+
15	20GDV123240	27.9	Neg		Neg	Neg
16	20GDV123134	29	+	Neg	Neg	+
17	20GDV123133	29.3	Neg		Neg	Neg
18	20GDV123185	30.2	Neg		Neg	Neg
19	20GDV123244	30.8	Neg		Neg	Neg
20	20GDV123246	31.6	Neg		Neg	Neg
		Total	14/20	3/12	4/20	12/20
		NP LoD	0.1ng/ml	0.5ng/ml	5ng/ml	100ng/ml

No Cross reactions

Cross reacting substance	Concentration	Cross-Reactivity
Influenza, A/Beijing/262/95 (H1N1)	4000ngHA/ml	No
Adeno virus type 1	1x10 ⁶ TCID ₅₀ /ml	No
Adeno virus type 2	5x10 ⁵ TCID ₅₀ /ml	No
Enterovirus	6.8x10 ⁵ TCID ₅₀ /ml	No
Measles virus	5x10 ⁶ TCID ₅₀ /ml	No
Mumps virus	5x10 ⁶ TCID ₅₀ /ml	No
Rhinovirus type 1A	4.2x10 ⁵ TCID ₅₀ /ml	No
Bordetella pertussis	1x10 ⁶ CFU/ml	No
Corynebacterium propinquum	1x10 ⁶ CFU/ml	No
Haemophilus influenzae	1x10 ⁶ CFU/ml	No
Lactobacillus fermentum	1x10 ⁶ CFU/ml	No
Legionella pneumophila	1x10 ⁶ CFU/ml	No
Neisseria meningitides	1x10 ⁶ CFU/ml	No
Neisseria gonorrhoeae	1x10 ⁶ CFU/ml	No
Staphylococcus epidermidis	1x10 ⁶ CFU/ml	No
Streptococcus pneumoniae	1x10 ⁶ CFU/ml	No
Streptococcus pyogenes	1x10 ⁶ CFU/ml	No
Escherichia coli	1x10 ⁶ CFU/ml	No
Respiratory syncytial virus (Type A)	3x10 ⁵ TCID ₅₀ /ml	No
Respiratory syncytial virus (Type B)	3x10 ⁵ TCID ₅₀ /ml	No
Coronavirus (229E)	1x10 ^{4.5} TCID ₅₀ /ml	No
Coronavirus (OC43)	1x10 ⁵ TCID ₅₀ /ml	No
Coronavirus (NL63)	1x10 ⁴ TCID ₅₀ /ml	No
MERS-Coronavirus (Florida/USA-2_Saudi Arabia_2014)	4x10 ⁴ TCID ₅₀ /ml	No

Reagent and Materials

- ① COVID-19 Ag test devices
- ② Extraction buffer tube
- ③ Nozzle cap
- ④ Sterile swab
- ⑤ Instruction for use





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