GENEDIA W COVID-19 Ag _ Comparison with other Rapid Kits

Company (Country)	GC MS (Korea)	Abbott Diagnostics Scarborough, Inc.	Access Bio, Inc	SD BIOSENSOR, (Korea)	RapiGEN Inc. (Korea)	GenBody, Inc. (Korea)
Product						
Product name	GENEDIA W COVID-19 Ag	BinaxNOW™ COVID-19 Ag Card	CareStart COVID-19 Antigen test	STANDARD Q COVID-19 Ag Test	BIOCREDIT COVID-19 Ag	GenBody COVID-19 Ag
Specimen	Nasopharyngeal swab Sputum	Nasopharyngeal swab	Nasopharyngeal swab	Nasopharyngeal swab	Nasopharyngeal swab	Nasopharyngeal swab
Running time	10 min	15 min	10 min	30 min	5-8 min	15-20 min
LoD	750 $TCID^{50}/mL$	1,250 $TCID^{50}/mL$ (22.5 TCID/Swab)	800 $TCID^{50}/mL$	1,250 $TCID^{50}/mL$		2,870 $TCID^{50}/mL$
Specificity	100% (CI : 97.11% - 100%)	98.5% (CI : 92% - 100%)	100% (CI 81.57% – 100%)	99.68% (95% 98.22 – 99.99%)	100%	98% (CI 92.96% -99.76%)
Sensitivity	98% (CI : 89.1%% - 100%) (onset within 7 days)	97.1% (CI : 85.1% - 99.9%) (onset within 7 days)	83.33% (CI 43.65% – 97.00%)	96.52% (CI 91.33 – 99.04%)	96%	90.0% (CI 73.47% -97.89%)
Buffer Package	20 / Separately	1 bottle	20 / Separately	20 / Separately	20 / Separately	2 bottle
Packing unit	20 Test / kit	40 Test / kit	20 Test / kit	25 Test / kit	20 Test / kit	25 Test / kit
Certificate	Korea export - CE-IVD	US-EUA	US-EUA	Brazil ANVISA - CE-IVD	CE-IVD / Russia	CE-IVD

GENEDIA W COVID-19 Ag _Comparison with BinaxNOW & CareStart

Company (Country)	GC MS (Korea)	Abbott Diagnostics Scarborough, Inc.	Access Bio, Inc	Remark
Product				
Product name	GENEDIA W COVID-19 Ag	BinaxNOW™ COVID-19 Ag Card	CareStart COVID-19 Antigen test	
Specimen	Nasopharyngeal swab Sputum	Nasopharyngeal swab	Nasopharyngeal swab	GCMS : Valid at most of the samples, even with sputum in commonly used samples of in-patients
Running time	10 min	15 min	10 min	GCMS : Much faster
LoD	750 $TCID^{50}/mL$	1,250 $TCID^{50}/mL$ (22.5 TCID/Swab)	800 $TCID^{50}/mL$	GCMS : Among currently available AG RDT test in the market, GCMS's product has the lowest Limit of Detection
Specificity	100% (CI : 97.11% - 100%)	98.5% (CI : 92% - 100%)	100% (CI 81.57% – 100%)	GCMS : Since there is always a trade-off between sensitivity & specificity, GCMS focused on eliminating false positive results. The concerns with false positive Covid-19 might become a critical issue during the Flu-season during the 2nd wave of Covd-19
Sensitivity	98% (CI : 89.1%% - 100%) (onset within 7 days)	97.1% (CI : 85.1% - 99.9%) (onset within 7 days)	83.33% (CI 43.65% – 97.00%)	GCMS: GCMS included not only samples in the early phase of infections, but also samples from randomly staged infections in the clinical trials. Therefore, GCMS's product has the broad range of CI values.
Buffer Package	20 / Separately	1 bottle	20 / Separately	GCMS: Minimize the cross contamination by providing individual buffer tube. This is not only for reducing the chance of contamination. But samples can be also homogeneously mixed. This in return can ensure a smooth and gentle flow, which can be essential for lateral flow Rapid Test.
Packing unit	20 Test / kit	40 Test / kit	20 Test / kit	
Certificate	Korea export - CE-IVD	US-EUA	US-EUA	

GENEDIA W COVID-19 Ag _Comparison with BinaxNOW & CareStart

- Positive results broken down by days since symptom onset

① GENEDIA W COVID-19 Ag

Days Since Symptom Onset	RT-PCR Positive (+)	GENEDIA W COVID-19 Ag Positive (+)	*PPA *PPA: Positive predictive agreement
≤7	**49**	**48**	**98%**
Asymptomatic	24	18	75%

② BinaxNOW™ COVID-19 Ag Card

Days Since Symptom Onset	RT-PCR Positive (+)	BinaxNOW™ COVID-19 Ag Card Positive (+)	*PPA
≤7	35	34	97.1%
Asymptomatic	N/A	N/A	N/A

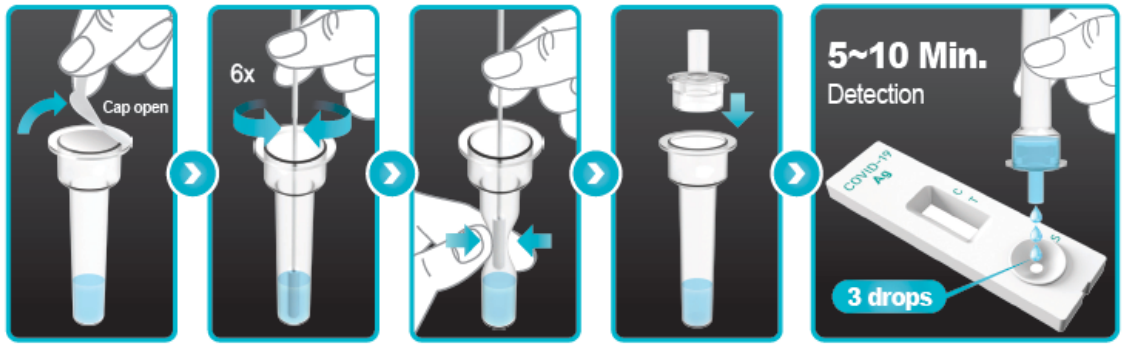
③ CareStart COVID-19 Antigen test

Days Since Symptom Onset	RT-PCR Positive (+)	CareStart COVID-19 Antigen test Positive (+)	PPA
≤5	6	5	**83.33% **Testing is performed by operators with no laboratory experience and who are representative of the intended users.
Asymptomatic	N/A	N/A	N/A

GENEDIA W COVID-19 Ag _ Comparison with BinaxNOW

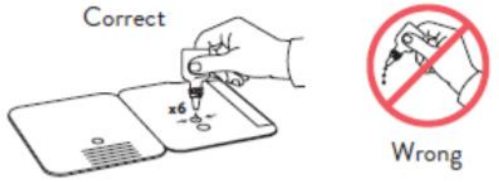
- Test procedure

① GENEDIA W COVID-19 Ag



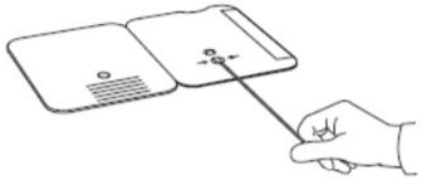
② BinaxNOW™ COVID-19 Ag Card

1. Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the **TOP HOLE,** slowly add **6 DROPS** to the **TOP HOLE** of the swab well. **DO NOT** touch the card with the dropper tip while dispensing.



High possibility of contamination

2. Insert sample into **BOTTOM HOLE** and firmly push upwards so that the swab tip is visible in the **TOP HOLE.**



3. Rotate (twirl) swab shaft 3 times **CLOCKWISE** (to the right). Do not remove swab.